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As filed with the Securities and Exchange Commission on January 18, 2013

Registration No. 333-185391

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**AMENDMENT NO. 1**  
**TO**  
**Form S-4**  
**REGISTRATION STATEMENT UNDER**  
**THE SECURITIES ACT OF 1933**

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**BIOSANTE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b>	<b>2386</b>	<b>58-2301143</b>
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

**111 Barclay Boulevard**  
**Lincolnshire, Illinois 60069**  
**(847) 478-0500**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Stephen M. Simes**  
**Vice Chairman, President and Chief Executive Officer**  
**BioSante Pharmaceuticals, Inc.**  
**111 Barclay Boulevard**  
**Lincolnshire, Illinois 60069**  
**(847) 478-0500**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Copies to:**

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**Amy E. Culbert, Esq.**  
**Oppenheimer Wolff & Donnelly LLP**  
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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement and the effective time of the merger of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., a Delaware corporation, with and into BioSante Pharmaceuticals, Inc., a Delaware corporation, as described in the Agreement and Plan of Merger dated as of October 3, 2012, as amended, and as attached as Annex A to the joint proxy statement/prospectus forming part of this registration statement.

If the securities being registered on this Form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a  
smaller reporting company)

Smaller reporting company

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer)

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

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**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this joint proxy statement/prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This joint proxy statement/prospectus is not an offer to sell and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY COPY—SUBJECT TO COMPLETION, DATED JANUARY 18, 2013



PROPOSED MERGER—YOUR VOTE IS VERY IMPORTANT

To our Stockholders:

On October 3, 2012, BioSante Pharmaceuticals, Inc. (BioSante) and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI), entered into a merger agreement pursuant to which ANI will merge with and into BioSante, with BioSante continuing as the surviving company. The boards of directors of BioSante and ANI have approved unanimously the merger agreement and the merger and believe that the merger of the two companies will create more value than either company could achieve individually. The combined company that will result from the merger will be a fully integrated specialty pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and the current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of approximately 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger (as determined prior to an anticipated reverse stock split of BioSante common stock), assuming BioSante's net cash is \$18.0 million as of the determination date.

BioSante common stock is listed on The NASDAQ Global Market and trades under the symbol "BPAX". On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the closing sale price of BioSante common stock was \$1.36 per share. ANI is a privately held specialty pharmaceutical company. Following completion of the merger, the combined company is expected to be renamed "ANI Pharmaceuticals, Inc." and to change its trading symbol on The NASDAQ Global Market. ANI has reserved the symbol "ANIP" for this purpose.

This joint proxy statement/prospectus provides you with detailed information about the special meetings of stockholders of BioSante and ANI to consider the merger and related business. **Your vote is very important.** Whether or not you plan to attend your respective company's special meeting of stockholders, please submit your proxy as soon as possible to make sure that your shares are represented at the applicable meeting. In addition to being a proxy statement for both BioSante and ANI, this document is also a prospectus to be used by BioSante when issuing BioSante common stock to ANI stockholders in connection with the merger. BioSante and ANI encourage you to read the entire document carefully. **Please pay particular attention to the section entitled "Risk Factors" beginning on page 38 for a discussion of the risks related to the merger, the combined company following completion of the merger, and the business and operations of each of BioSante and ANI.**

BioSante and ANI are excited about the opportunities that the proposed merger brings to both BioSante and ANI stockholders and thank you for your consideration and continued support.

Handwritten signature of Stephen M. Simes in black ink.

Stephen M. Simes  
Vice Chairman, President and  
Chief Executive Officer  
BioSante Pharmaceuticals, Inc.

Handwritten signature of Arthur S. Przybyl in black ink.

Arthur S. Przybyl  
President and Chief Executive Officer  
ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the BioSante common stock to be issued pursuant to the merger or determined if the information in this joint proxy statement/prospectus is accurate or adequate. Any representation to the contrary is a criminal offense.**

This joint proxy statement/prospectus is dated January , 2013 and is first being mailed or otherwise delivered to stockholders of BioSante and ANI on or about January 25, 2013.

## REFERENCES TO ADDITIONAL INFORMATION

This joint proxy statement/prospectus forms a part of a registration statement on Form S-4 filed by BioSante Pharmaceuticals, Inc. with the Securities and Exchange Commission (SEC). It constitutes a prospectus of BioSante under Section 5 of the Securities Act of 1933, as amended (the Securities Act), and the rules and regulations thereunder, with respect to the shares of BioSante common stock to be issued to holders of capital stock of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. in the merger. In addition, it constitutes a proxy statement under Section 14(a) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and the rules and regulations thereunder, and a notice of meeting with respect to the BioSante special meeting of stockholders. It also constitutes a proxy statement of ANI and a notice of meeting with respect to the ANI special meeting of stockholders.

BioSante has supplied all information contained in this joint proxy statement/prospectus relating to BioSante and ANI has supplied all information contained in this joint proxy statement/prospectus relating to ANI.

If you would like to request documents from BioSante or ANI, please send a request by telephone or email to either BioSante or ANI at the following address:

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069  
Attention: Investor Relations  
Tel: (847) 478-0500 ext. 120  
Email: [info@biosantepharma.com](mailto:info@biosantepharma.com)

ANIP Acquisition Company d/b/a  
ANI Pharmaceuticals, Inc.  
210 Main Street West  
Baudette, Minnesota 56623  
Attention: Investor Relations  
Tel: (218) 634-3500  
Email: [arthur.przybyl@anipharmaceuticals.com](mailto:arthur.przybyl@anipharmaceuticals.com)

**If you would like to request documents, please do so by February 22, 2013 in order to receive them before the special meetings.** See "Where You Can Find More Information" beginning on page 300.

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**BioSante Pharmaceuticals, Inc.**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS  
To Be Held On March 15, 2013**

Dear BioSante Stockholder:

A special meeting of the stockholders of BioSante Pharmaceuticals, Inc. will be held on March 15, 2013 at 8:00 a.m., local time, at BioSante's corporate office located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069, for the following purposes:

1. To consider and vote upon a proposal to adopt the agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended, a copy of which is attached as Annex A to the joint proxy statement/prospectus accompanying this notice, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.
2. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.
3. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc."
4. To consider and vote upon a proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.
5. To consider and vote upon a proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and/or 3.

Stockholders also will consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

The board of directors of BioSante has fixed January 17, 2013 as the record date for the determination of BioSante stockholders entitled to notice of, and to vote at, the BioSante special meeting or any adjournments or postponements of the BioSante special meeting. Only holders of record of BioSante common stock and BioSante class C special stock at the close of business on the BioSante record date are entitled to notice of, and to vote at, the BioSante special meeting. At the close of business on the record date, BioSante had 24,422,240 shares of common stock and 65,211 shares of BioSante class C special stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposals No. 1, 2 and 3. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting, is required for approval of BioSante Proposals No. 4 and 5. Please also note that the approval of BioSante Proposal No. 1 is not conditioned upon the approval of BioSante Proposals No. 2, 3, 4 or 5; however, the approval of BioSante Proposals No. 2 and 3 is**

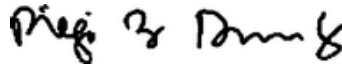
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conditioned upon the approval of BioSante Proposal No. 1 by the BioSante stockholders and the approval of the corresponding proposal by the ANI stockholders.

Even if you plan to attend the BioSante special meeting in person, BioSante requests that you complete, sign and return the enclosed proxy card and thus ensure that your shares will be represented at the BioSante special meeting if you are unable to attend. If you sign, date and mail your proxy card without indicating how you wish to vote, your proxy will be counted as a vote in favor of BioSante Proposals No. 1 through 5. If you fail to return your proxy card, the effect will be that your shares will not be counted for purposes of determining whether a quorum is present at the BioSante special meeting and will count as a vote against BioSante Proposals No. 1 through 3. If you do attend the BioSante special meeting and wish to vote in person, you may withdraw your proxy and vote in person.

The BioSante board of directors has determined that the merger agreement and the transactions contemplated by it, including the merger and the issuance of shares of BioSante common stock in the merger, are advisable and in the best interests of BioSante and its stockholders. The BioSante board of directors unanimously has approved and adopted the merger agreement and the transactions contemplated by it, including the merger and the issuance of shares of BioSante common stock in the merger, and recommends that BioSante stockholders vote "FOR" the adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and "FOR" the other merger related proposals.

By Order of the Board of Directors,



Phillip B. Donenberg  
*Senior Vice President, Finance,  
Chief Financial Officer and Secretary*

January 22, 2013  
Lincolnshire, Illinois

**IMPORTANT NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS FOR BIOSANTE'S SPECIAL MEETING TO BE HELD ON  
MARCH 15, 2013**

The accompanying joint proxy statement/prospectus is available at [www.proxyvote.com/BioSante](http://www.proxyvote.com/BioSante).

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**ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.**

**NOTICE OF SPECIAL MEETING OF STOCKHOLDERS  
To Be Held On March 15, 2013**

Dear ANI Stockholder:

A special meeting of the stockholders of ANI will be held on March 15, 2013 at 9:00 a.m., local time, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087, for the following purposes:

1. To consider and vote upon a proposal to adopt the agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended, a copy of which is attached as Annex A to the joint proxy statement/prospectus accompanying this notice, and the transactions contemplated thereby, including the merger.
2. To consider and vote upon a proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

Stockholders also will consider and act on any other matters as may properly come before the special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

The board of directors of ANI has fixed January 17, 2013 as the record date for the determination of ANI stockholders entitled to notice of, and to vote at, the ANI special meeting or any adjournments or postponements of the ANI special meeting. Only holders of record of ANI capital stock at the close of business on the ANI record date are entitled to notice of, and to vote at, the ANI special meeting. At the close of business on the record date, ANI had 2,375,312 shares of series D convertible preferred stock, 34,810 shares of series C convertible preferred stock, 78,491 shares of series B convertible preferred stock, 102,774 shares of series A convertible preferred stock and 23,613 shares of common stock outstanding and entitled to vote.

**Your vote is important. The affirmative vote of holders of a majority of the shares of ANI common stock, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D convertible preferred stock having voting power outstanding on the record date for the ANI special meeting is required for approval of ANI Proposal No. 1. The affirmative vote of holders of a majority of ANI common stock, calculated on an as-converted basis, present in person or represented by proxy at the ANI special meeting is required for approval of ANI Proposal No. 2.**

Even if you plan to attend the ANI special meeting in person, ANI requests that you complete, sign and return the enclosed proxy card and thus ensure that your shares will be represented at the ANI special meeting if you are unable to attend. If you sign, date and mail your proxy card without indicating how you wish to vote, your proxy will be counted as a vote in favor of ANI Proposals No. 1 and 2. If you fail to return your proxy card, the effect will be that your shares will not be counted for purposes of determining whether a quorum is present at the ANI special meeting and will count as a vote against ANI Proposal No. 1. If you do attend the ANI special meeting and wish to vote in person, you may withdraw your proxy and vote in person.

The ANI board of directors has determined that the merger agreement and the transactions contemplated by it, including the merger, are advisable and in the best interests of ANI and its stockholders. The ANI board of directors has unanimously approved and adopted the merger

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agreement and the transactions contemplated by it, including the merger, and recommends that ANI stockholders vote "FOR" the adoption of the merger agreement and the transactions contemplated thereby, including the merger, and "FOR" the adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

By Order of the Board of Directors,

A handwritten signature in black ink, consisting of a large, stylized 'C' followed by a wavy line and another large, stylized 'C'.

Charlotte C. Arnold  
*Vice President and Chief Financial Officer*

Baudette, Minnesota  
January 22, 2013

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References to "BioSante" and "ANI" in this joint proxy statement/prospectus refer to BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., respectively. References to the "combined company" refer to BioSante, as the surviving entity after the merger and incorporating the merged business of ANI. Except as otherwise noted, references to "we," "us" or "our" refer to both BioSante and ANI. References to the "merger agreement" refer to that certain agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended from time to time.

Except as otherwise noted, references to "BioSante common stock" refer to shares of common stock, par value \$0.0001 per share, of BioSante, and references to "BioSante class C special stock" refer to shares of class C special stock, par value of \$0.0001 per share, of BioSante. Except as otherwise noted, references to "BioSante capital stock" refer to shares of BioSante common stock and BioSante class C special stock. References to the *BioSante stockholders* refer to holders of shares of BioSante common stock and/or shares of BioSante class C special stock. All BioSante share and per share

numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Except as otherwise noted, references to "*ANI series D preferred stock*," "*ANI series C preferred stock*," "*ANI series B preferred stock*," "*ANI series A preferred stock*" and "*ANI common stock*" refer to shares of series D convertible preferred stock, par value \$0.10 per share, of ANI, series C convertible preferred stock, par value \$0.10 per share, of ANI, series B convertible preferred stock, par value \$0.10 per share, of ANI, series A convertible preferred stock, par value \$0.10 per share, of ANI, and common stock, par value \$0.10 per share, of ANI, respectively, and references to "*ANI preferred stock*" refer to shares of ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock, collectively. Except as otherwise noted, references to "*ANI capital stock*" refer to shares of ANI preferred stock and ANI common stock. References to the *ANI stockholders* refer to holders of shares of ANI capital stock. All ANI share and per share numbers have been adjusted retroactively to reflect the one-for-ten reverse stock split effected on January 28, 2011.

BioSante owns or has rights to various trademarks, trade names or service marks, including *BioSante*<sup>®</sup>, *LibiGel*<sup>®</sup>, *GVAX*<sup>™</sup>, *The Pill-Plus*<sup>™</sup> and *Elestrin*<sup>™</sup>. ANI owns or has rights to various trademarks, trade names or service marks, including *Cortenema*<sup>®</sup> and *Reglan*<sup>®</sup>. This joint proxy statement/prospectus also contains trademarks, trade names and service marks of others.

## QUESTIONS AND ANSWERS ABOUT THE MERGER

*The following section provides answers to frequently asked questions about the merger. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a BioSante or ANI stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q: What is the merger?**

A: BioSante and ANI have entered into an agreement and plan of merger, which is referred to in this joint proxy statement/prospectus as the merger agreement, that contains the terms and conditions of the proposed merger of BioSante and ANI. If the merger is completed, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. This transaction is referred to as the merger.

**Q: Why are BioSante and ANI proposing to effect the merger?**

A: BioSante and ANI both believe that the merger of the two companies will be able to create more value than either company could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. For a more complete description of the reasons for the merger, see the sections entitled "The Merger—BioSante Reasons for the Merger" beginning on page 128 and "The Merger—ANI Reasons for the Merger" beginning on page 132.

**Q: What will ANI stockholders receive in the merger?**

A: Upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. See the section entitled "The Merger Agreement—Merger Consideration and Adjustment" beginning on page 156. The exchange ratios are subject to potential adjustment as described in the merger agreement, depending upon the amount of "net cash" of BioSante, as defined in the merger agreement, and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, and thus will not be determined until that time. Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is \$18.0 million as of the determination date.

Pursuant to the terms of ANI's certificate of incorporation, (i) before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00 plus all declared but unpaid dividends; (ii) before any amounts are paid to the holders of shares of ANI series B preferred stock, ANI series A preferred stock or ANI common stock, the holders of shares of ANI series C preferred stock are entitled to receive an amount per share equal to \$110.00 plus all declared but unpaid dividends; (iii) before any amounts are paid to the holders of shares of ANI series A preferred stock or ANI common stock, the holders of shares of ANI series B preferred stock are entitled to receive an amount per share equal to \$110.00 plus all declared but unpaid dividends; (iv) before any amounts are paid to the holders of shares of ANI

common stock, the holders of shares of ANI series A preferred stock are entitled to receive an amount per share equal to \$100.00 plus all declared but unpaid dividends; and (v) after payments have been made to all holders of ANI preferred stock, the remaining assets of ANI will be distributed ratably to the holders of ANI common stock, including holders of ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock who elect to convert into BioSante common stock in lieu of receiving the stated dollar preference amounts described above, and ANI series D preferred stock. The stated value of each series of ANI preferred stock set forth above is subject to adjustment as provided in ANI's certificate of incorporation. The exchange ratios in the merger agreement reflect these preferential payments. **As a result of such provisions, it is likely that holders of shares of ANI series A preferred stock, ANI series B preferred stock, ANI series C preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.**

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was \$18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

No fractional shares of BioSante common stock will be issued to ANI stockholders in connection with the merger. Instead, ANI stockholders will be entitled to receive cash in lieu of any fractional shares of BioSante common stock that they otherwise would be entitled to receive in connection with the merger.

For a more complete discussion of what ANI stockholders will receive in connection with the merger, see the sections entitled "The Merger Agreement—Merger Consideration and Adjustment" beginning on page 156.

**Q: How will BioSante stockholders be affected by the merger?**

A: The merger will have no effect on the number of shares of BioSante common stock or BioSante class C special stock held by BioSante stockholders as of immediately prior to completion of the merger (subject to any changes in outstanding shares of BioSante common stock and BioSante class C special stock as a result of the reverse stock split described elsewhere in this joint proxy statement/prospectus). However, it is expected that upon completion of the merger shares of BioSante common stock will represent only an aggregate of approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is \$18.0 million as of the determination date. If BioSante's net cash is higher than \$18.0 million as of the determination date, then shares of BioSante common stock will represent a higher percentage, but no more than 49.9 percent, of the outstanding shares of common stock of the combined company. If BioSante's net cash is less than \$18.0 million as of the determination date, then shares



of BioSante common stock will represent a lower percentage of the outstanding shares of common stock of the combined company. One of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than \$17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

For illustrative purposes only, if you are a BioSante stockholder and hold five percent of the outstanding shares of BioSante common stock immediately prior to completion of the merger and do not also hold any shares of ANI capital stock, then upon completion of the merger, you will hold an aggregate of approximately 2.35 percent of the outstanding shares of common stock of the combined company immediately following completion of the merger, assuming BioSante's net cash is \$18.0 million as of the determination date, and approximately 2.32 percent of the outstanding shares of common stock of the combined company immediately following completion of the merger, assuming BioSante's net cash is \$17.0 million as of the determination date.

**Q: Can the value of the transaction change between now and the time the merger is completed?**

A: Yes. The market value of BioSante common stock can change between now and the time the merger is completed and the exchange ratios are subject to adjustment based on BioSante's net cash. The exchange ratios will not change, however, if the market value of BioSante common stock changes. Therefore, the market value of the total transaction, and of the BioSante common stock to be issued to ANI stockholders in the merger, will increase or decrease as the market value of BioSante common stock increases or decreases. In addition, the market value of the total transaction may change as a result of an adjustment of the exchange ratios triggered by a change in BioSante's net cash between now and the net cash determination date.

**Q: Who will be the directors and executive officers of the combined company following the merger?**

A: Following the merger, the board of directors of the combined company will be as follows:

<u>Name</u>	<u>Current Principal Affiliation</u>
Robert E. Brown, Jr.	ANI
Tracy L. Marshbanks, Ph.D.	ANI
Thomas A. Penn	ANI
Arthur S. Przybyl	ANI
Robert Schrepfer	ANI
Fred Holubow	BioSante
Ross Mangano	BioSante

Robert E. Brown, Jr., ANI's chairman of the board, will be chairman of the board of the combined company.

Following the merger, the executive officers of the combined company will be the current executive officers of ANI, who are as follows:

<u>Name</u>	<u>Position</u>
Arthur S. Przybyl	President and Chief Executive Officer
Charlotte C. Arnold	Vice President and Chief Financial Officer
James G. Marken	Vice President, Operations
Robert J. Jamnick	Vice President, Quality and Product Development

**Q: What are the conditions to the completion of the merger?**

A: The obligations of each of BioSante and ANI to consummate the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

- the adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to effect the reverse stock split and change the company's corporate name;
- the adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders;
- the absence of any legal prohibition to completing the merger;
- the effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part;
- the continued listing of BioSante's common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger; and
- the receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

- the representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date;
- the other party to the merger agreement having performed or complied in all material respects with all agreements and covenants required to be performed or complied with by it at or before the closing of the merger;
- the other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement; and
- no material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

- BioSante's net cash as of the closing being no less than \$17.0 million, as calculated and as adjusted pursuant to the provisions of the merger agreement; and
- no new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

**Q: What will happen to BioSante or ANI if, for any reason, the merger does not close?**

A: BioSante and ANI have invested significant time and incurred, and expect to continue to incur, significant expenses related to the proposed merger. In the event the merger does not close, each

of BioSante and ANI will review all alternatives then available to it. Failure to complete the merger could result in other adverse effects, as discussed in "Risk Factors—Risks Related to the Merger" beginning on page 38.

**Q: When do BioSante and ANI expect the merger to be completed?**

A: The merger will be completed upon the filing of a certificate of merger with the Secretary of State of the State of Delaware, but such filing only will be made upon the satisfaction or waiver (if permissible) of the conditions specified in the merger agreement, including receipt of the necessary approvals of BioSante and ANI stockholders at their respective special meetings and other customary closing conditions. It is possible that factors outside the control of BioSante and ANI could result in the merger not being completed or being completed later than expected. Although the exact timing of completion of the merger cannot be predicted with certainty, BioSante and ANI currently anticipate completing the merger in the first quarter of 2013.

**QUESTIONS AND ANSWERS FOR BIOSANTE STOCKHOLDERS  
ABOUT THE BIOSANTE SPECIAL MEETING**

*The following section provides answers to frequently asked questions about the BioSante special meeting of stockholders. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as a BioSante stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q: What proposals will be voted on at the BioSante special meeting?**

A: The following proposals will be voted on at the BioSante special meeting:

- The first proposal to be voted upon is whether to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger. See "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 1—Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger and the Issuance of Shares of BioSante Common Stock in the Merger," "The Merger" and "The Merger Agreement" beginning on pages 96, 116 and 156, respectively, for a more detailed description of the transaction.
- The second proposal to be voted upon is whether to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five. See "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 2—Approval of Amendment to BioSante's Certificate of Incorporation to Effect Reverse Split of BioSante Common Stock and Class C Special Stock at the Discretion of BioSante and ANI at a Ratio of Either One-for-Two, One-for-Three, One-for-Four or One-for-Five" beginning on page 97 for a more detailed description of the proposed amendment.
- The third proposal to be voted upon is whether to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante in connection with the merger to "ANI Pharmaceuticals, Inc." See "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 3—Approval of Amendment to BioSante's Certificate of Incorporation to Change Corporate Name" beginning on page 108 for a more detailed description of the proposed amendment.
- The fourth proposal to be voted upon is whether to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger. See "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 4—Advisory Vote on Golden Parachute Compensation" beginning on page 109 for a more detailed description of the advisory vote.
- The fifth proposal to be voted upon is whether to adjourn the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first, second and third proposals. See "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 5—Approval of Possible Adjournment of the BioSante Special Meeting" beginning on page 110 for a more detailed description of the possible adjournment.

**Q: What risks should I consider before I vote on the proposed merger transaction and other merger related proposals?**

A: You should review the section entitled "Risk Factors" beginning on page 38.

**Q: How does the BioSante board of directors recommend that BioSante stockholders vote?**

A: After careful consideration, the BioSante board of directors unanimously has approved the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and each of the proposals described in this joint proxy statement/prospectus that BioSante stockholders are being asked to consider, and has determined that they are advisable, fair to and in the best interests of BioSante stockholders. Accordingly, the BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" each such proposal.

**Q: Why is the proposal to amend BioSante's charter to effect the reverse stock split included in this joint proxy statement/prospectus and is it necessary for the completion of the merger?**

A: It is expected that immediately prior to the effective time of the merger, BioSante will effect a reverse split of the BioSante common stock and BioSante class C special stock at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five (with the exact ratio to be determined by BioSante and ANI immediately prior to completion of the merger). The reverse stock split is intended to ensure that the listing rules of The NASDAQ Stock Market are satisfied in connection with the issuance of shares of BioSante common stock in the merger. Under the listing rules of The NASDAQ Stock Market, the combined company must file an initial listing application in connection with the merger and comply with the initial listing rules of the applicable NASDAQ market to continue to be listed on such market following the merger. BioSante common stock is required to be listed on The NASDAQ Global Market or The NASDAQ Capital Market as a condition to closing the merger. The initial listing rules of The NASDAQ Global Market and The NASDAQ Capital Market require a company to have, among other things, a \$4.00 per share minimum bid price. Because the current per share price of BioSante common stock is less than \$4.00, the reverse stock split is necessary to meet the minimum bid listing requirement.

**Q: Why is the proposal to amend BioSante's charter to effect the change in BioSante's corporate name included in this joint proxy statement/prospectus and is it necessary for the completion of the merger?**

A: Both BioSante and ANI believe that the change in the corporate name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." will allow for recognition of the combined company's business following completion of the merger. The current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the completion of the merger. The approval of the amendment to BioSante's certificate of incorporation to effect the change in corporate name by the BioSante stockholders is a condition to closing the merger.

**Q: Can I dissent and require appraisal of my shares?**

A: No. Under the Delaware General Corporation Law, BioSante stockholders will not have appraisal rights in connection with the merger or any of the other proposals described in this joint proxy statement/prospectus that the BioSante stockholders are being asked to consider. See "The Merger—Appraisal Rights" beginning on page 152.

**Q: When and where is the BioSante special meeting?**

A: The BioSante special meeting of stockholders will be held on Friday, March 15, 2013 at 8:00 a.m., local time, at BioSante's corporate offices located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069 to consider and vote on the proposals related to the merger agreement and the transactions contemplated by it. For additional information relating to the BioSante special meeting, please see the section entitled "The Special Meeting of BioSante Stockholders" beginning on page 92.

**Q: Who is soliciting my proxy?**

A: This proxy is being solicited by the BioSante board of directors.

**Q: What do I do now?**

A: BioSante urges you to read carefully and consider this joint proxy statement/prospectus, including its annexes, and consider how the proposed merger affects you.

In order for your shares to be represented at the BioSante special meeting:

- you can vote by telephone or through the Internet by following the instructions included on the enclosed proxy card;
- you can indicate on the enclosed proxy card how you would like to vote and sign and return the proxy card in the accompanying pre-addressed postage paid envelope; or
- you can attend the BioSante special meeting in person.

If you hold your shares in "street name," please refer to the enclosed proxy card or the information forwarded by your bank, broker or other holder of record to see what options are available to you.

**Q: Who is entitled to vote at the BioSante special meeting?**

A: Holders of record of BioSante common stock and BioSante class C special stock at the close of business on January 17, 2013 are entitled to notice of and to vote at the BioSante special meeting. As of January 17, 2013, 24,422,240 shares of BioSante common stock were issued and outstanding and entitled to vote and 65,211 shares of BioSante class C special stock were issued and outstanding and entitled to vote.

**Q: What is the difference between holding shares as a stockholder of record and as a beneficial owner?**

A: If your shares are registered directly in your name with BioSante's transfer agent, Computershare Trust Company, N.A., you are considered, with respect to those shares, the "stockholder of record." These proxy materials are sent to you by mail directly by BioSante.

If your shares are held in a stock brokerage account or by a bank or other holder of record, you are considered the "beneficial owner" of shares held in street name. These proxy materials are forwarded to you by your broker, bank or other holder of record who is considered, with respect to those shares, the stockholder of record. As the beneficial owner, you have the right to direct your broker, bank or other holder of record on how to vote your shares held in your account.

**Q: If I am a stockholder of record of BioSante capital stock, how do I vote?**

A: You may vote by proxy over the Internet by visiting the website established for that purpose at <https://www.proxyvote.com> and following the instructions (please note you must type an "s" after http), or you may vote by mail or by telephone. Alternatively, if you are a stockholder of record, you may vote in person at the BioSante special meeting. You will receive a ballot when you arrive.

**Q: If I am a beneficial owner of shares held in street name, how do I vote?**

A: You may vote by proxy over the Internet by visiting the website established for that purpose at <https://www.proxyvote.com> and following the instructions (please note you must type an "s" after http), or you may vote by mail or by telephone. If you are a beneficial owner of shares held in street name and you wish to vote in person at the BioSante special meeting, you must obtain a valid proxy from the organization that holds your shares.

**Q: What can I do if I change my mind after I vote my shares?**

A: A stockholder of record may revoke its proxy at any time before it is used on the date of the BioSante special meeting by delivering to the corporate secretary of BioSante:

- written notice of revocation,
- a duly executed proxy bearing a later date or time than that of the previously submitted proxy, or
- a later dated vote by Internet or telephone, or a ballot cast in person at the BioSante special meeting.

If you are a beneficial owner of BioSante capital stock, you may submit new voting instructions by contacting your bank, broker or other holder of record. You also may vote in person if you obtain a legal proxy as described in the answer to the previous question. All shares that have been properly voted and not revoked will be voted at the BioSante special meeting.

**Q: What shares are included on the proxy card?**

A: If you are a stockholder of record of BioSante capital stock, you will receive only one proxy card for all the shares of BioSante capital stock you hold in certificate form and in book-entry form.

If you are a beneficial owner of BioSante capital stock, you will receive voting instructions, and information regarding consolidation of your vote, from your bank, broker or other holder of record.

**Q: What are the voting requirements to approve each of the proposals that will be voted on at the BioSante special meeting?**

A:

<u>Proposal</u>	<u>Vote Required</u>
Adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger	Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote
Approval of amendment to effect reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five	Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote
Approval of amendment to effect change of corporate name to "ANI Pharmaceuticals, Inc."	Majority of the outstanding shares of BioSante common stock and BioSante class C special stock, voting together as a single class, and entitled to vote
Approval, on an advisory (non-binding) basis, of the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger	Majority of the shares of BioSante common stock and BioSante class C special stock present in person or represented by proxy, voting together as a single class, and entitled to vote when a quorum is present
Approval of adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first three proposals	Majority of the shares of BioSante common stock and BioSante class C special stock present in person or represented by proxy, voting together as a single class, and entitled to vote when a quorum is present

In connection with the execution of the merger agreement, all of BioSante's directors, executive officers and affiliated entities, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI,

pursuant to which each such BioSante stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, in favor of the two charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby. As of the record date for the BioSante special meeting, the shares of BioSante capital stock owned by all of BioSante's directors, executive officers and affiliated entities and thus subject to the voting agreements constituted approximately two percent of the total outstanding voting power of BioSante on that date.

See the section entitled "Voting and Other Ancillary Agreements—BioSante Voting Agreements" beginning on page 168 for more information regarding these voting agreements.

**Q: What constitutes a quorum at the BioSante special meeting?**

A: The presence at the BioSante special meeting, either in person or by proxy, of the holders of one-third of the outstanding shares of BioSante common stock and BioSante class C special stock entitled to vote shall constitute a quorum for the transaction of business. Abstentions and broker non-votes are counted as present and entitled to vote for purposes of determining a quorum. A "broker non-vote" occurs when a bank, broker or other holder of record holding shares for a beneficial owner does not vote on a particular proposal because that holder does not have discretionary voting power for that particular item and has not received instructions from the beneficial owner.

**Q: Could other matters be decided at the BioSante special meeting?**

A: As of the date of the printing of this joint proxy statement/prospectus, neither BioSante nor ANI knew of any matters to be raised at the BioSante special meeting other than those referred to in this joint proxy statement/prospectus. If other matters are properly presented at the BioSante special meeting for consideration, the proxy committee appointed by the BioSante board of directors (the persons named in your proxy card if you are a BioSante stockholder of record) will have the discretion to vote on those matters for you.

**Q: Who will count the vote?**

A: An officer of BioSante or a designee will tabulate the votes and act as inspector of the election.

**Q: Who is paying for this proxy solicitation?**

A: BioSante will bear the cost of soliciting proxies, including the printing, mailing and filing of this joint proxy statement/prospectus, the proxy card and any additional information furnished to BioSante stockholders. BioSante has engaged Phoenix Advisory Partners, a proxy solicitation firm, to solicit proxies from BioSante stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of BioSante common stock for the forwarding of solicitation materials to the beneficial owners of BioSante common stock. BioSante will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.



**Q: Whom should I call with questions?**

A: If you have additional questions, you should contact:

**BioSante Pharmaceuticals, Inc.**  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069  
Attention: Investor Relations  
Phone Number: (847) 478-0500, ext. 120  
Email Address: [info@biosantepharma.com](mailto:info@biosantepharma.com)

If you would like additional copies of this joint proxy statement/prospectus, you should contact:

**AST Phoenix Advisors**  
110 Wall Street, 27th Floor  
New York, New York 10005  
Telephone: (877) 478-5038  
Email Address: [info@phoenixadvisorsast.com](mailto:info@phoenixadvisorsast.com)

**QUESTIONS AND ANSWERS FOR ANI STOCKHOLDERS  
ABOUT THE ANI SPECIAL MEETING**

*The following section provides answers to frequently asked questions about the ANI special meeting of stockholders. This section, however, only provides summary information. These questions and answers may not address all issues that may be important to you as an ANI stockholder. You should read carefully the entire joint proxy statement/prospectus, including each of the annexes.*

**Q: What proposals will be voted on at the ANI special meeting?**

A: The following proposals will be voted on at the ANI special meeting:

- The first proposal to be voted upon is whether to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger. See "Matters Being Submitted to a Vote of ANI Stockholders—ANI Proposal No. 1—Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger," "The Merger" and "The Merger Agreement" beginning on pages 114, 116 and 156, respectively, for a more detailed description of the transaction.
- The second proposal to be voted upon is whether to adjourn the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the first proposal. See "Matters Being Submitted to a Vote of ANI Stockholders—ANI Proposal No. 2—Approval of Possible Adjournment of the ANI Special Meeting" beginning on page 115 for a more detailed description of the possible adjournment.

**Q: What risks should I consider before I vote on the proposed merger transaction?**

A: You should review the section entitled "Risk Factors" beginning on page 38.

**Q: How does the ANI board of directors recommend that ANI stockholders vote?**

A: After careful consideration, the ANI board of directors has unanimously approved the merger agreement, including the merger, and each of the proposals described in this joint proxy statement/prospectus that the ANI stockholders are being asked to consider, and has determined that they are advisable, fair to and in the best interests of ANI stockholders. Accordingly, the ANI board of directors unanimously recommends that ANI stockholders vote "**FOR**" each such proposal.

**Q: Can I dissent and require appraisal of my shares?**

A: Yes. Under the Delaware General Corporation Law, ANI stockholders will have appraisal rights in connection with the merger. See "The Merger—Appraisal Rights" beginning on page 152.

**Q: When and where is the ANI special meeting?**

A: The ANI special meeting of stockholders will be held on Friday, March 15, 2013 at 9:00 a.m., local time, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087 to consider and vote on the proposals related to the merger agreement and the transactions contemplated by it. For additional information relating to the ANI special meeting, please see the section entitled "The Special Meeting of ANI Stockholders" beginning on page 111.

**Q: Who is soliciting my proxy?**

A: This proxy is being solicited by the ANI board of directors.

**Q: What do I do now?**

A: ANI urges you to read carefully and consider this joint proxy statement/prospectus, including its annexes, and consider how the proposed merger affects you.

In order for your shares to be represented at the ANI special meeting:

- you can indicate on the enclosed proxy card how you would like to vote and sign and return the proxy card in the accompanying pre-addressed postage paid envelope; or
- you can attend the ANI special meeting in person.

**Q: Who is entitled to vote at the ANI special meeting?**

A: Every stockholder of ANI on the record date is entitled to vote at the ANI special meeting. Holders of record of ANI capital stock at the close of business on January 17, 2013 are entitled to notice of and to vote at the ANI special meeting. As of January 17, 2013, 2,375,312 shares of ANI series D preferred stock, 34,810 shares of ANI series C preferred stock, 78,491 shares of ANI series B preferred stock, 102,774 shares of ANI series A preferred stock and 23,613 shares of ANI common stock were issued and outstanding and entitled to vote.

**Q: How do I vote?**

A: You may vote by mail, or alternatively, you may vote in person at the ANI special meeting. You will receive a ballot when you arrive.

**Q: What can I do if I change my mind after I vote my shares?**

A: A stockholder of record may revoke its proxy at any time before it is used on the date of the ANI special meeting by delivering to the corporate secretary of ANI:

- written notice of revocation,
- a duly executed proxy bearing a later date or time than that of the previously submitted proxy, or
- a later dated vote by a ballot cast in person at the ANI special meeting.

**Q: What shares are included on the proxy card?**

A: If you are a stockholder of record of ANI capital stock, you will receive only one proxy card for all the shares of ANI capital stock you hold in certificate form.

**Q: What are the voting requirements to approve each of the proposals that will be voted on at the ANI special meeting?**

A:

<u>Proposal</u>	<u>Vote Required</u>
Adoption of the merger agreement and the transactions contemplated thereby, including the merger	Majority of the outstanding shares of ANI capital stock entitled to vote, calculated on an as-converted basis, voting as a single class, and 65 percent of the outstanding shares of ANI series D preferred stock entitled to vote
Approval of adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the adoption of the merger agreement and the transactions contemplated thereby, including the merger	Majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis, present in person or represented by proxy and voting as a single class

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

See the section entitled "Voting and Other Ancillary Agreements—ANI Voting Agreements" beginning on page 168 for more information regarding this and other voting agreements.

**Q: What constitutes a quorum at the ANI special meeting?**

A: The presence at the ANI special meeting, either in person or by proxy, of the holders of a majority of the voting power of the issued and outstanding shares of ANI capital stock entitled to vote will constitute a quorum for the transaction of business. Abstentions are counted as present and entitled to vote for purposes of determining a quorum.

**Q: Could other matters be decided at the ANI special meeting?**

A: As of the date of the printing of this joint proxy statement/prospectus, neither BioSante nor ANI knew of any matters to be raised at the ANI special meeting other than those referred to in this joint proxy statement/prospectus. If other matters are properly presented at the ANI special meeting for consideration, the proxy committee appointed by the ANI board of directors (the persons named in your proxy card) will have the discretion to vote on those matters for you.

**Q: Who will count the vote?**

A: An officer of ANI or a designee will tabulate the votes and act as inspector of the election.

**Q: Who is paying for this proxy solicitation?**

A: ANI will bear the cost of soliciting proxies, including the printing, mailing and filing of this joint proxy statement/prospectus, the proxy card and any additional information furnished to the ANI stockholders.

**Q: Whom should I call with questions?**

A: If you have additional questions, you should contact:

**ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.**  
210 Main Street West  
Baudette, Minnesota 56623  
Telephone: (218) 634-3500  
Investor Relations: arthur.przybyl@anipharma.com

If you would like additional copies of this joint proxy statement/prospectus, you should contact:

**AST Phoenix Advisors**  
110 Wall Street, 27th Floor  
New York, New York 10005  
Telephone: (877) 478-5038  
Email Address: info@phoenixadvisorsast.com

## SUMMARY

*This summary highlights selected information from this joint proxy statement/prospectus and may not contain all of the information that is important to you. To better understand the merger and the other proposals being considered at the special meetings, you should read this entire joint proxy statement/prospectus carefully, including the attached Annexes, and the other documents to which you are referred herein. See "Where You Can Find More Information" beginning on page 300.*

### The Companies

#### ***BioSante Pharmaceuticals, Inc.***

BioSante Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The following are BioSante's products, either approved or in clinical development:

- LibiGel—once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction, specifically hypoactive sexual desire disorder.
- Male testosterone gel—once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc.
- GVAX cancer vaccines—a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.
- The Pill-Plus (triple component contraceptive)—once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.
- Elestrin—once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc., BioSante's licensee.

BioSante's corporate offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069 and its telephone number is (847) 478-0500. BioSante's website is located at [www.biosantepharma.com](http://www.biosantepharma.com). The information contained on or connected to BioSante's website is expressly not incorporated by reference into this joint proxy statement/prospectus. Additional information about BioSante is included elsewhere in this joint proxy statement/prospectus. See the sections entitled "BioSante's Business," "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and BioSante's financial statements beginning on pages 175, 193 and F-1, respectively.

#### ***ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.***

ANI is a fully integrated specialty branded and generic pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies. Over the last two years ANI has launched three new products and currently has 11 products in development. ANI's targeted areas of product development include narcotics, anti-cancers and hormones (potent compounds), and extended release niche generic prescription product opportunities.

ANI's corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623, and its telephone number is (218) 634-3500. ANI's website is located at [www.anipharmaceuticals.com](http://www.anipharmaceuticals.com). The

information contained on or connected to ANI's website is expressly not incorporated by reference into this joint proxy statement/prospectus. Additional information about ANI is included elsewhere in this joint proxy statement/prospectus. See the sections entitled "ANI's Business," "ANI's Management's Discussion and Analysis of Financial Condition and Result of Operations" and ANI's financial statements beginning on pages 211, 222 and F-47, respectively.

### **Summary of the Merger**

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger. A copy of the merger agreement is attached as Annex A to this joint proxy statement/prospectus. You are encouraged to read the merger agreement in its entirety because it is the legal document that governs the merger. For a more complete discussion of the merger, see the sections entitled "The Merger" and "The Merger Agreement" beginning on pages 116 and 156, respectively.

### **Reasons for the Merger**

The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing manufacturing and marketing branded and generic prescription pharmaceuticals. BioSante and ANI both believe that the merger of the two companies will be able to create more value than either company could achieve individually.

Each of the boards of directors of BioSante and ANI also considered other reasons for the merger, as described herein. For example, the BioSante board of directors considered, among other reasons:

- The consideration of BioSante's anticipated near- and long-term operations and performance on an independent, stand-alone basis, the substantial additional financing that would be needed to sustain such operations assuming BioSante continued its LibiGel development program or in-licensed or acquired additional technologies or product candidates, and the risk that such substantial additional financing could not be obtained on terms favorable to BioSante, or at all, in light of a volatile economy and uncertain capital markets.
- The consideration of strategic alternatives to the proposed merger with ANI, including other merger transactions with other companies, continuing to operate BioSante on a stand-alone basis, in-licensing or acquiring additional technologies or product candidates and undertaking a liquidation of BioSante, and the belief that the proposed merger with ANI would permit the BioSante stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to BioSante and its stockholders.
- The belief that the combination of BioSante's and ANI's businesses would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, and the uncertain capital markets, which BioSante historically has relied upon to raise additional financing to fund its product development efforts.
- Historical and current information concerning ANI's business, financial performance, financial condition, operations and management and the results of a due diligence investigation of ANI conducted by BioSante's management and advisors.
- The opportunity for the BioSante stockholders to participate in the potential future value of the combined company, including future potential value from ANI's established contract manufacturing operations, niche generic prescription products and products in development.

In addition, the ANI board of directors considered, among other reasons, the following:

- That the existing BioSante product lines fit well within the ANI platform of hormone-based products.
- That ANI would be able to leverage its knowledge of the hormone-based products market to further the existing BioSante product lines.
- The fact that the remaining cash resources expected to be available at the closing of the merger would provide the combined company with enough capital to enable it to meet its operational needs beyond 2013.
- The belief that the combination of the two businesses will result in accelerated growth and more value for the ANI stockholders than the ANI business could create on its own, given the combination of the product lines of the two companies, ANI's need for additional capital and the well-capitalized balance sheet that the combined company will have.
- The belief that potential future license and other royalty fees due to BioSante for its FDA-approved male testosterone gel and other products could generate significant future cash flow for the combined company.
- The belief that the combined company will have access to a greater number of capital market opportunities as a public company than ANI would have as a privately held company.
- That the exchange ratios in the merger will result in the ANI stockholders owning approximately 53 percent of the outstanding shares of the combined company following the merger, assuming BioSante's net cash on the determination date is \$18.0 million.

For a more complete discussion of BioSante's and ANI's reasons for the merger, see the sections entitled "The Merger—BioSante Reasons for the Merger" and "The Merger—ANI Reasons for the Merger" beginning on pages 128 and 132, respectively.

#### **Opinion of Oppenheimer & Co. Inc.**

In connection with the merger, the BioSante board of directors received a written opinion, dated October 3, 2012, of BioSante's financial advisor, Oppenheimer & Co. Inc., referred to as "Oppenheimer & Co." or "BioSante's financial advisor," as to the fairness, from a financial point of view and as of the date of the opinion, to BioSante of the exchange ratios used in the merger. The full text of Oppenheimer & Co.'s written opinion, dated October 3, 2012, which describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken, is attached to this joint proxy statement/prospectus as Annex G. Oppenheimer & Co.'s opinion was provided to the BioSante board of directors in connection with its evaluation of the exchange ratios from a financial point of view to BioSante and does not address any other aspect of the merger. Oppenheimer & Co.'s opinion does not address, among other things, the underlying business decision of BioSante to effect the merger, the relative merits of the merger as compared to any alternative business strategies that might exist for BioSante or the effect of any other transaction in which BioSante might engage and does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to any matters relating to the merger. For a more complete discussion of Oppenheimer & Co.'s opinion, see the section entitled "The Merger—Opinion of Oppenheimer & Co. Inc." beginning on page 134.

#### **Risk Factors**

Both BioSante and ANI are subject to various risks associated with their respective businesses and financial condition. In addition, the merger, as well as the possibility that the merger may not be



completed, pose a number of risks to BioSante and ANI and their respective stockholders, including the following risks:

- The issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will dilute substantially the voting power of current BioSante stockholders.
- The exchange ratios in the merger agreement depend on a variety of factors, including ANI's certificate of incorporation, BioSante's net cash and the market price of BioSante common stock, and changes in those ratios could result in dilution to the BioSante and/or ANI stockholders.
- The announcement and pendency of the merger could have an adverse effect on BioSante's stock price and/or the business, financial condition, results of operations, or business prospects for BioSante and/or ANI.
- Failure to complete the merger could impact negatively BioSante's and ANI's respective businesses, financial condition or results of operations or BioSante's stock price.
- Some of the directors and executive officers of BioSante and ANI have interests in the merger that are different from, or in addition to, those of the other BioSante and ANI stockholders.
- The merger agreement and the voting agreements contain provisions that could discourage or make it difficult for a third party to acquire BioSante or ANI prior to completion of the merger.
- Completion of the merger is subject to a number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible, not waived, the merger will not be completed.
- The combined company's stock price may be volatile, and the market price of its common stock may decline in value following the merger.

In addition, BioSante, ANI and the combined company are subject to various risks associated with their respective businesses. These risks are discussed in greater detail in the section entitled "Risk Factors" beginning on page 38. BioSante and ANI both encourage you to read and consider all of these risks carefully.

#### **Merger Consideration and Adjustment**

Upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger and thus will not be determined until that time. Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company, assuming BioSante's net cash is \$18.0 million as of the determination date.

Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00

(subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. The exchange ratios in the merger agreement reflect these preferential payments. **As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.**

The following table illustrates the percentage ownership of the combined company by BioSante's and ANI's current stockholders assuming various amounts of net cash of BioSante as of the determination date.

<u>BioSante's Net Cash as of Determination Date Calculated Pursuant to Merger Agreement</u>	<u>BioSante Stockholder Ownership of Outstanding Shares of Combined Company</u>	<u>ANI Stockholder Ownership of Outstanding Shares of Combined Company</u>
\$23.0 million or more	49.9%	50.1%
22.0 million	49.4%	50.6%
21.0 million	48.8%	51.2%
20.0 million	48.2%	51.8%
19.0 million	47.6%	52.4%
18.0 million	47.0%	53.0%
17.0 million	46.4%	53.6%

As described in more detail below under "—Conditions to Completion of the Merger," one of the conditions to ANI's obligations to complete the merger, unless waived by ANI, is BioSante's net cash as of the closing date being no less than \$17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was \$18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

No fractional shares of BioSante common stock will be issued to ANI stockholders in connection with the merger. Instead, ANI stockholders will be entitled to receive cash in lieu of any fractional shares of BioSante common stock that they otherwise would be entitled to receive in connection with the merger.

BioSante will issue a press release after the final determination of the exchange ratios announcing the final exchange ratios and BioSante's net cash balance at the determination date.

There will be no adjustment to the total number of shares of BioSante common stock that ANI stockholders will be entitled to receive as a result of changes in the market price of BioSante common stock. Accordingly, the market value of the shares of BioSante common stock issued in connection with the merger will depend on the market value of the shares of BioSante common stock at the time of the

merger, and could vary significantly from the market value on the date of this joint proxy statement/prospectus.

For a more complete discussion of what ANI stockholders will receive in connection with the merger and the determination of the exchange ratios, see the section entitled "The Merger Agreement—Merger Consideration and Adjustment" beginning on page 156.

#### **Treatment of ANI Stock Options and Warrants**

All options and warrants to purchase shares of ANI capital stock outstanding immediately prior to the effective time of the merger will terminate and will no longer be outstanding immediately after the merger, except for certain warrants which although not cancelled in connection with the merger will not represent the right to acquire any equity or other interest in the combined company after the merger.

For a more complete discussion of the treatment of ANI stock options and warrants, see the section entitled "The Merger—Treatment of ANI Stock Options and Warrants" beginning on page 159.

#### **Treatment of BioSante Stock Options, Warrants and Convertible Senior Notes**

All options and warrants to purchase shares of BioSante common stock will remain outstanding immediately after the merger, but the number of shares subject to and the exercise price applicable to such options and warrants will be adjusted to reflect the reverse stock split anticipated to take place immediately prior to the effective time of the merger. Pursuant to the terms of BioSante's equity-based compensation plans, all outstanding options to acquire shares of BioSante common stock will vest immediately and become exercisable in full upon completion of the merger. However, as a result of the anticipated reverse stock split, all such options likely will terminate unexercised since the exercise prices of such options currently range from \$2.02 to \$220.92 per share and the employment or other service of the holder of such options, other than those held by the two BioSante directors who will remain as directors of the combined company after the merger, will be terminated in connection with the merger. As of December 31, 2012, BioSante had an aggregate of 1.1 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding stock options and an aggregate of 4.7 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding warrants. The exercise prices of the warrants currently range from \$1.50 to \$24.00 per share.

All outstanding 3.125% convertible senior notes due May 1, 2013 of BioSante will remain outstanding immediately after the merger, but the conversion price and number of shares of BioSante common stock issuable upon any conversion of such notes will be adjusted to reflect the reverse stock split anticipated to take place immediately prior to the effective time of the merger. As of December 31, 2012, the outstanding principal amount of such notes was \$8.3 million and BioSante had an aggregate of 370,871 shares of BioSante common stock reserved for issuance upon the conversion of such notes. The conversion price of the notes is currently \$22.32 per share.

#### **Management of the Combined Company Following the Merger**

Following the merger, the board of directors of the combined company will be comprised of seven members, including two current members of the BioSante board of directors and five current members of the ANI board of directors. Robert E. Brown, Jr., ANI's chairman of the board, will be chairman of

the board of the combined company. Following the merger, the directors of the combined company will be as follows:

<u>Name</u>	<u>Current Principal Affiliation</u>
Robert E. Brown, Jr.	ANI
Tracy L. Marshbanks, Ph.D.	ANI
Thomas A. Penn	ANI
Arthur S. Przybyl	ANI
Robert Schrepfer	ANI
Fred Holubow	BioSante
Ross Mangano	BioSante

Following the merger, the executive officers of the combined company will be the current executive officers of ANI:

- Arthur S. Przybyl—President and Chief Executive Officer
- Charlotte C. Arnold—Vice President and Chief Financial Officer
- James G. Marken—Vice President, Operations
- Robert J. Jamnick—Vice President, Quality and Product Development

For a more complete discussion of the management of the combined company after the merger, see the section entitled "Management of the Combined Company Following the Merger" beginning on page 250.

**Interests of BioSante's Directors and Officers in the Merger**

In considering the recommendation of the BioSante board of directors to BioSante stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and the other matters to be acted upon by BioSante stockholders at the BioSante special meeting, BioSante stockholders should be aware that members of the BioSante board of directors and BioSante's officers have interests in the merger that may be different from, or in addition to, or conflict with, the interests of BioSante stockholders.

Interests of the BioSante directors and officers relate to:

- The continuing service of each of Fred Holubow and Ross Mangano as directors of the combined company following completion of the merger and the payment of cash and equity compensation in consideration for such service, as described in more detail under "Management of the Combined Company After the Merger—Director Compensation."
- Change in control and severance payments and continued benefits to which BioSante's current executive officers will become entitled following completion of the merger and their anticipated termination of employment with BioSante. Assuming that the merger is completed on the date of the BioSante special meeting and the executive officers are terminated on such date, such individuals would receive approximately the amounts set forth in the table below.

<u>Name</u>	<u>Cash</u>	<u>Perquisites/ Benefits</u>	<u>Total</u>
Stephen M. Simes	\$ 1,490,100	\$ 87,949	\$ 1,578,049
Phillip B. Donenberg	770,000	74,156	844,156
Michael C. Snabes, M.D., Ph.D.	526,400	44,972	571,372

- The accelerated vesting of all unvested BioSante stock options held by the BioSante directors and officers, exercisable for an aggregate of 381,525 shares of BioSante common stock at exercise prices ranging from \$4.08 to \$220.92 per share, all of which options are currently out-of-the-money and likely will terminate unexercised either 90 days or one year after their termination of employment or service upon completion of the merger.
- The right to continued indemnification and insurance coverage for directors and officers of BioSante pursuant to the terms of the merger agreement.

The BioSante board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and to recommend that BioSante stockholders approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and related matters. Other than full disclosure of these potential conflicts of interest, the BioSante board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock.

For a more complete discussion of the interests of the directors and executive officers of BioSante in the merger, see the section entitled "The Merger—Interests of BioSante's Directors and Executive Officers in the Merger" beginning on page 143.

### **Interests of ANI's Directors and Officers in the Merger**

In considering the recommendations of the ANI board of directors to ANI stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger, and the other matters to be acted upon by ANI stockholders at the ANI special meeting, ANI stockholders should be aware that members of the ANI board of directors and ANI's officers have interests in the merger that may be different from, or in addition to, or conflict with, the interests of ANI stockholders.

Interests of the ANI directors and officers relate to:

- The board of directors of the combined company will be comprised of the five individuals that are current members of the ANI board of directors and two individuals that are current members of the BioSante board of directors and such directors, with the exception of Mr. Przybyl, will receive cash and equity compensation for such services, as described in more detail under "Management of the Combined Company After the Merger—Director Compensation."
- The fact that Robert E. Brown, Jr., ANI's chairman of the board, will continue as chairman of the board of the combined company.
- The fact that the executive officers of the combined company will be the current executive officers of ANI and such officers will receive compensation for such service as described in more detail under "Management of the Combined Company After the Merger—Officer Compensation."
- The fact that the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately \$707,705 to \$3,309,410 (assuming BioSante's net cash as of the determination date is \$18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions."

- The fact that MVP Capital and HVC, two firms affiliated with three of ANI's directors, will receive fees of approximately \$350,000 and \$40,000, respectively, upon closing of the merger. This is in addition to unpaid amounts due under existing monitoring arrangements with ANI, which will terminate at closing and which are expected not to exceed \$120,000 for MVP Capital and \$30,000 for HVC, assuming a closing on or before March 31, 2013.
- The right to continued indemnification and insurance coverage for directors and executive officers of ANI following completion of the merger pursuant to the terms of the merger agreement.

The ANI board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger, and to recommend that ANI stockholders approve the merger agreement and the transactions contemplated thereby, including the merger. Other than full disclosure of these potential conflicts of interest, the ANI board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger.

For a more complete discussion of the interests of the directors and executive officers of ANI in the merger, see the section entitled "The Merger—Interests of ANI's Directors and Officers in the Merger" beginning on page 148.

### **Conditions to Completion of the Merger**

BioSante and ANI expect to complete the merger after all conditions to the merger in the merger agreement are satisfied or, if permissible, waived. BioSante and ANI currently expect to complete the merger in the first quarter of 2013. However, it is possible that factors outside of BioSante's or ANI's control could require BioSante and ANI to complete the merger at a later time or not complete it at all. The obligations of each of BioSante and ANI to complete the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

- The adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to effect the reverse stock split and change the company's corporate name.
- The adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders.
- The absence of any legal prohibition to completing the merger.
- The effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4, of which this joint proxy statement/prospectus forms a part, filed by BioSante with the SEC.
- The continued listing of BioSante common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger.
- The receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

- The representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date.
- The other party to the merger agreement having performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it at or before the closing of the merger.
- The other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement.
- No material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

- BioSante's net cash as of the closing being no less than \$17.0 million, as calculated and as adjusted pursuant to the terms of the merger agreement.
- No new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

For a more complete discussion of the conditions to the completion of the merger, see the section entitled "The Merger Agreement—Conditions to Completion of the Merger" beginning on page 159.

#### **No Solicitation**

Each of BioSante and ANI has agreed that, with certain exceptions, BioSante and ANI and their respective officers, directors, employees and advisors will not:

- Solicit, initiate, encourage, facilitate or induce the making of any acquisition proposal.
- Enter into, continue or otherwise participate in any discussions or negotiations regarding or otherwise facilitate or induce any effort or attempt to make or implement any acquisition proposal.
- Approve, endorse or recommend any acquisition proposal.
- Agree, resolve or commit to do any of the foregoing.

The merger agreement does not, however, prohibit BioSante from considering a bona fide acquisition proposal from a third party if certain specified conditions are met. For a more complete description of the prohibition on solicitations of acquisition proposals from third parties, see "The Merger Agreement—No Solicitation" beginning on page 160.

#### **Termination of the Merger Agreement**

Either BioSante or ANI can terminate the merger agreement, which would prevent the merger from being consummated, under certain circumstances as set forth below:

- By mutual written consent of BioSante and ANI.
- By BioSante or ANI, if the merger has not been completed by May 31, 2013, subject to extension to no later than July 31, 2013 based on the date of filing of the registration statement

on Form S-4 of which this joint proxy statement/prospectus forms a part, except that a party whose material breach of the merger agreement resulted in the failure of the merger to occur by such date cannot seek termination for this reason.

- By BioSante or ANI, if any applicable law irrevocably prohibits or makes the merger illegal or a governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that permanently restrains, enjoins or otherwise prohibits the merger, except that the right to terminate the merger agreement for this reason is not available to any party who has not used reasonable best efforts to cause such law or order to be lifted.
- By BioSante or ANI, if ANI stockholders fail to adopt the merger agreement at the ANI stockholder meeting or if BioSante stockholders fail to adopt the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger, and approve the amendments to BioSante's certificate of incorporation at the BioSante stockholder meeting.
- By ANI, if either of the following occur, each a "BioSante triggering event":
  - BioSante fails to include in this joint proxy statement/prospectus the recommendation of the BioSante board of directors to the BioSante stockholders in favor of adoption of the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and approval of the amendments to BioSante's certificate of incorporation.
  - Prior to the BioSante special meeting the BioSante board of directors has withdrawn or made a change, or publicly proposed to withdraw or make a change, in its recommendation to its stockholders to adopt the merger agreement, including the issuance of shares of BioSante common stock in the merger, and to approve the amendments to BioSante's certificate of incorporation in a manner adverse to ANI.
- By BioSante, if BioSante enters into a superior proposal in accordance with the terms of the merger agreement. For a more detailed description of BioSante's ability to terminate the merger agreement in connection with a superior proposal, see the section entitled "The Merger Agreement—No Solicitation".
- By BioSante or ANI, if the other party has breached any of its representations, warranties, covenants or other agreements contained in the merger agreement or if any representation or warranty has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied, provided that if such breach or inaccuracy is curable, then the merger agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of notice of such breach or inaccuracy if such breach has not been cured.
- By ANI, if after BioSante receives an acquisition proposal, BioSante has materially breached its obligations under the merger agreement with respect to the acquisition proposal.

For a more complete discussion of the circumstances under which the merger agreement may be terminated, see the section entitled "The Merger Agreement—Termination" beginning on page 164.

#### **Termination Fees and Expenses**

If the merger agreement is terminated under certain circumstances, BioSante will be required to pay ANI a termination fee of \$1.0 million. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to \$500,000 for ANI's expenses in connection with the transaction. Any expenses paid by BioSante will be credited against the termination fee if the termination fee subsequently becomes payable by BioSante. If the merger agreement is



terminated under certain circumstances, ANI will be required to pay BioSante a termination fee of \$750,000.

For a more complete discussion of termination fees and expenses, see the section entitled "The Merger Agreement—Termination Fees and Expenses" beginning on page 165.

#### **Vote Required**

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger and the issuance of shares of BioSante common stock in the merger, and the proposals to approve the two BioSante charter amendments to effect the reverse stock split and change the corporate name. The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting, is required for approval of the proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger and the proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger and the issuance of shares of BioSante common stock in the merger, and/or the proposals to approve the two BioSante charter amendments to effect the reverse stock split and change the corporate name. For a more complete discussion of the matters to be considered by the BioSante stockholders at the BioSante special meeting and the vote required to approve such matters, see the section entitled "Matters Being Submitted to a Vote of BioSante Stockholders" beginning on page 96.

The affirmative vote of holders of a majority of the shares of ANI common stock, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D convertible preferred stock having voting power outstanding on the record date for the ANI special meeting is required for approval of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger. The affirmative vote of holders of a majority of ANI common stock, calculated on an as-converted basis, present in person or represented by proxy at the ANI special meeting is required for approval of the proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of the proposal to adopt the merger agreement and the transactions contemplated thereby including the merger. For a more complete discussion of the matters to be considered by the ANI stockholders at the ANI special meeting and the vote required to approve such matters, see the section entitled "Matters Being Submitted to a Vote of ANI Stockholders" beginning on page 114.

#### **Voting Agreements**

In connection with the execution of the merger agreement, all of BioSante's directors, executive officers and affiliated entities, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI, pursuant to which each such BioSante stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, in favor of the two charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby. As of the record date for the BioSante special meeting, the shares of BioSante capital stock owned by all of BioSante's directors, executive officers and affiliated entities and thus subject to the voting agreements constituted approximately two percent of the total outstanding voting power of BioSante on that date.

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

For a more complete discussion of the voting agreements, see the section entitled "Voting and Other Ancillary Agreements" beginning on page 168. For a more complete discussion of the beneficial ownership of BioSante's and ANI's directors, executive officers and affiliates, see the sections entitled "Principal Stockholders of BioSante" and "Principal Stockholders of ANI" beginning on pages 274 and 276, respectively.

### **Material U.S. Federal Income Tax Consequences of the Merger**

The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended, and it is a condition to the completion of the merger that BioSante and ANI each receive a written opinion from their respective outside legal counsel regarding such qualification. As a result of the "reorganization," ANI stockholders generally will not recognize gain or loss for U.S. federal income tax purposes upon the exchange of their shares of ANI capital stock for shares of BioSante common stock in connection with the merger. However, if an ANI stockholder receives cash in lieu of a fractional share of BioSante common stock, then such stockholder generally will recognize gain or loss in an amount equal to the difference between such stockholder's adjusted tax basis in the fractional share and the amount of cash received. Moreover, an ANI stockholder who perfects appraisal rights and receives cash in exchange for such stockholder's shares of ANI capital stock will recognize gain or loss measured by the difference between the amount of cash received and such stockholder's adjusted tax basis in those shares. BioSante stockholders generally will not recognize gain or loss for U.S. federal income tax purposes as a result of the merger.

Tax matters are very complicated, and the tax consequences of the merger to a particular BioSante or ANI stockholder will depend in part on such stockholder's circumstances. Accordingly, BioSante and ANI urge you to consult your own tax advisor for a full understanding of the tax consequences of the merger to you, including the applicability and effect of federal, state, local and foreign income and other tax laws. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger" beginning on page 172.

### **Regulatory Approvals**

Neither BioSante nor ANI is required to make any filings or to obtain any approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, BioSante must comply with applicable federal and state securities laws and The NASDAQ Stock Market rules and regulations in connection with the issuance of shares of BioSante common stock in the merger, including the filing with the SEC of the registration statement of which this joint proxy statement/prospectus is a part. For a more complete discussion of the regulatory approvals required in connection with the merger, see the section entitled "The Merger—Regulatory Approvals" beginning on page 151.

### **Anticipated Accounting Treatment**

The merger will be accounted for as a "reverse acquisition" pursuant to which ANI will be considered the acquiring entity for accounting purposes in accordance with U.S. generally accepted accounting principles, referred to as U.S. GAAP. As such, ANI will allocate the total purchase consideration to BioSante's tangible and identifiable intangible assets and liabilities based on their relative fair values at the date of the completion of the merger. ANI's historical results of operations will replace BioSante's historical results of operations for all periods prior to the merger. After completion of the merger, the results of operations of both companies will be included in BioSante's financial statements. For a more complete discussion of the anticipated accounting treatment of the merger, see the section entitled "The Merger—Anticipated Accounting Treatment" beginning on page 151.

### **Appraisal Rights**

If the merger is completed, ANI stockholders are entitled to appraisal rights under Section 262 of the Delaware General Corporation Law. Holders of BioSante common stock and BioSante class C special stock are not entitled to appraisal rights in connection with the merger. For a more complete discussion of the appraisal rights, see the provisions of Section 262 of the Delaware General Corporation Law, attached to this joint proxy statement/prospectus as Annex H, and the section entitled "The Merger—Appraisal Rights" beginning on page 152.

### **Comparison of Stockholder Rights**

Both BioSante and ANI are incorporated under the laws of the State of Delaware; and, accordingly, the rights of the stockholders of each are currently, and will continue to be, governed by the Delaware General Corporation Law and their respective certificates of incorporation and bylaws. If the merger is completed, ANI stockholders will become stockholders of BioSante, and their rights will be governed by the Delaware General Corporation Law, the certificate of incorporation of BioSante and the bylaws of BioSante. The rights of BioSante contained in the certificate of incorporation and bylaws of BioSante differ from the rights of ANI stockholders under the certificate of incorporation and bylaws of ANI, as more fully described under the section entitled "Comparison of Rights of Holders of BioSante Stock and ANI Stock" beginning on page 286.

### **Contingent Value Rights**

BioSante plans to issue contingent value rights (referred to as CVRs) to holders of BioSante common stock as of immediately before completion of the merger. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of a record date of March 15, 2013. The CVRs will be non-transferable and not attached to the shares of BioSante common stock. The CVRs will be rights to receive potential cash payments in connection with a LibiGel transaction (as defined in the contingent value rights agreement) upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante and a rights agent. The aggregate cash payments to be received by holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program during the 10-year period following completion of the merger, and will not exceed \$40 million in the aggregate. The form of the contingent value rights agreement is attached to this joint proxy statement/prospectus as Annex F. For a more complete discussion of the CVRs, see the section entitled "Contingent Value Rights" beginning on page 170.

**SELECTED HISTORICAL FINANCIAL INFORMATION AND UNAUDITED PRO FORMA  
CONDENSED COMBINED FINANCIAL INFORMATION AND DATA**

**Selected Historical Financial Data of BioSante**

The selected financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011, 2010 and 2009 are derived from BioSante's audited financial statements included in this joint proxy statement/prospectus beginning on page F-1. The selected financial data as of December 31, 2009, 2008 and 2007 and for the years ended December 31, 2008 and 2007 are derived from BioSante's financial statements, which are not included in this joint proxy statement/prospectus. The statement of operations data for the nine months ended September 30, 2012 and 2011, as well as the balance sheet data as of September 30, 2012 and 2011 are derived from BioSante's unaudited financial statements included in this joint proxy statement/prospectus beginning on page F-32. The selected historical financial data below should be read in conjunction with "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and BioSante's financial statements and related notes appearing elsewhere in this joint proxy statement/prospectus. The historical results are not necessarily indicative of results to be expected in any future period.

	Nine Months Ended September 30,		Year Ended December 31,				
	2012	2011	2011	2010	2009	2008	2007
	(in thousands, except per share data)						
<b>Statement of Operations Data:</b>							
Revenue	\$ 333	\$ 321	\$ 435	\$ 2,474	\$ 1,258	\$ 3,781	\$ 493
Expenses							
Research and development	14,454	37,481	44,182	39,706	13,681	15,790	4,751
General and administration	5,328	5,258	6,982	5,940	5,374	5,125	4,331
Acquired in-process research and development	—	—	—	—	9,000	—	—
Excess consideration paid over fair value	—	—	—	—	20,192	—	—
Licensing expense	—	—	50	269	300	836	—
Depreciation and amortization	88	118	148	168	137	43	90
Total expenses	19,870	42,857	51,362	46,083	48,684	21,794	9,172
Other (expense) income— Convertible note fair value adjustment	(4,037)	(1,929)	(23)	(1,871)	33	—	—
Other expense—Investment impairment charge	—	—	—	(286)	—	—	—
Other interest (expense) income	(278)	(510)	(674)	(675)	(135)	588	1,095
Other income	—	15	15	245	—	—	—
Income tax benefit	122	—	—	—	—	—	—
Net loss	\$ (23,730)	\$ (44,960)	\$ (51,609)	\$ (46,196)	\$ (47,528)	\$ (17,425)	\$ (7,584)
Basic and diluted net loss per common share(1)	\$ (1.14)	\$ (2.86)	\$ (3.15)	\$ (4.21)	\$ (8.40)	\$ (3.83)	\$ (1.79)
Weighted average number of common shares and common equivalent shares outstanding(1)	20,841	15,745	16,398	10,985	5,659	4,551	4,247

(1) All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

	As of September 30,		As of December 31,				
	2012	2011	2011	2010	2009	2008	2007
(in thousands, except per share data)							
<b>Balance Sheet Data:</b>							
Cash, cash equivalents and short-term investments	\$ 38,049	\$ 69,600	\$ 57,225	\$ 38,155	\$ 29,858	\$ 14,787	\$ 30,655
Total assets	43,212	74,891	62,380	44,767	36,437	17,679	31,241
Total current liabilities (includes short-term convertible senior notes in 2010)	10,922	11,500	7,228	8,183	3,930	3,853	1,516
Convertible senior notes, total long-term	—	19,242	17,337	17,436	16,676	—	—
Stockholders' equity	32,290	44,149	37,815	19,147	15,830	13,826	29,725

(1) All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

**Selected Historical Financial Data of ANI**

The selected financial data as of December 31, 2011 and 2010 and for the years ended December 31, 2011 and 2010 are derived from ANI's audited financial statements and are included in this joint proxy statement/prospectus beginning on page F-48. The statement of operations data for the nine months ended September 30, 2012 and 2011, as well as the balance sheet data as of September 30, 2012 and 2011 are derived from ANI's unaudited financial statements included in this joint proxy statement/prospectus beginning on page F-84. The financial data should be read in conjunction with "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" and ANI's financial statements and related notes appearing elsewhere in this joint proxy statement/prospectus. The historical results are not necessarily indicative of results to be expected in any future period.

	Nine Months Ended September 30,		Year Ended December 31,	
	2012	2011	2011	2010
(in thousands, except per share data)				
<b>Statement of Operations Data:</b>				
Net revenues	\$ 15,050	\$ 11,955	\$ 16,515	\$ 8,975
Total operating expenses	14,075	12,163	16,510	11,806
Net loss	\$ (351)	\$ (1,768)	\$ (2,428)	\$ (9,273)
Net loss attributed to common stockholders	\$ (4,782)	\$ (2,642)	\$ (4,914)	\$ (7,810)
Basic and diluted net loss per common share	\$ (439.32)	\$ (298.31)	\$ (693.61)	\$ (1,673.92)

	As of September 30,		As of December 31,	
	2012	2011	2011	2010
(in thousands)				
<b>Balance Sheet Data:</b>				
Cash, cash equivalents and short-term investments, including restricted cash and investments	\$ 148	\$ 27	\$ —	\$ —
Total assets	13,559	11,646	12,676	10,514
Total current liabilities	6,368	5,876	6,161	5,955
Other long-term obligations, excluding current portion	—	15,182	16,582	12,202
Redeemable convertible preferred stock	46,155	23,722	24,216	35,808
Accumulated deficit	(40,048)	(34,126)	(35,370)	(44,444)
Total stockholders' deficit	(38,964)	(33,134)	(34,284)	(43,452)

## Summary Unaudited Pro Forma Condensed Combined Financial Data of BioSante and ANI

The following summary unaudited pro forma condensed combined financial data is intended to show how the merger might have affected historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet, and was prepared based on the historical financial results reported by BioSante and ANI. The following should be read in conjunction with the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239, the audited and unaudited historical financial statements of BioSante and ANI and the notes thereto beginning on pages F-1 and F-47, respectively, the sections entitled "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 193 and "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" beginning on page 222, and the other information contained in this joint proxy statement/prospectus. The following information does not give effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

The merger will be accounted for as a reverse acquisition under the accounting rules for business combinations. Under the reverse acquisition method of accounting, ANI will be treated as the accounting acquiror and BioSante will be treated as the "acquired" company for financial reporting purposes because, immediately upon completion of the merger, ANI stockholders prior to the merger will hold a majority of the voting interest of the combined company. In addition, the seven member board of directors of the combined company will be comprised of five of the current members of the ANI board of directors; and therefore, ANI's current board of directors will possess majority control of the board of directors of the combined company. Members of the current management of ANI will be responsible for the management of the combined company and the majority of the combined company's activities will be activities related to ANI's current business.

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The pro forma adjustments reflecting the completion of the merger are based upon the acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth in the notes to the unaudited pro forma condensed combined financial statements.

The summary unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The summary unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the unaudited historical statements of operations of BioSante and ANI for their respective nine-month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The summary unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective year ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

The historical financial data has been adjusted to give pro forma effect to events that are (i) directly attributable to the merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition and certain other adjustments.

The unaudited pro forma condensed combined financial data is presented for illustrative purposes only and is not necessarily indicative of the financial condition or results of operations of future periods or the financial condition or results of operations that actually would have been realized had the entities been combined during the periods presented. In addition, as explained in more detail in the accompanying notes to the unaudited pro forma condensed combined financial statements (see the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239), the preliminary acquisition-date fair value of the identifiable assets acquired and liabilities assumed reflected in the unaudited pro forma condensed combined financial statements is subject to adjustment and may vary from the actual amounts that will be recorded upon completion of the merger.

	<u>For the Year Ended December 31, 2011</u>	<u>For the Nine Months Ended September 30, 2012</u>
	(in thousands)	
<b>Unaudited Pro Forma Condensed Combined Statements of Operations Data:</b>		
Revenue	\$ 16,950	\$ 15,383
Operating Expenses:		
Cost of sales (excluding depreciation and amortization)	6,861	6,292
Salaries and benefits	12,586	8,318
Freight	253	243
Research and development	39,123	11,738
Selling, general and administrative	8,318	6,327
Licensing expense	50	—
Depreciation and amortization	3,123	2,345
Total operating expenses	70,314	35,263
Net loss	\$ (56,479)	\$ (25,399)
Net loss from continuing operations available to common shareholders	\$ (56,685)	\$ (25,503)

	<u>As of September 30, 2012</u>
	(in thousands)
<b>Unaudited Pro Forma Condensed Combined Balance Sheet Data:</b>	
Cash and cash equivalents	\$ 38,197
Total assets	76,306
Accounts payable	3,301
Accrued compensation	4,364
Other accrued expenses	4,429
Returned goods reserve	388
Borrowing under line of credit	3,429
Convertible senior notes	7,593
Interest on convertible senior notes	108
Current liabilities of discontinued operations	378
Accumulated deficit	(47,302)
Stockholders' equity	52,316

**COMPARATIVE HISTORICAL AND UNAUDITED PRO FORMA PER SHARE DATA**

The following table sets forth certain historical, unaudited pro forma condensed combined and pro forma condensed combined equivalent financial information and reflects:

- *BioSante and ANI Historical Data:* the historical BioSante net loss and book value per share of BioSante common stock and the historical ANI net loss and book value per share of ANI common stock;
- *Combined Company Pro Forma Data:* the unaudited pro forma combined company net loss after giving effect to the merger on an acquisition basis as if the merger had been completed on January 1, 2011, and book value per share after giving effect to the merger on an acquisition basis as if the merger had been completed on September 30, 2012; and
- *ANI Pro Forma Equivalent Data:* the unaudited pro forma ANI equivalent share data, including net loss per series D preferred share, and book value per series D preferred share, calculated by multiplying the unaudited pro forma combined company data by an assumed exchange ratio of 10.3502 shares of BioSante common stock for each share of series D preferred stock.

The following information does not give effect to the proposed reverse stock split of BioSante common stock described in BioSante Proposal No. 2. You should read the table below in conjunction with the audited and unaudited financial statements of BioSante and ANI beginning on pages F-1 and F-47, respectively, of this joint proxy statement/prospectus, and the related notes thereto. You also are urged to read the section entitled "Unaudited Pro Forma Condensed Combined Financial Statements" beginning on page 239.

	<u>As of and For the Year Ended December 31, 2011</u>	<u>As of and For the Nine Months Ended September 30, 2012</u>
	(in thousands)	
<b>BioSante Historical Data:</b>		
Basic and diluted net loss per common share	\$ (3.15)	\$ (1.14)
Book value per share	—	—
<b>ANI Historical Data:</b>		
Basic and diluted net loss per common share	\$ (693.61)	\$ (439.32)
Book value per share	—	\$ —
<b>Combined Company Pro Forma Data:</b>		
Basic and diluted net loss per common share	\$ (1.28)	\$ (0.52)
Book value per share	—	\$ 1.00
<b>ANI Pro Forma Equivalent Data*:</b>		
Basic and diluted net loss per series D preferred share	\$ (13.25)	\$ (5.38)
Book value per series D preferred share	—	\$ 10.35

\* In comparison, if the ANI Pro Forma Equivalent Data were calculated by multiplying the unaudited pro forma combined company data by 0.53, which represents the percentage of ownership of the combined company expected to be held by the current ANI stockholders as of immediately following the completion of the merger (without taking into account any shares of BioSante common stock held by ANI stockholders prior to the completion of the merger), as determined pursuant to the exchange ratios, and assuming BioSante's net cash is \$18.0 million as of the determination date, the basic and diluted net loss per common share as of and for the year ended December 31, 2011 would have been \$(0.68) and the basic and diluted net loss per common share for the nine months ended September 30, 2012 and the book value per share as of September 30, 2012 would have been \$(0.28) and \$0.53, respectively.



**MARKET PRICE AND DIVIDEND INFORMATION****BioSante**

The table below sets forth, for the calendar quarters indicated, the high and low daily sales prices per share of BioSante common stock, which trades on The NASDAQ Global Market under the symbol "BPAX", as reported by The NASDAQ Global Market. There is no established public trading market for BioSante class C special stock. BioSante's fiscal year ends on December 31<sup>st</sup>.

**BioSante Common Stock**

<u>Fiscal Year Ended December 31, 2011</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 15.24	\$ 9.72
Second Quarter	19.20	11.58
Third Quarter	24.12	12.12
Fourth Quarter	16.56	2.28

<u>Fiscal Year Ended December 31, 2012</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 7.38	\$ 2.64
Second Quarter	4.56	2.00
Third Quarter	2.62	1.21
Fourth Quarter	1.97	1.08

<u>Fiscal Year Ended December 31, 2013</u>	<u>High</u>	<u>Low</u>
First Quarter (through January 15, 2013)	\$ 1.48	\$ 1.25

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, BioSante had 453 holders of record of BioSante common stock and six record holders of BioSante class C special stock.

BioSante never has declared or paid cash dividends on its capital stock and does not intend to pay any cash dividends in the foreseeable future. Holders of BioSante class C special stock are not eligible to receive dividends. Any future determination to pay cash dividends will be at the discretion of the BioSante board of directors and will depend upon BioSante's financial condition, operating results, capital requirements, deployment of resources and ability to engage in strategic transactions, whether or not the merger is consummated, and such other factors as the BioSante board of directors deems relevant.

On October 3, 2012, the last trading day prior to announcement of the merger, the last reported sale price of BioSante common stock was \$1.80, for an aggregate market value of BioSante of \$44.0 million. On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the last reported sale price of BioSante common stock was \$1.36, for an aggregate market value of BioSante of \$33.2 million. Assuming the issuance on such date of an aggregate of 27.9 million shares of BioSante common stock based on an exchange ratio of 10.3502 for the ANI series D preferred stock and an exchange ratio of zero for all other shares of ANI capital stock, if the merger was completed on such date, the market value attributable to the ANI common stock in the aggregate, or approximately 53 percent of the outstanding shares of the combined company, would equal \$38.0 million.

The following table sets forth information concerning the beneficial ownership of:

- each person known by BioSante to beneficially own more than five percent of BioSante's voting capital stock;

- each of BioSante's current directors and each nominee for director, including persons who are expected to become directors of the combined company following completion of the merger; and
- all of BioSante's current directors and executive officers as a group, prior to the completion of the merger and immediately following the completion of the merger.

The pre-merger percentage of beneficial ownership is calculated in relation to the 24,422,240 shares of BioSante common stock that were outstanding as of December 31, 2012 and the post-merger percentage of beneficial ownership is calculated in relation to an estimated 52,337,228 shares of common stock of the combined company outstanding upon completion of the merger, assuming that the exchange ratio to be used in connection with the merger is approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and zero for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus but giving effect to the anticipated issuance of an estimated 321,737 shares of ANI series D preferred stock to ANI's executive officers and an additional ANI employee in connection with the transaction bonus arrangements as described elsewhere in this joint proxy statement/prospectus). Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options and warrants currently exercisable or that become exercisable within 60 days of December 31, 2012 are outstanding for the purpose of computing the percentage of capital stock owned by such person or group. However, such unissued shares of capital stock are not deemed to be outstanding for calculating the percentage of capital stock owned by any other person. Except as otherwise indicated and subject to the voting agreements described under the section entitled "Voting and Other Ancillary Agreements," BioSante believes that the beneficial owners of its capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable.

Name of Beneficial Owner	Pre-Merger		Post-Merger	
	BioSante Common Stock and Common Stock Equivalents	Percent of Class	BioSante Common Stock and Common Stock Equivalents	Percent of Class
Louis W. Sullivan, M.D.	52,147	*	52,147	*
Stephen M. Simes	275,652	1.1%	275,652	*
Fred Holubow	34,372	*	34,372	*
Ross Mangano	418,397	1.7%	418,397	*
Edward C. Rosenow, III, M.D.	27,586	*	27,586	*
John T. Potts, Jr., M.D.	8,636	*	8,636	*
Stephen A. Sherwin, M.D.	41,890	*	41,890	*
Robert E. Brown, Jr.	0	*	14,248,043	27.2%
Arthur S. Przybyl	0	*	0	*
Tracy L. Marshbanks, Ph.D.	0	*	4,085,016	7.8%
Thomas T. Penn	0	*	14,248,043	27.2%
Robert Schrepfer	0	*	0	*
All current BioSante directors and executive officers as a group (nine persons)	1,042,589	4.2%	18,785,828	35.8%

\* Represents beneficial ownership of less than one percent.

For detailed information regarding the beneficial ownership of certain stockholders of BioSante, ANI and the combined company upon completion of the merger, see the sections entitled "Principal Stockholders of BioSante," "Principal Stockholders of ANI" and "Principal Stockholders of Combined Company" in this joint proxy statement/prospectus.

Because the market price of BioSante common stock is subject to fluctuation, the market value of the shares of BioSante common stock that holders of ANI capital stock will receive in the merger may increase or decrease. The foregoing information reflects only historical information. This information may not provide meaningful information to ANI stockholders in determining whether to approve ANI Proposal No. 1. ANI stockholders are urged to obtain current market quotations for BioSante common stock and to review carefully the other information contained in this joint proxy statement/prospectus or referenced in this joint proxy statement/prospectus. Historical stock prices are not indicative of future stock prices.

Following completion of the merger and assuming the successful reapplication to The NASDAQ Global Market for initial inclusion of BioSante common stock on the NASDAQ Global Market, the BioSante common stock of BioSante, including the shares of BioSante common stock issued to ANI stockholders in connection with the merger, will continue to be listed on The NASDAQ Global Market.

## **ANI**

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, ANI had 11 holders of record of ANI series D preferred stock, 12 holders of record of ANI series C preferred stock, 12 holders of record of ANI series B preferred stock, five holders of record of ANI series A preferred stock and 10 holders of record of ANI common stock.

Other than a one-time dividend on the ANI series A preferred stock declared and paid in additional shares of ANI series A preferred stock in 2006, ANI has never paid a dividend on its capital stock. Any determination to pay dividends to holders of ANI capital stock in the future will be at the discretion of the ANI board of directors and will depend on many factors, including ANI's financial condition, results of operations, general business conditions, and any other factors the ANI board of directors deems relevant.

ANI is a private company and shares of its capital stock are not publicly traded.

## RISK FACTORS

*In addition to the other information included in this joint proxy statement/prospectus, BioSante and ANI stockholders should consider carefully the following risk factors before deciding whether to vote in favor of the adoption of the merger agreement and the approval of the transactions contemplated thereby, including the merger. If any of the risks described below actually occurs, the respective businesses, operating results, financial condition or stock prices of BioSante, ANI or the combined company could be materially adversely affected.*

### Risks Related to the Merger

***The issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will dilute substantially the voting power of current BioSante stockholders.***

Pursuant to the terms of the merger agreement, it is anticipated that BioSante will issue shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is \$18.0 million as of the determination date. After such issuance, the shares of BioSante common stock outstanding immediately prior to completion of the merger will represent approximately 47 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger. These ownership percentages may change depending upon the amount of BioSante's net cash as of a determination date prior to completion of the merger. Accordingly, the issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will reduce significantly the relative voting power of each share of BioSante common stock held by current BioSante stockholders. Consequently, the BioSante stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger.

***The exchange ratios in the merger agreement are dependent upon not only the terms of the merger agreement, but also the terms of ANI's certificate of incorporation, which contains provisions that give preference to holders of shares of ANI series D preferred stock and, to a lesser extent, holder of shares of other series of ANI preferred stock. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.***

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of ANI capital stock issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00 (subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. The exchange ratios in the merger agreement reflect these preferential payments. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.

***The exchange ratios in the merger agreement are subject to adjustment based on BioSante's net cash as of a determination date prior to completion of the merger, which could dilute further the ownership of either the BioSante or ANI stockholders in the combined company.***

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of ANI capital stock issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. If BioSante has more than \$18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than \$18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In no event, however, will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than \$17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

The items that will constitute BioSante's net cash at the determination date set forth in the merger agreement are subject to a number of factors, some of which are outside the control of BioSante and many of which are outside the control of ANI. For a more detailed discussion of the calculation of BioSante's net cash at the determination date set forth in the merger agreement and to view a table that illustrates how changes in BioSante's net cash at the determination date will affect the exchange ratios, see "The Merger Agreement—Merger Consideration and Adjustment" and "The Merger Agreement—Determination of BioSante's Net Cash" beginning on page 156 and page 158, respectively.

***The exchange ratios are not adjustable based on the market price of BioSante common stock and if the market price of BioSante common stock fluctuates, the market value of the shares of BioSante common stock to be received by the ANI stockholders in connection with the merger is subject to change prior to completion of the merger.***

The aggregate number of shares of BioSante common stock to be issued to ANI stockholders is expected to represent approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is \$18.0 million as of the determination date. The exchange ratios, as such ratios are calculated pursuant to the formulas set forth in the merger agreement, are based on the number of shares of BioSante common stock and ANI capital stock outstanding as of immediately prior to completion of the merger, and in the case of BioSante, a certain percentage of the number of certain warrants to purchase shares of BioSante common stock outstanding as of such date, and will not be determined until that time. The exchange ratios will be adjusted upward or downward only as a result of changes to the outstanding capital stock of either or both of BioSante and ANI as of immediately prior to completion of the merger and changes to BioSante's net cash as of a determination date prior to completion of the merger. No adjustments to the exchange ratios will be made based on changes in the trading price of BioSante common stock or the value of ANI capital stock prior to completion of the merger. Changes in the trading price of BioSante common stock or the value of ANI capital stock may

result from a variety of factors, including, among others, general market and economic conditions, changes in BioSante's or ANI's respective businesses, operations and prospects, market assessment of the likelihood that the merger will be completed as anticipated or at all, and regulatory considerations. Many of these factors are beyond BioSante's or ANI's control. As a result, the value of the shares of BioSante common stock issued to ANI stockholders in connection with the merger could be substantially less or substantially more than the current market value of BioSante common stock.

***The exchange ratios are not adjustable based on issuances by BioSante of additional shares of BioSante common stock either upon the exercise of options or warrants or the conversion of convertible securities or otherwise, which issuances would result in additional dilution to the BioSante stockholders.***

As of December 31, 2012, BioSante had outstanding options to purchase an aggregate of approximately 1.1 million shares of BioSante common stock, warrants to purchase an aggregate of approximately 4.7 million shares of BioSante common stock, an aggregate of 65,211 shares of BioSante class C special stock that are convertible into 65,211 shares of BioSante common stock and an aggregate of \$8.3 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 that are convertible into an aggregate of 370,871 shares of BioSante common stock. BioSante is not prohibited under the terms of the merger agreement from issuing additional equity securities under certain circumstances, including securities issued pursuant to the exercise of outstanding options or warrants or the conversion or exchange of outstanding convertible senior notes. It is possible that prior to completion of the merger BioSante may issue additional equity securities. The exchange ratios in the merger agreement, which are designed to result in the issuance by BioSante of shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante's net cash is \$18.0 million as of the determination date, are not adjustable based on issuances by BioSante of additional shares of BioSante common stock. Therefore, any such issuances by BioSante would result in additional dilution to the BioSante stockholders.

***The announcement and pendency of the merger could have an adverse effect on the trading price of BioSante common stock and/or the business, financial condition, results of operations or business prospects for BioSante and/or ANI.***

While there have been no significant adverse effects to date, the announcement and pendency of the merger could disrupt BioSante's and/or ANI's businesses in the following ways, among others:

- third parties may seek to terminate and/or renegotiate their relationships with BioSante or ANI as a result of the merger, whether pursuant to the terms of their existing agreements with BioSante and/or ANI or otherwise; and
- the attention of BioSante and/or ANI management may be directed toward completion of the merger and related matters and may be diverted from the day-to-day business operations of their respective companies, including from other opportunities that otherwise might be beneficial to BioSante or ANI.

Should they occur, any of these matters could adversely affect the trading price of BioSante common stock or harm the financial condition, results of operations or business prospects of BioSante, ANI and/or the combined company.

***Failure to complete the merger could negatively impact BioSante's and ANI's respective businesses, financial condition or results of operations or the trading price of BioSante common stock.***

The completion of the merger is subject to a number of conditions and there can be no assurance that the conditions to the completion of the merger will be satisfied. If the merger is not completed, BioSante and/or ANI, as applicable, will be subject to several risks, including:

- the current trading price of BioSante common stock may reflect a market assumption that the merger will occur, meaning that a failure to complete the merger could result in a decline in the trading price of BioSante common stock;
- certain executive officers and/or directors of BioSante may seek other employment opportunities, and the departure of any of BioSante's executive officers and the possibility that the company would be unable to recruit and hire an executive could impact negatively BioSante's business and operating results;
- the BioSante board of directors will need to reevaluate BioSante's strategic alternatives, which alternatives may include a sale of the company, liquidation of the company or other strategic transaction;
- BioSante may be required to reimburse ANI for expenses of up to \$500,000 or pay a termination fee of \$1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;
- ANI may be required to pay BioSante a termination fee of \$750,000 if the merger agreement is terminated by BioSante under certain circumstances;
- BioSante and ANI are expected to incur substantial transaction costs in connection with the merger whether or not the merger is completed;
- neither BioSante nor ANI would realize any of the anticipated benefits of having completed the merger; and
- under the merger agreement, each of BioSante and ANI is subject to certain restrictions on the conduct of its business prior to completion of the merger, which restrictions could adversely affect their ability to realize certain of their respective business strategies or take advantage of certain business opportunities.

If the merger is not completed, these risks may materialize and affect materially and adversely either or both companies' respective businesses, financial condition, results of operations, or, in the case of BioSante, the trading price of BioSante common stock.

***BioSante and ANI have incurred and will continue to incur significant transaction costs in connection with the merger, some of which will be required to be paid even if the merger is not completed.***

BioSante and ANI have incurred and will continue to incur significant transaction costs in connection with the merger. These costs are primarily associated with the fees of their respective attorneys and accountants and BioSante's financial advisor. Most of these costs will be paid by the party incurring the costs even if the merger is not completed. In addition, if the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante may be required to pay ANI a termination fee of \$1.0 million or ANI may be required to pay BioSante a termination fee of \$750,000. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to \$500,000 for its expenses in connection with the transaction. If the merger is completed, the combined company will bear the transaction costs of both BioSante and ANI in connection with the merger, including financial advisor, legal and accounting fees and expenses.

***Because the merger will be completed after the date of the BioSante and ANI special meetings of stockholders, it is possible that at the time of your special meeting, you will not know the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger.***

Subject to the terms of the merger agreement, at the effective time of the merger, each share of ANI capital stock issued and outstanding immediately prior to the merger will be canceled, extinguished and automatically converted into the right to receive that number of shares of BioSante common stock as determined pursuant to the exchange ratios described in the merger agreement. The exchange ratios depend on the net cash of BioSante as of a determination date prior to completion of the merger. The determination date is defined as the date that is 14 days prior to the date of the BioSante special meeting as set forth in this joint proxy statement/prospectus, subject to extension for adjournment of the BioSante special meeting and subject to a dispute resolution provisions in the event there is a dispute between BioSante and ANI as to the amount of net cash of BioSante as of the determination date. Under the merger agreement, BioSante's "net cash" is defined as generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. In the event of a dispute regarding the amount of net cash of BioSante as of the determination date, it is possible that the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger may not be available at the time of the BioSante special meeting or the ANI special meeting.

***Some of the directors and executive officers of BioSante and ANI have interests in the merger that are different from, or in addition to, those of the other BioSante and ANI stockholders.***

When considering the recommendation by the BioSante board of directors that the BioSante stockholders vote "for" each of the proposals being submitted to the BioSante stockholders at the BioSante special meeting and the recommendation by the ANI board of directors that the ANI stockholders vote "for" each of the proposals being submitted to the ANI stockholders at the ANI special meeting, the BioSante and ANI stockholders should be aware that certain of the directors and executive officers of BioSante and ANI have arrangements that provide them with interests in the merger that are different from, or in addition to, those of the stockholders of BioSante and ANI.

For instance, in connection with the merger, Fred Holubow and Ross Mangano, each a current member of the BioSante board of directors, will continue to serve as a director of the combined company following completion of the merger and will receive cash and equity compensation in consideration for such service. The employment of each of BioSante's three executive officers will terminate immediately following completion of the merger and they will be entitled to receive severance benefits ranging from approximately \$571,400 to \$1,578,000 in connection with such termination.

All of the current directors of ANI will serve as directors of the combined company following completion of the merger and will receive certain cash and equity compensation in consideration for such service. Likewise, all of the executive officers of ANI will continue to serve as executive officers of the combined company following completion of the merger and will receive cash and equity compensation in consideration for such service. In addition, the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately \$707,705 to \$3,309,410 (assuming BioSante's net cash as of the determination date is \$18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions." In addition, certain of ANI's executive officers and directors are expected to own a significant number of shares of common stock of the combined company following completion of the merger. See "Principal Stockholders of Combined Company."



The directors and executive officers of BioSante and ANI also have certain rights to indemnification and to directors' and officers' liability insurance that will be provided by the combined company following completion of the merger. See the sections entitled "The Merger—Interests of BioSante's Directors and Executive Officers in the Merger" and "The Merger—Interests of ANI's Directors and Officers in the Merger" beginning on pages 143 and 148, respectively.

The board of directors of each of BioSante and ANI were aware of these potential interests and considered them in making their respective recommendations to approve the proposals being submitted to the BioSante stockholders at the BioSante special meeting, with respect to the BioSante stockholders, and to approve the proposals being submitted to the ANI stockholders at the ANI special meeting, with respect to the ANI stockholders.

***The merger agreement and the voting agreements contain provisions that could discourage or make it difficult for a third party to acquire BioSante or ANI prior to completion of the merger.***

The merger agreement contains provisions that make it difficult for BioSante or ANI to entertain a third-party proposal for an acquisition of BioSante or ANI. These provisions include:

- the general prohibition on BioSante's and ANI's soliciting or engaging in discussions or negotiations regarding any alternative acquisition proposal;
- the requirement that BioSante reimburse ANI for expenses of up to \$500,000 or pay a termination fee of \$1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;
- the requirement that ANI pay BioSante a termination fee of \$750,000 if the merger agreement is terminated by BioSante under certain circumstances; and
- the requirement that BioSante and ANI submit the proposals described in this joint proxy statement/prospectus, as applicable, to a vote of their respective stockholders even if their respective board of directors changes its recommendation with respect to such proposals, as applicable.

See the sections entitled "The Merger Agreement—No Solicitation", "The Merger Agreement—Meetings of Stockholders; Change in Board Recommendation" and "The Merger Agreement—Termination Fees and Expenses" beginning on pages 160, 162 and 165, respectively.

Pursuant to the voting agreements entered into between (i) BioSante and certain stockholders of ANI and (ii) ANI and the directors, executive officers and certain stockholders of BioSante, each such director, executive officer and applicable stockholder has agreed not to take any actions that BioSante or ANI, as applicable, is prohibited from taking pursuant to the no-solicitation restrictions contained in the merger agreement. In addition, holders of shares representing approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger, and ANI is required under the terms of the merger agreement to convene and hold the ANI special meeting regardless of any change in the recommendation of the ANI board of directors. Likewise, holders of shares representing approximately two percent of the outstanding capital stock of BioSante as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of the shares of BioSante common stock, and the approval of the BioSante charter amendments, and BioSante is required under the terms of the merger agreement to convene and hold the BioSante

special meeting regardless of any change in the recommendation of the BioSante board of directors. See the section entitled "Voting and Other Ancillary Agreements" beginning on page 168.

These provisions might discourage an otherwise interested third party from considering or proposing an acquisition of BioSante or ANI, even one that may be deemed of greater value than the merger to BioSante stockholders or ANI stockholders, as applicable. Furthermore, even if a third party elects to propose an acquisition, the concept of a termination fee or payment of the other party's expenses may result in that third party offering a lower value to BioSante stockholders or ANI stockholders, as applicable, than such third party might otherwise have offered.

***Because the lack of a public market for shares of ANI capital stock makes it difficult to evaluate the fairness of the merger, ANI stockholders may receive consideration in the merger that is greater than or less than the fair value of the shares of capital stock of ANI.***

ANI is privately held and its outstanding capital stock is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair value of ANI or its shares of capital stock. Since the percentage of BioSante's equity to be issued to the ANI stockholders was determined based on negotiations between the parties, it is possible that the value of the BioSante common stock to be issued in connection with the merger will be greater than the fair value of ANI. Alternatively, it is possible that the value of the shares of BioSante common stock to be issued in connection with the merger will be less than the fair value of ANI.

***The vote to approve the merger with BioSante is effectively controlled by the holders of ANI series D preferred stock.***

In order to approve the merger agreement and transactions contemplated under the merger agreement, ANI requires the vote of (i) the majority of the outstanding shares of ANI capital stock entitled to vote, calculated on an as-converted basis and voting as a single class, and (ii) 65 percent of the outstanding shares of ANI series D preferred stock entitled to vote. On an as-converted basis, the number of ANI series D preferred stock represents 90.8 percent of the total number of shares of ANI capital stock outstanding and entitled to vote. As a result, assuming that holders of more than 65% of the ANI series D preferred stock all vote such stock for (or against) the merger, both votes described in (i) and (ii) above would be decided, and holders of ANI common stock, or series A, B or C preferred stock, would be unable to affect the outcome of the vote.

***If the merger does not qualify as a reorganization under Section 368(a) of the Code, ANI and the ANI stockholders may be required to pay substantial U.S. federal income taxes as a result of the merger.***

BioSante and ANI intend, and will be relying on the opinion of their respective tax counsel, that the merger will qualify as a "reorganization" under Section 368(a) of the Code. BioSante and ANI currently anticipate that neither ANI nor, generally, the U.S. holders of shares of ANI capital stock will recognize taxable gain or loss as a result of the merger. However, neither BioSante nor ANI has requested, or intends to request, a ruling from the Internal Revenue Service (IRS) with respect to the tax consequences of the merger, and there can be no assurance that the companies' position or the opinion of either company's respective tax counsel would be sustained if challenged by the IRS. Accordingly, if there is a final determination that the merger does not qualify as a "reorganization" under Section 368(a) of the Code and is taxable for U.S. federal income tax purposes (i) ANI would recognize taxable gain on its deemed receipt of BioSante common stock in exchange for the sale of substantially all of ANI's assets and assumption of ANI liabilities to the extent the fair market value of the BioSante common stock deemed received plus the ANI liabilities assumed by BioSante in the merger exceed ANI's adjusted tax basis in its assets deemed sold to BioSante, with such gain offset by available net operating losses and other tax attributes of ANI, if any, and (ii) ANI stockholders generally would recognize taxable gain or loss on their receipt of BioSante common stock in connection

with the merger in an amount equal to the difference between such stockholder's adjusted tax basis in their shares of ANI capital stock and the fair market value of the BioSante common stock and cash received in lieu of fractional shares, if any. Any unpaid ANI tax liability incurred if the merger does not qualify as a reorganization would be assumed by BioSante in the merger. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger" beginning on page 172.

***The shares of BioSante common stock to be received by ANI stockholders as a result of the merger will have different rights from shares of ANI preferred stock or ANI common stock.***

Following completion of the merger, ANI stockholders will no longer be stockholders of ANI, but will be stockholders of BioSante. There will be important differences between your current rights as an ANI stockholder and the rights to which you will be entitled as a BioSante stockholder. See "Comparison of Rights of Holders of BioSante Stock and ANI Stock" beginning on page 286 for a discussion of the different rights associated with BioSante common stock and ANI preferred stock and ANI common stock.

***BioSante may not issue CVRs to holders of BioSante common stock prior to the merger and, even if issued, the CVRs will not be certificated or transferable and may not result in any cash payments to holders of CVRs.***

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to holders of BioSante common stock, there is no assurance that the CVRs will be issued at all or based on the terms currently set forth in the form of the contingent value rights agreement. See "Contingent Value Rights" for more information on the terms of the CVRs and the contingent value rights agreement. BioSante currently has not entered into the contingent value rights agreement and the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the anticipated tax impact of the distribution and issuance of the CVRs to the holders of BioSante common stock. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as currently contemplated may be changed prior to BioSante entering into the contingent value rights agreement.

Even if CVRs are issued, they will not be certificated or transferable and may not result in any cash payments to holders of CVRs. Under the contingent value rights agreement, the combined company will not have any obligation, other than an obligation to act in good faith to pursue, engage in, negotiate, enter into or consummate an actual or potential LibiGel transaction (as such term is defined in the contingent value rights agreement).

***BioSante and ANI may waive one or more of the conditions to the merger without resoliciting stockholder approval for the merger.***

Certain conditions to BioSante's and ANI's obligations to complete the merger may be waived, in whole or in part, to the extent legally allowed, either unilaterally or by agreement of BioSante and ANI. In the event of a waiver of a condition, the boards of directors of BioSante and ANI will evaluate the materiality of any such waiver to determine whether amendment of this joint proxy statement/prospectus and resolicitation of proxies is necessary. In the event that the board of directors of BioSante or ANI determines any such waiver is not significant enough to require resolicitation of stockholders, it will have the discretion to complete the merger without seeking further stockholder approval. The conditions requiring the approval of each company's stockholders cannot, however, be waived.

## **Risks Related to the Combined Company if the Merger is Completed**

***If any of the events described in "Risks Related to BioSante" or "Risks Related to ANI" occur, those events could cause the potential benefits of the merger not to be realized.***

Following completion of the merger, the combined company will be susceptible to many of the risks described in the sections herein entitled "Risks Related to BioSante," "Risks Related to ANI" and "Risks Related to the Combined Company." To the extent any of the events in the risks described in those sections occur, those events could cause the potential benefits of the merger not to be realized and the market price of the combined company's common stock to decline.

***The success of the merger will depend, in large part, on the ability of the combined company following completion of the merger to realize the anticipated benefits from combining the businesses of BioSante and ANI.***

The merger involves the integration of two companies that previously have operated independently with principal offices in two distinct locations. Due to legal restrictions, BioSante and ANI are able to conduct only limited planning regarding the integration of the two companies prior to completion of the merger. Significant management attention and resources will be required to integrate the two companies after completion of the merger. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the merger and the operations of the combined company;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the merger; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by completing the merger and integrating the companies' operations.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

***The merger will result in changes to the BioSante board of directors and the combined company may pursue different strategies than either BioSante or ANI may have pursued independently.***

If BioSante and ANI complete the merger, the composition of the BioSante board of directors will change in accordance with the merger agreement. Following completion of the merger, the combined company's board of directors will consist of seven members, including two of the current directors of BioSante and five of the current directors of ANI. Currently, it is anticipated that the combined company will continue to advance the product development efforts and business strategies of ANI primarily. However, because the composition of the board of directors of the combined company will

consist of directors from both BioSante and ANI, the combined company may determine to pursue certain business strategies that neither ANI nor BioSante would have pursued independently.

***Ownership of the combined company's common stock may be highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company's stock price to decline.***

Upon completion of the merger, ANI's directors and executive officers continuing with the combined company, together with their respective affiliates, are expected to beneficially own or control approximately 41 percent of the combined company (see the sections entitled "Principal Stockholders of ANI" beginning on page 276 and "Principal Stockholders of Combined Company" beginning on page 280 for more information on the estimated ownership of the combined company following the merger). Accordingly, these directors, executive officers and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the combined company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company's assets or any other significant corporate transaction. These stockholders also may exert influence in delaying or preventing a change in control of the combined company, even if such change in control would benefit the other stockholders of the combined company. In addition, the significant concentration of stock ownership may affect adversely the market value of the combined company's common stock due to investors' perception that conflicts of interest may exist or arise.

***Future results of the combined company may differ materially from the unaudited pro forma financial statements presented in this joint proxy statement/prospectus and the financial forecasts prepared by ANI in connection with discussions concerning the merger.***

The future results of the combined company may be materially different from those shown in the unaudited pro forma condensed combined financial statements presented in this joint proxy statement/prospectus, which show only a combination of the historical results of BioSante and ANI, and the financial forecasts prepared by ANI in connection with discussions concerning the merger. BioSante and ANI expect to incur significant costs associated with completion of the merger and combining the operations of the two companies. The exact magnitude of these costs is not yet known, but is estimated to be approximately \$3.1 million. Furthermore, these costs may decrease the capital that the combined company could use for continued development of the combined company's business in the future or may cause the combined company to seek to raise new capital sooner than expected.

***The combined company's ability to utilize BioSante's or ANI's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the merger.***

Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the historic business of BioSante is not treated as being continued by the combined entity for the two-year period beginning on the date of the merger (referred to as the "continuity of business requirement"), the pre-transaction net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. In 2009, an "ownership change" occurred with respect to BioSante, and it is expected that the merger with ANI will result in another "ownership change" of BioSante. Accordingly, the combined company's ability to utilize BioSante's net operating loss and tax credit carryforwards may be substantially limited. These limitations, in turn, could result in increased

future tax payments for the combined company, which could have a material adverse effect on the business, financial condition or results of operations of the combined company.

Under Section 384 of the Code, available net operating loss carryovers of BioSante or ANI may not be available to offset certain gains arising after the merger from assets held by the other corporation at the effective time of the merger. This limitation will apply to the extent that the gain is attributable to an unrealized built-in-gain in the assets of BioSante or ANI existing at the effective time of the merger. To the extent that any such gains are recognized in the five year period after the merger upon the disposition of any such assets, the net operating loss carryovers of the other corporation will not be available to offset such gains (but the net operating loss carryovers of the corporation that owned such assets will not be limited by Section 384 although they may be subject to other limitations under Section 382 as described above).

***The price of BioSante common stock after the merger is completed may be affected by factors different from those currently affecting the price of BioSante common stock.***

Upon completion of the merger, holders of ANI capital stock who receive shares of BioSante common stock in connection with the merger will become holders of BioSante common stock. The business of BioSante differs significantly from the business of ANI; and, accordingly, the results of operations of the combined company and the trading price of BioSante common stock following completion of the merger may be affected significantly by factors different from those currently affecting the independent results of operations of BioSante. For a discussion of the businesses of BioSante and ANI and of certain factors to consider in connection with those businesses, see the sections entitled "BioSante's Business," "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations," "ANI's Business," "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited and unaudited historical financial statements of BioSante and ANI, including the notes thereto, which are included elsewhere in this joint proxy statement/prospectus, and the other information contained in this joint proxy statement/prospectus.

***The NASDAQ Global Market considers the anticipated merger of BioSante and ANI to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante; and therefore, has required that BioSante submit a new initial listing application, which requires certain actions on the part of the combined company which may not be successful and, if unsuccessful, could make it more difficult for holders of shares of the combined company to sell their shares.***

The NASDAQ Global Market considers the merger proposed in this joint proxy statement/prospectus to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante and has required that BioSante submit a new initial listing application. The NASDAQ Global Market may not approve BioSante's new initial listing application for The NASDAQ Global Market on a timely basis, or at all. If this occurs and the merger is still completed, you may have difficulty converting your investments into cash effectively.

Additionally, as part of the new initial listing application, BioSante will be required to submit, among other things, a plan for the combined company to effect a reverse stock split. A reverse stock split likely would increase the per share trading price by an as yet undetermined multiple. The change in share price may affect the volatility and liquidity of the combined company's stock, as well as the marketplace's perception of the stock. As a result, the relative price of the combined company's stock may decline and/or fluctuate more than in the past, and you may have trouble converting your investments in the combined company into cash effectively.

***The combined company's management will be required to devote substantial time to comply with public company regulations.***

As a public company, the combined company will incur significant legal, accounting and other expenses that ANI did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including those related to corporate governance practices. The combined company's management and other personnel will need to devote a substantial amount of time to these requirements. Certain members of ANI's management, which will continue as the management of the combined company, do not have significant experience in addressing these requirements. Moreover, these rules and regulations will increase the combined company's legal and financial compliance costs relative to those of ANI and will make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective internal control for financial reporting and disclosure controls and procedures. In particular, the combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management and the combined company's independent registered public accounting firm to report on the effectiveness of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company's compliance with these requirements will require that it incur substantial accounting and related expenses and expend significant management efforts. The combined company will need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404 of the Sarbanes-Oxley Act. The costs of hiring such staff may be material and there can be no assurance that such staff will be immediately available to the combined company. Moreover, if the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of the combined company's financial reports, the market price of the combined company's common stock could decline and the combined company could be subject to sanctions or investigations by The NASDAQ Global Market, the SEC or other regulatory authorities.

***After completion of the merger, the combined company will possess not only all of the assets but also all of the liabilities of both BioSante and ANI. Discovery of previously undisclosed or unknown liabilities could have an adverse effect on the combined company's business, operating results and financial condition.***

Acquisitions involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. After completion of the merger, the combined company will possess not only all of the assets, but also all of the liabilities of both BioSante and ANI. Although BioSante conducted a due diligence investigation of ANI and its known and potential liabilities and obligations, and ANI conducted a due diligence investigation of BioSante and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise after completion of the merger, which could have an adverse effect on the combined company's business, operating results and financial condition.

***BioSante and ANI do not expect the combined company to pay cash dividends.***

BioSante and ANI anticipate that the combined company will retain its earnings, if any, for future growth and therefore not pay any cash dividends in the foreseeable future. Investors seeking cash dividends should not invest in the combined company's common stock for that purpose.

***Anti-takeover provisions in the combined company's charter and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or management and could make a third-party acquisition of the combined company difficult.***

The combined company's certificate of incorporation and bylaws, as amended, will contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of the combined company's common stock.

***The sale or availability for sale of a substantial number of shares of common stock of the combined company after the merger and after expiration of the lock-up period could adversely affect the market price of such shares after the merger.***

Sales of a substantial number of shares of common stock of the combined company in the public market after the merger or after expiration of the lock-up period, or the perception that these sales could occur, could adversely affect the market price of such shares and could materially impair the combined company's ability to raise capital through equity offerings in the future. BioSante and ANI are unable to predict what effect, if any, market sales of securities held by significant stockholders, directors or officers of the combined company or the availability of these securities for future sale will have on the market price of the combined company's common stock after the merger.

## **Risks Related to BioSante**

### ***Risks Related to BioSante's Financial Condition and Future Capital Requirements***

***BioSante has not generated significant revenues and does not expect to in the near future. BioSante has a history of operating losses, expects continuing losses and may never become profitable.***

Substantially all of BioSante's revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. In order to generate new and significant revenues, BioSante must develop and commercialize successfully its own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully, or acquire additional new products that generate or have the potential to generate revenues. Because of the numerous risks and uncertainties associated with BioSante's and its strategic partners' product development programs and BioSante's ability to acquire additional new products, BioSante is unable to predict when it will be able to generate significant revenue or become profitable, if at all. BioSante incurred a net loss of \$51.6 million for the year ended December 31, 2011 and a net loss of \$23.7 million for the nine months ended September 30, 2012. As of September 30, 2012, BioSante's accumulated deficit was \$241.0 million. BioSante expects to continue to incur substantial and continuing losses for the foreseeable future. These losses will increase if BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development. Even if BioSante's approved products, products in development or any additional new products BioSante may acquire or in-license are introduced commercially, BioSante may never achieve market acceptance and it may never generate sufficient revenues or receive sufficient license fees or royalties on its licensed products and technologies in order to achieve or sustain future profitability.



***Because BioSante has no source of significant recurring revenue, BioSante must depend on financing or partnering to sustain its operations. BioSante likely will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and BioSante may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.***

Developing products requires substantial amounts of capital. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials will be approximately \$15 to \$18 million each, or a combined \$30 to \$36 million spread over 18 months. No assurance can be provided, however, that BioSante's cost estimates will be correct. It is possible that the two new LibiGel Phase III efficacy trials will cost more than BioSante anticipates. If BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development, BioSante will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and it may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

BioSante's future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of its clinical development programs, including the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them and if BioSante in-licenses additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to BioSante's products;
- the success, progress, timing and costs of BioSante's business development efforts to implement business collaborations, licenses and other business combinations or transactions, and its efforts to evaluate various strategic alternatives available with respect to its products and its company.
- BioSante's ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;
- BioSante's ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of BioSante's products;
- the outstanding principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013 (convertible senior notes) that are scheduled to mature and become due and payable on May 1, 2013 and BioSante's ability to avoid a "fundamental change" or an "event of default" under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- BioSante's operating expenses; and
- the resolution of BioSante's pending purported class action and shareholder derivative litigation and any amount it may be required to pay in excess of its directors' and officers' liability insurance.

BioSante's future capital requirements and projected expenditures are based upon numerous assumptions and subject to many uncertainties, and actual requirements and expenditures may differ

significantly from its projections. To date, BioSante has relied primarily upon proceeds from sales of its equity securities to finance its business and operations. BioSante likely will need to raise additional capital to fund its operations. As of September 30, 2012, BioSante had \$38.0 million of cash and cash equivalents. BioSante does not have any existing credit facilities under which it may borrow funds. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations, including in particular the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them. As of September 30, 2012, BioSante has \$8.3 million in principal amount of convertible senior notes outstanding that mature on May 1, 2013. Assuming the merger is completed during the first quarter of 2013 and BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the closing condition under the merger agreement to have at least \$17.0 million of "net cash," as defined in the merger agreement, available upon the closing of the merger. If the merger is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing to operate its business as an independent, stand-alone company, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier in order to create a "cash cushion" and take advantage of favorable financing conditions.

The December 2011 announcement of the results of BioSante's prior completed LibiGel Phase III efficacy trials has significantly depressed the trading price of BioSante common stock and harmed BioSante's ability to raise additional capital. BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in BioSante's LibiGel Phase III development program, the future value of the company and/or if economic and market conditions deteriorate. BioSante has on file effective shelf registration statements that allow it to raise up to an aggregate of \$102.4 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, under applicable SEC rules, if BioSante has a public float of less than \$75.0 million, it can only offer to sell under the registration statement up to one-third of its public float during any 12-month period. BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to it, or at all. If adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to make changes to its operations to reduce costs. As an alternative to raising additional financing, BioSante may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, e.g., GVAX cancer vaccines, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights BioSante has under its existing license agreements or decide or be forced to explore other strategic alternatives, such as selling or merging the company or winding down its operations and liquidating the company. In such case, the BioSante stockholders could lose some or all of their investment.

***Raising additional funds by issuing additional equity securities may cause dilution to existing BioSante stockholders, raising additional funds by issuing additional debt financing may restrict BioSante's operations and raising additional funds through licensing arrangements may require BioSante to relinquish proprietary rights.***

If BioSante raises additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of its stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of its existing stockholders. In addition, the issuance of any equity securities could be at a discount to the market price.

If BioSante incurs additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for its business activities, and BioSante could be subject to covenants that restrict its ability to operate its business and make distributions to its stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of BioSante's assets, as well as prohibitions on the ability of BioSante to create liens, pay dividends, redeem its stock or make investments. There is no assurance that any equity or debt financing transaction will be available on terms acceptable to BioSante, or at all.

As an alternative to raising additional financing by issuing additional equity or debt securities, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under BioSante's existing license agreements or enter into other business collaborations or combinations, including a possible sale or merger of its company. If BioSante raises additional funds through licensing arrangements, BioSante may be required to relinquish greater or all rights to BioSante's products at an earlier stage of development or on less favorable terms than BioSante otherwise would choose.

***BioSante has substantial indebtedness, in the form of convertible senior notes, which notes BioSante may not be able to pay when they become due and payable on May 1, 2013, or earlier if BioSante experiences a "fundamental change" or an "event of default" under the indenture governing such notes.***

As of December 31, 2012, BioSante had \$8.3 million in aggregate principal amount of convertible senior notes outstanding. The annual interest payment on these notes is approximately \$259,000. At maturity, on May 1, 2013, the entire then remaining aggregate outstanding principal amount of the convertible senior notes will become due and payable. In addition, upon the occurrence of a "fundamental change", holders of the convertible senior notes may require BioSante to purchase their notes prior to the May 1, 2013 maturity date. A fundamental change includes a significant change in BioSante's ownership; the first day the majority of its board of directors does not consist of continuing directors; the consummation of certain recapitalizations, reclassifications, or changes of common stock, share exchanges or consolidations or mergers; or the termination of trading of its common stock (which will be deemed to have occurred if its common stock is neither listed for trading on a United States national securities exchange nor any United States system of automated dissemination of quotations of securities prices or traded in over-the-counter securities markets). The proposed merger between BioSante and ANI will not amount to a "fundamental change" under the indenture. Additionally, the aggregate principal amount of the outstanding convertible senior notes will become due and payable upon an uncured or unwaived event of default. Although BioSante believes it will be able to pay the aggregate outstanding principal amount of its convertible senior notes plus accrued interest when the notes mature on May 1, 2013, it is possible that BioSante may not have sufficient funds to pay the aggregate principal amount of its then outstanding convertible senior notes when they mature on May 1, 2013, or become due and payable earlier if BioSante were to experience a "fundamental change" or an "event of default" under the indenture governing such notes.

***The indentures governing BioSante's convertible senior notes contains covenants, which if not complied with, could result in an event of default and the acceleration of all amounts due under the notes.***

The indenture governing BioSante's convertible senior notes contains covenants, such as the requirement to pay accrued interest on May 1 and November 1 of each year, the requirement to repurchase the notes upon a "fundamental change," as defined in the indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If BioSante does not comply with the covenants in the indenture, an event of default could occur and all amounts due under the notes could become immediately due and payable. Upon the occurrence of an event of default under the indenture, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Although it is possible BioSante could negotiate a waiver with the trustee and the holders of the notes, such a waiver likely would involve significant costs. It also is possible that BioSante could refinance or restructure its obligations under the notes; however, such a refinancing or restructuring also likely would involve significant costs and likely would result in higher interest rates than the current 3.125% annual interest rate on the notes.

***Future purchases, exchanges or restructurings of BioSante's outstanding convertible senior notes could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of BioSante's existing stockholders and/or decrease its cash balance.***

In February 2012, BioSante entered into privately-negotiated securities exchange agreements with one of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,868,055 shares of its common stock, as adjusted to reflect its one-for-six reverse stock split effected on June 1, 2012, to the note holder in exchange for the cancellation of an aggregate of \$9.0 million principal amount of BioSante's convertible senior notes, including accrued and unpaid interest. In July 2012, BioSante entered into a privately-negotiated securities exchange agreement with two of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,784,070 shares of its common stock to the note holder in exchange for the cancellation of an aggregate of \$3.5 million principal amount of BioSante's convertible senior notes and accrued and unpaid interest of \$20,686. As a result of these exchanges, an aggregate of \$8.3 million principal amount of the convertible senior notes remained outstanding as of September 30, 2012. From time-to-time, BioSante again may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of its company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante's available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante's cash balance. A significant decrease in BioSante's cash balance may impair its ability to execute strategic alternatives, including the proposed merger with ANI, or leave BioSante without sufficient cash remaining for operations.

***BioSante is subject to pending purported securities class action and shareholder derivative litigation, which could divert management's attention, harm its business and/or reputation and result in significant liabilities, as well as harm its ability to raise additional financing and execute certain strategic alternatives.***

BioSante is subject to pending purported securities class action and shareholder derivative litigation.

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of BioSante's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante's securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint on December 28, 2012.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming BioSante's directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante's corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante's operations, including its financial condition, results of operations, or cash flows.

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

#### **Risks Related to BioSante's Business**

***BioSante's two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that the two new LibiGel Phase III efficacy trials, if BioSante decides to pursue them, will not meet the co-primary and secondary endpoints, which could harm BioSante's business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.***

BioSante's lead near term product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved product. In June 2012,

BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials. This decision was based on an extensive analysis of previous efficacy data, consultation with key opinion leaders in FSD, testosterone therapy and placebo effects, as well as a meeting with the FDA. The protocol for the two new efficacy trials is in development. BioSante intends to apply for an FDA Special Protocol Assessment (SPA) agreement prior to initiating the two new efficacy trials. Currently, it is expected that the efficacy trials will include the same FDA-required efficacy endpoints as prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire.

The initiation of the two new LibiGel Phase III efficacy trials involves risk, especially since BioSante's prior LibiGel Phase III efficacy trials failed to meet the co-primary or secondary endpoints. Although the results indicated that LibiGel performed as predicted based on previous experience with testosterone products for female sexual dysfunction, the placebo response in the two efficacy trials was greater than expected; and therefore, LibiGel's results were not shown to be statistically different from placebo. No assurance can be provided that BioSante will be able to design the two new LibiGel Phase III efficacy trials to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. In addition, BioSante can provide no assurance that it will be able to obtain an FDA SPA agreement for such trials or that BioSante will initiate or complete the trials on a timely basis, or ever. Any of these possible results could harm BioSante's business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.

***Although BioSante's male testosterone gel is approved by the FDA, BioSante is uncertain as to when Teva will begin to market and sell the male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales in light of Teva's settlement agreement with a subsidiary of Abbott Laboratories.***

BioSante's male testosterone gel initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted a New Drug Application, which NDA was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

***Several of BioSante's products are in the clinical development stages and, depending on the product, likely will not be approved by regulatory authorities or introduced commercially for at least several years and likely more, if at all.***

Several of BioSante's products are in the clinical development stages and will require further development, preclinical and clinical testing and investment prior to obtaining required regulatory approvals and commercialization in the United States and abroad. Other than Elestrin and BioSante's male testosterone gel, none of BioSante's products have been approved by the FDA or other regulatory authorities; and accordingly, none of BioSante's products have been introduced commercially and most are not expected to be for several years and likely more, if at all. BioSante cannot assure you that any of its products in clinical development will:

- be developed successfully;
- prove to be safe and effective in clinical studies;
- meet applicable regulatory standards or obtain required regulatory approvals;

- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs;
- obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or
- be marketed successfully or achieve market acceptance by physicians and patients.

***If BioSante fails to obtain regulatory approval to manufacture commercially or sell any of its future products, or if approval is delayed or withdrawn, BioSante will be unable to generate revenue from the sale of its products.***

BioSante must obtain regulatory approval to sell any of its products in the United States and abroad. In the United States, BioSante must obtain the approval of the FDA for each product or drug that BioSante intends to commercialize. The FDA approval process typically is very lengthy and expensive, and approval never is certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development eventually are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, BioSante's products could take a significantly longer time to gain regulatory approval than BioSante expects or may never gain approval. If regulatory approval is delayed or never obtained, the credibility of BioSante's management, the value of BioSante and its operating results and liquidity would be affected adversely. Even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review and BioSante may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture of the product subsequently are discovered. The FDA also may require BioSante to commit to perform lengthy post-approval studies, for which BioSante would have to expend significant additional resources, which could have an adverse effect on its operating results and financial condition.

To obtain regulatory approval to market many of BioSante's products, costly and lengthy human clinical trials are required, and the results of the studies and trials are highly uncertain. As part of the FDA approval process, BioSante must conduct, at its own expense or the expense of current or potential licensees or other entities, clinical trials in human subjects on each of BioSante's products. BioSante expects the number of human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. Depending on the stage of development, BioSante may need to perform multiple pre-clinical studies using various doses and formulations before BioSante can begin human clinical trials, which could result in delays in BioSante's ability to market its products. Furthermore, even if BioSante obtains favorable results in pre-clinical studies on animals, the results in humans may be different.

In order to receive regulatory approval for commercial sale, BioSante must demonstrate that its products are safe and effective for use in the target human population. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. BioSante faces the risk that the results of its clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. As an example, BioSante's prior two pivotal LibiGel Phase III efficacy trials did not meet the co-primary endpoints of an increase in satisfying sexual events and an increase in desire and the secondary endpoint of a decrease in distress compared to placebo even though treatment with LibiGel in BioSante's Phase II clinical trial significantly increased satisfying sexual events compared to placebo. A number of companies in the

biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent BioSante from submitting for regulatory approval of its products.

Additional factors that can cause delay or termination of BioSante's human clinical trials include:

- slow subject enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- new or additional trials or studies that are designed differently in order to increase the chances of demonstrating efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and
- lack of funding.

Delays in BioSante's clinical trials could allow its competitors additional time to develop or market competing products and thus can be extremely costly in terms of lost sales opportunities and increased clinical trial costs.

***The process for obtaining FDA approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.***

BioSante's products in development will require the submission and approval of an NDA in order to obtain required approval by the FDA to commercially market the product. The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

- the information submitted may be insufficient to demonstrate that a product is safe and effective;
- the FDA might not approve the processes or facilities of a company, or those of its vendors, that will be used for the commercial manufacture of a product; or
- the FDA's interpretation of the nonclinical, clinical or manufacturing data provided in an NDA may differ from a company's interpretation of such data.

If the FDA determines that the clinical studies submitted for a product candidate in support of an NDA are not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the FDA does not agree with a company's interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical studies required to support an NDA could affect negatively a company's ability to obtain marketing authorization for a product and would have a material adverse effect on a company's business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during development or the review period.



***BioSante may not achieve projected goals and objectives in the time periods that BioSante anticipates or announce publicly, which could have an adverse effect on its business and could cause the price of BioSante common stock to decline.***

BioSante sets goals and objectives for, and makes public statements regarding, the timing of certain accomplishments and milestones regarding its business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the submission of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in BioSante's current clinical studies, the amount of time, effort and resources committed to its programs by BioSante and its current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving BioSante's products in development will advance or be completed in the time periods that BioSante or its strategic partners announce or expect, that BioSante or its current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that BioSante or its current and potential future strategic partners will be able to adhere to its current schedule for the achievement of key milestones under any of its development programs. If BioSante or any of its strategic partners fail to achieve one or more of these milestones as planned, BioSante's business could be affected adversely and materially and the trading price of BioSante common stock could decline. As an example, prior to BioSante's receipt of the results from its prior two pivotal LibiGel Phase III efficacy trials in December 2011, its objective with respect to LibiGel was to submit an NDA in 2012. This is obviously no longer an objective of BioSante's in light of the fact that unexpectedly BioSante's two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints.

BioSante also discloses from time-to-time projected financial information, including its cash position and anticipated cash burn rate and other expenditures, for future periods. These financial projections are based on management's current expectations and may not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

***If the market opportunities for BioSante's products are smaller than BioSante anticipates, then its future revenues and business may be affected adversely.***

From time-to-time, BioSante discloses estimated market opportunity data for its products and products in development. Although BioSante believes it has a reasonable basis for its market opportunity estimates, BioSante estimates may prove to be incorrect. If the market opportunities for BioSante's products are smaller than BioSante anticipates, its anticipated revenues from the sales or licensure of such products will be lower than BioSante anticipates.

***Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the market for BioSante's hormone therapy products and the trading price of BioSante common stock.***

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for

an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. BioSante's products differ from the products used in the WHI study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of BioSante's products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies, although the market now seems to have stabilized. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to BioSante's products, also could adversely affect BioSante's business and decrease the trading price of BioSante common stock.

***If clinical studies for BioSante's products are terminated, prolonged or delayed, it may be difficult for BioSante to find a strategic partner to assist it in the development and commercialization of its non-partnered products or commercialize such products on a timely basis, which would require BioSante to incur additional costs and delay or prevent its receipt of any revenue from potential product sales or licenses.***

BioSante may encounter problems with its completed, ongoing or planned clinical studies for its products that may cause it or the FDA to delay, suspend or terminate those studies or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or cause BioSante to suspend or terminate its ongoing and planned clinical studies for its products and negatively impact BioSante's ability to obtain regulatory approval or enter into strategic partnerships for, or market or sell, a particular product:

- conditions imposed on BioSante by the FDA or any foreign regulatory authority regarding the scope or design of its clinical studies;
- delay in developing, or BioSante's inability to obtain, a clinical dosage form, insufficient supply or deficient quality of its products or other materials necessary to conduct its clinical studies;
- negative or inconclusive results from clinical studies, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;
- serious and/or unexpected product-related side effects experienced by subjects in BioSante's clinical studies; or
- failure of BioSante's third-party contractors or its investigators to comply with regulatory requirements or otherwise meet their contractual obligations to BioSante in a timely manner.

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which BioSante's clinical studies are conducted all have the power to stop or recommend stopping its clinical studies prior to completion. BioSante's clinical studies for its products in development may not begin as planned, may need to be amended, suspended or terminated and may not be completed on schedule, if at all. This is particularly true if BioSante no longer believes it can

obtain regulatory approval for a particular product or if BioSante no longer has the financial resources to dedicate to a clinical development program for a particular product.

***BioSante relies on third parties to assist it in certain aspects of its clinical studies. If these third parties do not perform as required contractually or expected, BioSante's clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.***

BioSante relies on third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist it in certain aspect of its clinical studies. BioSante is responsible for confirming that BioSante's studies are conducted in accordance with applicable regulations and that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires BioSante to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. BioSante's reliance on these few third parties does not relieve it of these responsibilities. If the third parties assisting BioSante with certain aspects of its clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to BioSante's protocols or otherwise fail to generate reliable clinical data, BioSante may need to enter into new arrangements with alternative third parties and its clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, BioSante's ability to collect damages may be limited contractually.

***BioSante's products will remain subject to ongoing regulatory review even if BioSante receives marketing approval. If BioSante fails to comply with continuing regulations, BioSante could lose these approvals, and the sale of any future products could be suspended.***

Even if BioSante receives regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of BioSante's approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy (REMS). If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, result in more restrictive labeling than originally approved, force BioSante to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay BioSante's ability to obtain regulatory approvals in additional countries. In addition, BioSante will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

If BioSante fails to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with any future products, suppliers or manufacturing processes are discovered, BioSante could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;

- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

***BioSante may enter into additional strategic relationships with third parties to help develop and commercialize its products in development. If BioSante does not enter into such relationships, BioSante will need to undertake development and commercialization efforts on its own, which would be costly and could delay BioSante's ability to obtain required approvals for and commercialize its future products.***

A key element of BioSante's business strategy is BioSante's intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of its products. For example, BioSante has a strategic relationship with Meda Pharmaceuticals, Inc. with respect to Elestrin, with Teva with respect to BioSante's male testosterone gel, with Pantarhei Science with respect to The Pill Plus and with several third parties with respect to BioSante's GVAX cancer vaccines. BioSante currently does not have a strategic partner for LibiGel.

BioSante may enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, its products in development, including LibiGel, and any additional new products BioSante may acquire or in-license. BioSante faces significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. BioSante may not be able to negotiate additional strategic relationships on acceptable terms, or at all. BioSante is unable to predict when, if ever, it will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If BioSante is unable to negotiate additional strategic relationships for its products, BioSante may be forced to curtail the development of a particular product, reduce, delay or terminate its development program or one or more of its other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at BioSante's own expense. In addition, BioSante would then bear all the risk related to the development and commercialization of that product. If BioSante elects to increase its expenditures to fund development or commercialization activities on its own, BioSante may need to obtain additional capital, which may not be available to BioSante on acceptable terms, or at all. If BioSante does not have sufficient funds, BioSante will not be able to bring its products in development and any additional new products BioSante may acquire or in-license if they receive regulatory approvals to market and generate product revenue.

***If BioSante is unable to partner with a third party and obtain assistance for the potential commercialization of its products, if approved for commercial sale, BioSante would need to establish its own sales and marketing capabilities, which involves risk.***

BioSante does not have an internal sales and marketing organization and has limited experience in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing BioSante's own sales capabilities and increasing its marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if

BioSante enters into arrangements with third parties to perform sales, marketing and distribution services, revenues from sales of the product or the profitability of these product revenues are likely to be lower than if BioSante markets and sells any products that BioSante develops itself.

Although BioSante's preferred alternative would be to engage a pharmaceutical or other healthcare company with an existing sales and marketing organization and distribution systems to sell, market and distribute its products, if approved for commercial sale, if BioSante is unable to engage such a sales and marketing partner, BioSante may need to establish its own specialty sales force. Factors that may inhibit BioSante's efforts to commercialize any future products without strategic partners or licensees include:

- BioSante's inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put BioSante at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales and marketing capabilities depends on the progress towards commercialization of BioSante's products and because of the numerous risks and uncertainties involved with establishing its own sales and marketing capabilities, BioSante is unable to predict when, if ever, BioSante will establish its own sales and marketing capabilities. If BioSante is not able to partner with additional third parties and are unsuccessful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, BioSante will have difficulty commercializing its products, which would harm its business and financial condition.

***BioSante's current strategic relationships and any future additional strategic relationships it may enter into involve risks with respect to the development and commercialization of its products.***

A key element of BioSante's business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of BioSante's products. For example, BioSante has strategic relationships with Meda Pharmaceuticals, Inc. with respect to Elestrin, with Teva with respect to its male testosterone gel and with Pantarhei Science with respect to The Pill Plus and several third parties with respect to its GVAX cancer vaccines.

BioSante's current strategic relationships and any future additional strategic relationships BioSante may enter into involve a number of risks, including:

- business combinations or significant changes in a strategic partner's business strategy may affect adversely a strategic partner's willingness or ability to complete its obligations under any arrangement;
- BioSante may not be able to control the amount and timing of resources that its strategic partners devote to the development or commercialization of its partnered products;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;

- strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to delay research and development programs or commercialization of a partnered product;
- strategic partners may not commit adequate resources to the marketing and distribution of BioSante's partnered products, limiting BioSante's potential revenues from these products;
- disputes may arise between BioSante and its strategic partners that result in the delay or termination of the research, development or commercialization of its partnered products or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not maintain properly or defend BioSante's intellectual property rights or may use its proprietary information in a manner that could jeopardize or invalidate its proprietary information or expose BioSante to potential litigation;
- strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including BioSante's competitors; and
- strategic partners could terminate or delay the arrangement or allow it to expire, which would delay the development or commercialization of the partnered product and may increase the cost of developing or commercializing the partnered product.

***Although BioSante maintains the right to receive sales-based milestones of up to \$140 million, its ability to receive these milestones is dependent upon Meda Pharmaceuticals, Inc.'s ability to market and sell Elestrin, and based on Elestrin sales to date, BioSante believes it is unlikely that it will receive any sales-based milestone payments from Meda Pharmaceuticals in the foreseeable future, or at all.***

Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business, and which in turn had acquired BioSante's original licensee, Azur Pharma International II Limited (Azur)), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante continues to recognize certain royalty revenue from sales of Elestrin; however, such revenue is offset by its corresponding obligation to pay royalties to Antares, from whom BioSante licensed the technology underlying its Elestrin product. BioSante maintains the right to receive up to \$140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year. BioSante can provide no assurance that Meda Pharmaceuticals will be successful in marketing Elestrin, Elestrin will be accepted widely in the marketplace or that Meda Pharmaceuticals will remain focused on the commercialization of Elestrin, especially if Meda Pharmaceuticals does not experience significant Elestrin sales. Based on current sales of Elestrin, BioSante believes it is unlikely that BioSante will receive any sales-based milestone payments from Meda Pharmaceuticals in the near term, if at all.

***If BioSante's products in development receive FDA approval and are introduced commercially, they may not achieve expected levels of market acceptance, which could harm BioSante's business, financial position and operating results and could cause the trading price of BioSante common stock to decline.***

The commercial success of BioSante's products in development, if BioSante receives the required FDA or other regulatory approvals, and the commercial success of its male testosterone gel, which is FDA approved, but not yet commercially launched, are dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products,

if approved for commercial sale with respect to BioSante's products in development, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials with respect to BioSante's products in development;
- the existence, prevalence and severity of any side effects;
- the availability of competitive or alternative treatments and potential or perceived advantages or disadvantages compared to competitive or alternative treatments;
- the timing of market entry relative to competitive treatments;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of BioSante's products by third-party payors and governmental and other payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Some of these factors are not within BioSante's control, especially if BioSante has transferred all of the marketing rights associated with the product, as BioSante has with the U.S. marketing rights to Elestrin to Meda Pharmaceuticals, and the U.S. development and marketing rights to its male testosterone gel to Teva. BioSante's products may not achieve expected levels of market acceptance.

Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by other companies, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the use, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and in the future may result, in the discontinuance of product marketing. These situations, should they occur, could harm BioSante's business, financial position and results of operations, and the trading price of BioSante common stock could decline.

***Even if BioSante or its strategic partners successfully develop, obtain required regulatory approvals and commercialize any of its products under development, BioSante faces uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could affect adversely the commercial success of BioSante's products.***

BioSante's ability to collect significant revenues from sales of its products, if approved and commercialized, may depend on its ability, and the ability of any current or potential future strategic partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies;
- government health administration authorities; and
- other healthcare-related organizations.

Third-party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances

from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, BioSante or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect BioSante's ability to sell its products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for BioSante's products, which could affect adversely its business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which is referred to as the PPACA. This legislation may have far reaching consequences for life science companies like BioSante. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for BioSante's products, if approved, is substantially less than BioSante expects in the future, its business could be affected materially and adversely.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent BioSante from maintaining prices for its products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that BioSante's approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent BioSante from maintaining prices for such products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results.

***BioSante and its licensees depend on third-party manufacturers to produce its products and if these third parties do not manufacture successfully these products BioSante's business would be harmed.***

BioSante has no manufacturing experience or manufacturing capabilities for the production of its products for its clinical studies or, if approved, commercial sale. In order to continue to develop products, apply for regulatory approvals and commercialize BioSante's products following approval, if obtained, BioSante or its licensees must be able to manufacture or contract with third parties to manufacture its products in clinical and commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of BioSante's products may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing BioSante's products may make them prohibitively expensive. If supplies of any of BioSante's products become unavailable on a timely basis or at all or are contaminated or otherwise lost, BioSante's clinical studies could be seriously delayed or compromised, and with respect to its



approved products, its future revenue from royalties and milestone payments could be affected adversely.

***To the extent that BioSante or its licensees enter into manufacturing arrangements with third parties, BioSante and such licensees will depend upon these third parties to perform its obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond BioSante's control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for BioSante.***

BioSante's existing and future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute BioSante's products. If a natural disaster, business failure, strike or other difficulty occurs, BioSante may be unable to replace these contract manufacturers in a timely or cost-effective manner and the production of its products would be interrupted, resulting in delays and additional costs. Switching manufacturers or manufacturing sites would be difficult and time-consuming because the number of potential manufacturers is limited. In addition, before a product from any replacement manufacturer or manufacturing site can be commercialized, the FDA must approve that site. This approval would require regulatory testing and compliance inspections. A new manufacturer or manufacturing site also would have to be educated in, or develop substantially equivalent processes for, production of BioSante's products. It may be difficult or impossible to transfer certain elements of a manufacturing process to a new manufacturer or for BioSante to find a replacement manufacturer on acceptable terms quickly, or at all, either of which would delay or prevent its ability to develop and commercialize its products.

If third-party manufacturers fail to perform their obligations, BioSante's competitive position and ability to generate revenue may be affected adversely in a number of ways, including:

- BioSante and its strategic partners may be unable to initiate or continue clinical studies of its products that are under development;
- BioSante and its strategic partners may be delayed in submitting applications for regulatory approvals for its products that are under development; and
- BioSante and its strategic partners may be unable to meet commercial demands for any approved products.

In addition, if a third-party manufacturer fails to perform as agreed, BioSante's ability to collect damages may be contractually limited.

***If BioSante reallocates its resources to other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante may not be successful in developing such products and technologies and BioSante will be subject to all the risks and uncertainties associated with research and development of products and technologies.***

BioSante has explored the possibility of reallocating its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license. If BioSante decides to reallocate its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante cannot guarantee that any such allocation would result in the identification and successful development of one or more approved and

commercially viable products. The development of products and technologies is subject to a number of risks and uncertainties, including:

- the time, costs and uncertainty associated with the clinical testing required to demonstrate the safety and effectiveness of BioSante's products and obtain regulatory approvals;
- the ability to raise sufficient funds to fund the research and development of BioSante's products;
- the ability to find third party strategic partners to assist or share in the costs of product development, and potential dependence on such strategic partners, to the extent BioSante relies on them for future sales, marketing or distribution;
- the ability to protect the intellectual property rights associated with BioSante's products;
- litigation;
- competition;
- ability to comply with ongoing regulatory requirements;
- government restrictions on the pricing and profitability of products in the United States and elsewhere; and
- the extent to which third-party payers, including government agencies, private health care insurers and other health care payers, such as health maintenance organizations, and self-insured employee plans, will cover and pay for newly approved therapies.

***BioSante has very limited staffing and is dependent upon key employees and the limited use of independent contractors, the loss of some of which could affect adversely its operations.***

BioSante's success is dependent upon the efforts of a relatively small management team and staff. BioSante also has engaged independent contractors from time-to-time on an as needed, project by project, basis. In January 2012, in order to reduce BioSante's operating expenses, BioSante terminated several of its independent contractor arrangements and reduced its total employee headcount. In December 2012, BioSante terminated the remaining independent contractor arrangements and in January 2013 reduced its total employee headcount further. Such reductions in force, combined with BioSante's future business prospects and financial condition, put BioSante at risk of losing key personnel who BioSante will need going forward to implement its business strategies. BioSante has no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. BioSante has employment arrangements in place with its executive and other officers, but none of these executive and other officers is bound legally to remain employed with BioSante for any specific term. BioSante does not have key man life insurance policies covering its executive and other officers or any of its other employees. If key individuals leave BioSante, its business could be affected adversely if suitable replacement personnel are not recruited quickly. There is competition for qualified personnel in the biotechnology and biopharmaceutical industry in the suburban Chicago, Illinois area in all functional areas, which makes it difficult to retain and attract the qualified personnel necessary for the development and growth of BioSante's business. BioSante's financial condition and recent reductions in force and expense reductions may make it difficult for BioSante to retain current personnel and attract qualified employees and independent contractors in the future.

***If plaintiffs bring product liability lawsuits against BioSante, BioSante may incur substantial liabilities and may be required to delay development or limit commercialization of any of BioSante's products approved for commercial sale.***

BioSante faces an inherent risk of product liability as a result of the clinical testing of its products in development and the commercial sale of its products that have been or will be approved for

commercial sale. BioSante may be held liable if any product it develops causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for BioSante's products, injury to its reputation, withdrawal of clinical studies, costs to defend litigation, substantial monetary awards to clinical study participants or patients, loss of revenue and the inability to commercialize any products that BioSante develops.

BioSante currently maintains limited product liability insurance. BioSante may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, BioSante's insurance coverage. BioSante's insurance does not cover third parties' negligence or malpractice, and its clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct BioSante's clinical studies or otherwise carry out its business, BioSante may have to assume liabilities contractually for which it may not be insured. If BioSante is unable to look to its own or a third party's insurance to pay claims against them, BioSante may have to pay any arising costs and damages themselves, which may be substantial. Even if BioSante ultimately is successful in product liability litigation, the litigation likely would consume substantial amounts of its financial and managerial resources and may create adverse publicity, all of which likely would impair BioSante's ability to generate sales of the affected product and its other products. Moreover, product recalls may be issued at BioSante's discretion or at the direction of the FDA, other governmental agencies or other companies having regulatory control for its product sales. Product recalls generally are expensive and often have an adverse effect on the reputation of the products being recalled and of the product's developer or manufacturer.

BioSante may be required to indemnify third parties against damages and other liabilities arising out of its development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify BioSante against damages and other liabilities arising from their activities do not fulfill their obligations, then BioSante may be held responsible for those damages and other liabilities.

***Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on the trading price of BioSante common stock.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires BioSante's management to assess the effectiveness of its internal control over financial reporting and to provide a report by its registered independent public accounting firm addressing the effectiveness of BioSante's internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If BioSante is unable to assert that its internal control over financial reporting is effective or if BioSante's registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or identifies one or more material weaknesses in BioSante's internal control over financial reporting, BioSante could lose investor confidence in the accuracy and completeness of its financial reports, which in turn could have an adverse effect on the trading price of BioSante common stock. If BioSante fails to maintain the adequacy of its internal controls, BioSante may not be able to ensure that it can conclude on an ongoing basis that BioSante has effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal control over financial reporting could have an adverse effect on the trading price of BioSante common stock.

***BioSante's business is subject to increasingly complex corporate governance, public disclosure and accounting requirements that could affect adversely its business and financial results.***

BioSante is subject to changing rules and regulations of federal and state governments as well as the stock exchange on which BioSante common stock is listed. These entities, including the SEC and

The NASDAQ Stock Market, continue to issue new requirements and regulations in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC and The NASDAQ Stock Market to adopt additional rules and regulations in these areas. BioSante's efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from its other business activities.

***BioSante's operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.***

BioSante's principal executive office and its only business location is in Lincolnshire, Illinois, which is a suburb of Chicago. Natural disasters or other catastrophic events could disrupt BioSante's operations or those of its strategic partners, contractors and vendors. Even though BioSante believes it carries commercially reasonable business interruption and liability insurance, and its contractors may carry liability insurance that protect BioSante in certain events, BioSante might suffer losses as a result of business interruptions that exceed the coverage available under its and its contractors' insurance policies or for which it or its contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on BioSante's operations and financial results, and could delay its efforts to identify and execute any strategic opportunities.

**Risks Related to BioSante's Industry**

***Because BioSante's industry is very competitive, BioSante may not succeed in bringing certain of its products to market and any products BioSante or its strategic partners introduce commercially may not be successful.***

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than BioSante. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. BioSante cannot assure you that its potential competitors, some of whom are BioSante's strategic partners, will not succeed in developing similar technologies and products more rapidly than it does, commercially introducing such technologies and products to the marketplace prior to BioSante, or that these competing technologies and products will not be more effective or successful than any of those that BioSante currently is developing or will develop.

***Because the pharmaceutical industry is heavily regulated, BioSante faces significant costs and uncertainties associated with its efforts to comply with applicable regulations. Should BioSante fail to comply, it could experience material adverse effects on its business, operating results and financial position, and the trading price of BioSante common stock could decline.***

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act of 1970 and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of BioSante's products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

In addition to compliance with "current good manufacturing practice" regulations, commonly referred to as "cGMP" regulations and requirements, drug manufacturers must register each manufacturing facility with the FDA and list their drugs with the FDA. Manufacturers and distributors of prescription drug products also are required to be registered in the states where they are located and in certain states that require registration by out-of-state manufacturers and distributors. Manufacturers also must be registered with the U.S. Drug Enforcement Administration and similar applicable state and local regulatory authorities if they handle controlled substances, and also must comply with other applicable U.S. Drug Enforcement Administration and state requirements.

Despite BioSante's efforts at compliance, there is no guarantee that BioSante may not be deemed to be deficient in some manner in the future. If BioSante was deemed to be deficient in any significant way, its business, financial position and results of operations could be materially affected and the trading price of BioSante common stock could decline.

***The trend towards consolidation in the pharmaceutical and biotechnology industries may affect BioSante adversely.***

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend also may result in fewer potential strategic partners or licensees for BioSante's products and technology. Also, if a consolidating company is already doing business with its competitors, BioSante may lose existing licensees or strategic partners as a result of such consolidation. This trend may affect adversely BioSante's ability to enter into strategic arrangements for the development and commercialization of its products, and as a result may harm its business.

***Risks Related to BioSante's Intellectual Property***

***BioSante licenses rights to the technology underlying LibiGel and many of its other products and technologies from third parties. The loss of these rights, including in particular, BioSante's rights underlying LibiGel, could have an adverse effect on its business and future prospects and could cause the trading price of BioSante common stock to decline.***

BioSante licenses rights to certain technology underlying its gel products, including LibiGel, but not its male testosterone gel, from Antares Pharma, Inc., its GVAX cancer vaccines from The Johns Hopkins University and The Whitehead Institute for Biomedical Research, and The Pill Plus from Wake Forest University Health Sciences. BioSante may lose its rights to these technologies if BioSante breaches its obligations under the license agreements. Although BioSante intends to use commercially reasonable efforts to meet these obligations and to cause its sublicensees to meet these obligations, if BioSante violates or fails to perform any term or covenant of the license agreements, the other party to these agreements under certain circumstances may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve BioSante of its obligation to pay any royalty or license fees owed at the time of termination. In addition, it is possible that the licensors of the technology licensed by BioSante will not continue to maintain certain patents and other intellectual property rights, breach the agreements or take actions inconsistent with BioSante's license rights, which could harm BioSante's business.

***BioSante has licensed some of its products to third parties and any breach by these parties of their obligations under these license agreements or a termination of these license agreements by these parties could affect adversely the development and marketing of its licensed products. In addition, these third parties also may compete with BioSante with respect to some of its products.***

BioSante has licensed some of its products to third parties, including Meda Pharmaceuticals, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V., Valeant Pharmaceuticals, Aduro BioTech, Inc. and The John P. Hussman Foundation. All of these parties, except for Meda Pharmaceuticals, have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products, except for Valeant Pharmaceuticals, which has not agreed to be responsible for manufacturing the products. In addition, in the future BioSante may enter into additional similar license agreements. BioSante's products that it has licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. BioSante's current and future licensees may have different and, sometimes, competing priorities. BioSante cannot assure you that its strategic partners or any future third party to whom it may license its products will remain focused on the development and commercialization of its partnered products or will not otherwise breach the terms of its agreements with them, especially since these third parties also may compete with BioSante with respect to some of its products. Any breach of BioSante's agreements by its strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered products in these agreements if BioSante is unable to license the products to another party on substantially the same or better terms or continue the development and future commercialization of the products itself. As an example, BioSante's male testosterone gel initially was developed by BioSante, and then licensed to Teva for late stage clinical development and commercialization. Teva submitted an NDA for BioSante's male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva's NDA submission, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

***If BioSante is unable to protect its proprietary technology, it may not be able to compete as effectively.***

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. BioSante's success will depend, in part, upon its ability to obtain, enjoy and enforce protection for any products it develops or acquires under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of its trade secrets and operate without infringing the proprietary rights of third parties. BioSante relies on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect its proprietary technology. These legal means, however, afford only limited protection and may not adequately protect BioSante's rights or permit BioSante to gain or keep any competitive advantage.

Where appropriate, BioSante seeks patent protection for certain aspects of its technology. BioSante owned and licensed patents and patent applications, however, may not ensure the protection of its intellectual property for a number of other reasons:

- BioSante does not know whether its licensor's patent applications will result in issued patents.

- Competitors may interfere with BioSante's patents and patent process in a variety of ways. BioSante issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit its ability to stop competitors from marketing related products. Competitors also may have BioSante's patents reexamined by demonstrating to the U.S. Patent and Trademark Office examiner that the invention was not novel or was obvious.
- BioSante is engaged in the process of developing products. Even if BioSante receives a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around BioSante's patents. If BioSante receives a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on BioSante's patent. Even if the development of BioSante's products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Though patent term extension may be possible for particular products, any expiration of the applicable patent could have a material adverse effect on the sales and profitability of BioSante's products.
- Litigation also may be necessary to enforce patent rights BioSante holds or to protect trade secrets or techniques it owns. Intellectual property litigation is costly and may affect adversely BioSante's operating results. Such litigation also may require significant time by BioSante's management. In litigation, a competitor could claim that BioSante's issued patents are not valid or unenforceable for a number of reasons. If the court agrees, BioSante would lose protection on products covered by those patents.
- BioSante also may support and collaborate in research conducted by government organizations or universities. BioSante cannot guarantee that it will be able to acquire any rights to technology or products derived from these collaborations. If BioSante does not obtain required licenses or rights, it could encounter delays in product development while it attempts to design around other patents or it may be prohibited from developing, manufacturing or selling products requiring these licenses. There also is a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

BioSante also relies on unpatented proprietary technology. It is unclear whether efforts to secure BioSante's trade secrets will provide useful protection. BioSante relies on the use of registered trademarks with respect to the branded names of some of its products. BioSante also relies on common law trademark protection for some branded names, which are not protected to the same extent as its rights in the use of its registered trademarks. BioSante cannot assure you that it will be able to meaningfully protect all of its rights in its unpatented proprietary technology or that others will not independently develop and obtain patent protection substantially equivalent proprietary products or processes or otherwise gain access to its unpatented proprietary technology. BioSante seeks to protect its know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with BioSante's employees and consultants. Such agreements, however, may not be enforceable or may not provide meaningful protection for BioSante's proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that its competitors discover or independently develop similar or identical designs or other proprietary information. Enforcing a claim that someone else illegally obtained and is using BioSante's trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

***The patent protection for BioSante's products may expire before BioSante is able to maximize their commercial value which may subject BioSante to increased competition, inhibit its ability to find strategic partners and reduce or eliminate its opportunity to generate product revenue.***

The patents for BioSante's commercialized products and products in development have varying expiration dates and, when these patents expire, BioSante may be subject to increased competition and it may not be able to recover its development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which BioSante licenses from Antares Pharma are scheduled to expire in June 2022 and the U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD will expire in December 2028. Although BioSante has filed additional U.S. patent applications covering LibiGel, it can provide no assurance that such applications will be granted and that the patent applications will issue. In addition to patents, BioSante may receive three years of marketing exclusivity in the United States for LibiGel under the Hatch-Waxman Act and an additional six months of pediatric exclusivity, if BioSante decides to pursue regulatory approval for LibiGel. Depending upon if and when BioSante receives regulatory approval for LibiGel and its other products in development and the then expiration dates of the patents underlying LibiGel and such other products, BioSante may not have sufficient time to recover its development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

***Claims by others that BioSante's products infringe their patents or other intellectual property rights could adversely affect BioSante's operating results and financial condition.***

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and outside the United States until the application is published. Accordingly, BioSante cannot determine whether its technology would infringe on patents arising from these unpublished patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

- result in costly litigation;
- divert the time and attention of BioSante's technical personnel and management;
- cause product development delays;
- require BioSante to develop non-infringing technology; or
- require BioSante to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt BioSante's potential gross margins. In addition, BioSante cannot be sure that the necessary licenses would be available to BioSante on satisfactory terms, or that it could redesign its products or processes to avoid patent infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent BioSante from developing, manufacturing and selling some of its products, which could harm its business, financial condition and operating results. With respect to products which BioSante has licensed to others, BioSante's licensees may be responsible for the defense of any patent infringement claims, which would result in its dependence upon them to defend its intellectual property rights.



**Risks Related to BioSante Common Stock**

***The trading price of BioSante common stock has been volatile, and your investment in BioSante common stock or convertible senior notes could decline in value.***

The price of BioSante common stock has fluctuated in the past and it is likely that the price of BioSante common stock will continue to fluctuate in the future. Since January 1, 2011 through December 31, 2012, the sale price of BioSante common stock ranged from \$1.08 per share to \$24.12 per share. These prices reflect the one-for-six reverse stock split of BioSante's common stock that was effective at the close of business on June 1, 2012. The securities of small capitalization, biopharmaceutical companies, including BioSante, from time-to-time experience significant price fluctuations, often unrelated to the operating performance of these companies. In addition, as BioSante's convertible senior notes are convertible into shares of BioSante common stock, volatility or depressed prices of BioSante common stock could have a similar effect on the trading price of the notes. Interest rate fluctuations also can affect the price of BioSante's convertible senior notes. In particular, the market price of BioSante common stock and its convertible senior notes may fluctuate significantly due to a variety of factors, including:

- general stock market and general economic conditions in the United States and abroad, not directly related to BioSante or its business;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to BioSante's products in development or its competitors' products;
- actual or anticipated results of BioSante's clinical studies or those of its competitors;
- changes in anticipated or actual timing of BioSante's development programs, including delays or cancellations of clinical studies for its products;
- announcements of technological innovations or new products by BioSante or its competitors;
- announcements by licensors or licensees of BioSante's technology;
- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- developments concerning BioSante's efforts to identify and implement strategic opportunities and the terms and timing of any resulting transactions;
- public concern as to the safety or efficacy of or market acceptance of products developed by BioSante or its competitors;
- BioSante's cash and cash equivalents and its need and ability to obtain additional financing;
- equity sales by BioSante to fund its operations or restructure its outstanding convertible senior notes;
- changes in laws or regulations applicable to BioSante's products;
- the resolution of BioSante's pending purported class action and shareholder derivative litigation;
- developments or disputes concerning patents or other proprietary rights;
- period-to-period fluctuations in BioSante's financial results, including its cash and cash equivalents, operating expenses, cash burn rate or revenues;
- loss of key management;

- common stock sales and purchases in the public market by one or more of BioSante's larger stockholders, officers or directors;
- reports issued by securities analysts regarding BioSante common stock and articles published regarding its business and/or products;
- changes in the market valuations of other life science or biotechnology companies; and
- other financial announcements, including delisting of BioSante common stock from The NASDAQ Global Market, review of any of its filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in its filings with the SEC or its failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this report or in subsequent reports BioSante files with or submits to the SEC from time to time could have a material and adverse impact on the market price of BioSante common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. BioSante currently is subject to such litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm BioSante's business and financial condition, as well as the market price of BioSante common stock.

***Provisions in BioSante's charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to BioSante stockholders.***

Provisions of BioSante's certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire BioSante, even if doing so would be beneficial to its stockholders. These provisions include:

- authorizing the issuance of "blank check" preferred shares that could be issued by the BioSante board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- advance notice provisions in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by BioSante stockholders to bring business to be considered by its stockholders at a meeting or replace its board of directors.

***BioSante does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in BioSante common stock must come from increases in the fair market value and trading price of BioSante common stock.***

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## Risks Related to ANI

*In determining whether to approve the merger, you should read carefully the following risk factors. BioSante and ANI anticipate that immediately following the merger the business of the combined company will primarily be the business conducted by ANI immediately prior to the merger. You therefore should read carefully and consider the risks associated with the business of ANI because these risks also relate to the combined company following completion of the merger.*

***ANI has a history of losses and negative cash flow, expects losses and negative cash flow to continue for the foreseeable future and cannot offer any assurances that it will ever achieve profitability.***

ANI has never been profitable, has an accumulated deficit of \$35.4 million as of December 31, 2011 and \$40.0 million as of September 30, 2012, and other than during the nine months ended September 30, 2012, has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, ANI has been dependent on a variety of financing sources, including the issuance of equity securities and convertible notes, and revolving lines of credit.

ANI cannot guarantee that it will achieve sufficient revenues for profitability. Even if it achieves profitability, it cannot guarantee that it can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than anticipated, or if operating expenses exceed ANI's expectations or cannot be adjusted accordingly, then ANI's business, results of operations, financial condition and cash flows will be materially and adversely affected.

***ANI's future capital requirements will depend on a variety of factors, many of which are beyond its control, and ANI can offer no assurances that it will be successful in obtaining sufficient financing to cover such requirements on commercially reasonable terms or at all.***

ANI's future capital requirements will depend on many factors, including, but not limited to:

- relative proportions of net revenues comprised of contract manufacturing and sales of ANI generic and branded products;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches;
- business and product acquisitions; and
- regulatory actions.

Many of these factors will depend on circumstances beyond ANI's control. For example, ANI's net revenues are concentrated among three customers representing 21 percent, 16 percent and 16 percent of net revenues, respectively, during the year ended December 31, 2011, and 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled \$3.6 million, or approximately 64 percent of ANI's net accounts receivable. As a result, negotiated payment terms with these customers have a material impact on ANI's liquidity and working capital.

In addition, two of ANI's generic pharmaceutical products, Opium Tincture and Fluvoxamine Maleate tablets, account for approximately 30 percent of ANI's net revenues. As a result, regulatory actions with respect to these products, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on ANI's liquidity and working capital.

If ANI continues to incur losses and is not able to raise adequate funds to cover those losses, it may be required to curtail its activities, which could have a material adverse effect on its business, financial condition and/or results of operations. The continuing global economic uncertainty, exacerbated by the European debt crisis and the "fiscal cliff" in the United States, has resulted in extreme volatility in the capital markets and is threatening to once again tighten the credit markets. As a result, there can be no assurances that ANI would be successful in obtaining sufficient financing on commercially reasonable terms or at all. To the extent that ANI raises additional capital through the sale of securities, the issuance of those securities or shares underlying such securities would result in dilution that could be substantial to its and the combined company's stockholders. In addition, if ANI incurs additional debt financing, a substantial portion of its operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for business activities. If adequate funds are not available, ANI's business, financial condition and/or results of operations could be materially and adversely affected.

***ANI's anticipated revenue growth and profitability, if achieved, is dependent upon ANI's ability to develop and/or license, or otherwise acquire, and introduce new products on a timely basis in relation to its competitors' product introductions, and to navigate the regulatory hurdles before, during and after the introduction of its new products. ANI's failure to do so successfully could have a material adverse effect on its business, financial position and results of operations.***

ANI's future revenues and profitability will depend, to an extent, upon its ability to successfully develop, license or otherwise acquire, and commercialize, branded and generic pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort and financial resources. ANI may not be successful in commercializing products on a timely basis, if at all, which could adversely affect its business, financial position and results of operations.

Before any new prescription drug product can be marketed in the United States, marketing authorization approval is required by the FDA. The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. ANI may be unable to obtain requisite approvals on a timely basis for branded or generic products that it may develop, license or otherwise acquire. Moreover, if ANI obtains regulatory approval for a drug, it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict its potential market for the drug. Also, for products pending approval, ANI may obtain raw materials or produce batches of inventory to be used in bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, ANI could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect ANI's product introduction plans, business, financial position and results of operations.

The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), provides for a period of 180 days of generic marketing exclusivity for each abbreviated new drug application (ANDA) applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, the applicant generally enjoys higher market share, net revenues and gross margin for that product than otherwise would be the case. However, an ANDA sponsor's ability to obtain 180 days of generic marketing exclusivity may be dependent upon its ability to obtain FDA approval or tentative approval within 30 months of the FDA's acceptance of its ANDA. If ANI is unable to obtain approval or tentative approval within that time period, it may risk forfeiture of such marketing exclusivity. Even if ANI obtains FDA approval for its generic drug products, if it is not the first ANDA applicant to challenge a listed patent for such a product, it may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where ANI is required to share its exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on ANI's ability to market that product profitably and on its business, financial position and results of operations.

If ANI is unable to navigate its products through all of the regulatory hurdles it faces in a timely manner, its product introduction plans, business, financial position and results of operations could be materially adversely affected.

The FDA regulates and monitors all promotion advertising and of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

***ANI's operating results and financial condition may fluctuate.***

ANI's operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. The following events or occurrences, among others, could cause fluctuations in ANI's financial performance from period to period:

- development of new competitive products or generics by others;
- the timing and receipt of approvals by the FDA;
- the failure to obtain, delay in obtaining or restrictions or limitations on approvals from the FDA;
- difficulties or delays in resolving FDA-observed deficiencies at ANI's manufacturing facilities, which could delay ANI's ability to obtain approvals of pending FDA product applications;
- serious or unexpected health or safety concerns with ANI's products or product candidates;
- changes in the amount ANI is required to spend to develop, acquire or license new products, technologies or businesses;
- changes in the amount ANI spends to promote ANI's products;

- delays between ANI's expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;
- changes in treatment practices of physicians that currently prescribe ANI's products;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes that affect newly developed or newly acquired products;
- changes in laws and regulations concerning coverage and reimbursement of pharmaceutical products, including changes to Medicare, Medicaid, and similar state programs;
- increases in the cost of raw materials used to manufacture ANI's products;
- manufacturing and supply interruptions, including failure to comply with manufacturing specifications;
- the impact of third party patents and other intellectual property rights which ANI may be found to infringe, or may be required to license, and the potential damages or other costs it may be required to pay as a result of a finding that it infringes such intellectual property rights or a decision that it is required to obtain a license to such intellectual property rights;
- the mix of products that ANI sells during any time period;
- lower than expected demand for ANI's products;
- ANI's responses to price competition;
- ANI's ability to successfully integrate and commercialize the products, technologies and businesses it acquires or licenses, as applicable;
- expenditures as a result of legal actions;
- market acceptance of ANI's products;
- the impairment and write-down of goodwill or other intangible assets;
- disposition of ANI's primary products, technologies and other rights;
- termination or expiration of, or the outcome of disputes relating to, trademarks, patents, license agreements and other rights;
- changes in insurance rates for existing products and the cost and availability of insurance for new and existing products;
- general economic and industry conditions, including changes in interest rates affecting returns on cash balances and investments that affect customer demand;
- ANI's level of research and development activities;
- impairment or write-down of investments;
- costs and outcomes of any tax audits;
- costs and outcomes of any litigation involving intellectual property, drug pricing or reimbursement, product liability, customers or other issues; and
- timing of revenue recognition related to licensing agreements and/or strategic collaborations.

As a result, ANI believes that period-to-period comparisons of ANI's results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. The above factors may cause ANI's operating results to fluctuate and adversely affect ANI's financial condition and results of operations.

***ANI's obligations under its line of credit are secured by substantially all of its assets. If ANI defaults under the line of credit, the lender may take immediate possession of the collateral and dispose of it.***

Under its line of credit with Alostar Bank of Commerce, ANI may borrow on a revolving basis, based on a percentage of eligible accounts receivable and inventory, up to a maximum of \$5.0 million. The loan agreement bears interest daily at the greater of (i) LIBOR plus 5 percent or (ii) 6 percent. The line of credit is secured by substantially all of ANI's assets. The principal is repayable at the termination date, unless accelerated as a result of certain events of default. If ANI generates any proceeds from the collateral securing the line of credit, such proceeds must be paid to the lender up to the amount of any outstanding balance. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default. In addition, a usage fee equal to 0.375 percent per annum of the unused amounts under the facility and a management fee equal to \$18,000 per annum are assessed monthly. The revolving loan agreement expires in June 2015, but can be terminated early in the following circumstances: (a) automatically upon the commencement of insolvency proceedings by or against ANI, (b) at the option of the lender without notice upon any other event of default, and (c) at the option of ANI upon ten business days' prior written notice.

In the event of early termination, whether effected by ANI, the lender or automatically, ANI is obligated to pay an amount corresponding to a percentage of \$5.0 million, with such percentage being: 3 percent if termination occurs in the first year, 2 percent if termination occurs in the second year and 1 percent if termination occurs after the second year but prior to the last day of the term. The loan agreement contains customary representations, warranties and covenants. As of September 30, 2012, approximately \$3.4 million was outstanding under the loan agreement, at an effective interest rate of 6.0 percent.

Events of default under the agreement include, but are not limited to: (i) liquidation, bankruptcy or similar events; (ii) failure to pay any debts due on a timely basis; (iii) failure to observe any covenant or condition under the loan agreement, which failure, in most cases, is not cured within 30 days of written notice by lender; (iv) material misrepresentations; (v) ANI is restrained by court order from continuing to conduct all or any material part of ANI's business; (vi) certain money judgments are entered against ANI; and (vii) ANI challenges the validity or enforceability of the loan agreement in any proceeding. Remedies for events of default include acceleration of amounts owing under the loan agreement and taking immediate possession of, and selling, any collateral securing the loan, which would have a material adverse effect on ANI's profitability, business, financial position and results of operations.

***ANI's approved products may not achieve expected levels of market acceptance, which could have a material adverse effect on its profitability, business, financial position and results of operations.***

Even if ANI is able to obtain regulatory approvals for its pharmaceutical products, the success of those products is dependent upon market acceptance. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

- the availability of alternative products from ANI's competitors;
- the price of ANI's products relative to that of ANI's competitors;
- the timing of ANI's market entry;
- the ability to market ANI's products effectively to the retail level; and
- the acceptance of ANI's products by government and private formularies.

Some of these factors are not within ANI's control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and

techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and in the future may result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on ANI's profitability, business, financial position and results of operations.

***Certain of ANI's generic products are marketed without approved NDAs or ANDAs and ANI can offer no assurances that the FDA will not require ANI to seek approval for these products or withdraw them from the market. In either case, ANI's business, financial position and results of operations could be materially adversely affected.***

Certain of ANI's generic products are marketed without approved NDAs or ANDAs, specifically, Esterified Estrogen with Methyltestosterone and Opium Tincture. During the nine months ended September 30, 2012 and 2011, combined net revenues for these products were \$3.6 million and \$2.2 million, respectively and during the years ended December 31, 2011 and 2010, combined net revenues for these products were \$3.5 million and \$95,000, respectively.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide, titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While ANI believes that so long as it complies with applicable manufacturing and labeling standards, it will not be targeted for enforcement under the FDA's current enforcement policy, it can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

In addition, one group of products that ANI manufactures on behalf of a contract customer, and based on the sale of which ANI receives royalties, is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market, which could materially adversely affect ANI's contract manufacturing and royalty revenue. ANI's contract manufacturing revenue for this group of products for the nine months ended September 30, 2012 and 2011 was \$775,000 and \$1.1 million, respectively. ANI's royalties on the net sales of these products for the nine months ended September 30, 2012 and 2011 were \$220,000 and \$249,000, respectively. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was \$1.3 million and \$623,000, respectively. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were \$320,000 and \$118,000, respectively.



ANI's manufacture and distribution of drugs without approved NDAs or ANDAs could also result in legal actions by private parties, state governments or the federal government. These entities may allege that ANI has misrepresented the regulatory status of Esterified Estrogen with Methyltestosterone and Opium Tincture resulting in the submission of false claims to federal and state health care programs. Such legal actions could result in fines, penalties, reimbursement, and legal settlements that could bind the company going forward and materially affect ANI's ability to market these products as well as the profitability of ANI's business, financial position and results of operations.

***ANI began its own product development program in 2011 and expects to spend a significant amount of resources on research and development efforts that may not lead to successful product introductions. Failure to successfully introduce products into the market could have a material adverse effect on its business, financial position and results of operations.***

ANI conducts research and development primarily to enable it to manufacture and market approved pharmaceuticals in accordance with applicable regulations. As ANI develops new products, its research expenses likely will increase. Because of the inherent risk associated with research and development efforts in the industry, ANI's research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the FDA. Also, after ANI submits a marketing authorization application for a generic product, the FDA may change standards and/or request that ANI conduct additional studies and, as a result, ANI may incur total research and development costs to develop a particular product in excess of what it anticipated. Finally, ANI cannot be certain that any investment made in developing products will be recovered, even if it is successful in commercialization. To the extent that ANI spends significant resources on research and development efforts and is not able, ultimately, to introduce successful new products as a result of those efforts, its business, financial position and results of operations may be materially adversely affected.

***ANI is entirely dependent on periodic approval by the DEA for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, ANI is subject to strict regulation by the DEA and is subject to sanctions if it is unable to comply with related regulatory requirements.***

The Drug Enforcement Administration (DEA) regulates certain drug products containing controlled substances, such as opium, pursuant to the U.S. Controlled Substances Act (CSA). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, ANI must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is entirely dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture at levels that would maximize ANI's revenues or profits.

***ANI may have to engage in litigation, which could result in substantial cost or distraction, to enforce or defend its proprietary rights and which, if ANI did not prevail, could harm its business and make it more vulnerable to competition.***

In the future, ANI may have to engage in litigation to enforce or defend its proprietary rights, for example, its rights of market exclusivity with respect to certain of its products, or any trademarks it owns for its branded products, such as Cortenema® and Reglan®. In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there often can be very substantial and rapid declines in the branded product's sales; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. ANI believes that sales of its branded products have and will continue to benefit from the goodwill of the product name. ANI, therefore, considers market exclusivity and its trademark names to be of material value and acts to protect these rights from infringement.

***ANI may in the future be accused of infringing intellectual property rights of third parties and may have to engage in litigation to determine the scope and validity of third party patents and proprietary rights, which, if it does not prevail, could harm its business, results of operations, financial condition, cash flow and future prospects.***

Third parties in the future may file patent applications and obtain patents relating to ANI's products and technologies. Regardless of their ultimate merit, any infringement or other intellectual property claims against ANI's products and technologies may be expensive and time-consuming to litigate and may divert management attention. If any such claim were successful, ANI could be required to obtain licenses to a third party's technologies, patents or other proprietary rights or to their biological or chemical reagents in order to develop and market ANI's products. Moreover, ANI may choose to voluntarily seek such a license in order to avoid the expense and uncertainty of fully defending its position. In either event, such a license may not be available to ANI on acceptable terms or at all, and ANI may have to discontinue that portion of its business. In addition, to the extent ANI licenses its intellectual property to other parties, ANI may incur expenses as a result of contractual agreements in which ANI indemnifies those licensing its technologies against losses incurred if practicing its intellectual property infringes upon the proprietary rights of others. The failure to license any technologies or biological or chemical reagents required to develop or commercialize ANI's technologies or products at reasonable cost may harm ANI's business, results of operations, financial condition, cash flow and future prospects.

***ANI does not own or license any patents associated with its products, and its ability to protect and control unpatented trade secrets, know-how and other technological innovation is limited.***

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. ANI does not own or license any patents associated with its products and therefore does not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. ANI has a limited ability to protect and control trade secrets, know-how and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. Also, others may gain access to ANI's trade secrets, and ANI may not be able to meaningfully protect its rights to its unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide meaningful protection for ANI's trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and

control such trade secrets, know-how and innovation could harm the value of ANI's trade secrets, know-how and other technological innovation.

***ANI faces vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of its products. Such competition could have a material adverse effect on its business, financial position and results of operations and cash flows.***

The generic pharmaceutical industry is highly competitive. ANI faces competition from many U.S. and foreign manufacturers, some of whom are significantly larger than ANI. Its competitors may be able to develop products and processes competitive with or superior to ANI's for many reasons, including but not limited to the possibility that they may have:

- proprietary processes or delivery systems;
- larger research and development and marketing staffs;
- larger production capabilities in a particular therapeutic area;
- more products; or
- more experience in developing new drugs and greater financial resources, particularly with regard to manufacturers of branded products.

Any of these factors and others could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

***The use of legal, regulatory and legislative strategies by competitors, both branded and generic, including "authorized generics" and citizen's petitions, as well as the potential impact of proposed legislation, may increase ANI's costs associated with the introduction or marketing of ANI's generic products, could delay or prevent such introduction and/or could reduce significantly ANI's profit potential. These factors could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

ANI's competitors, both branded and generic, often pursue strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen's petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of ANI's product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements;
- initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals;
- filing suits for patent infringement that may delay regulatory approval of many generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which ANI seeks regulatory approval;

- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods;
- persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded name company to obtain new patented products serving as substitutes for the products withdrawn; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

In the United States, some companies have lobbied Congress for amendments to the Hatch-Waxman Act that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by the full amount of time spent in clinical trials rather than by only one half of the time that is currently permitted.

If proposals like these were to become effective, ANI's entry into the market and its ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on its business, financial position, results of operations and cash flows.

***ANI faces significant uncertainty with respect to the litigation brought against it and other manufacturers of metoclopramide and cannot provide assurances that the outcome of the matter will not have an adverse effect on its financial position, results of operations and/or cash flows from operations. In addition, ANI may be exposed to other product liability claims in the future.***

In February 2009, the FDA mandated a "black box" warning for the drug metoclopramide, specifically highlighting the risks of patients developing tardive dyskinesia, a movement disorder, when taking metoclopramide for longer than 12 weeks. As a result, numerous state-level lawsuits were brought against pharmaceutical manufacturers, both branded and generic, who ever had manufactured and/or sold metoclopramide. Among the defendants is ANI, which manufactures the generic version and since 2011 has been manufacturing the branded version under the name Reglan®. The plaintiffs in these lawsuits claim to have incurred bodily injuries as a result of ingestion of metoclopramide or Reglan® prior to the FDA's black box warning requirement. The allegations involve a failure, based on various state-level consumer protection laws, to adequately warn patients and doctors about the risks of using metoclopramide for longer than 12 weeks as evidenced by the FDA's mandate to strengthen the labeled warning. ANI has been named and served in 79 separate complaints between December 2009 and November 2012, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, ANI was dismissed with prejudice as a defendant in all of the cases brought in New Jersey.

As the state-level litigation progressed, the generic pharmaceutical defendants appealed to the U.S. Supreme Court arguing that generic companies could not comply with state laws that required them to strengthen their labels because generic companies are prohibited by federal law from making any changes except those adopted by the brand or mandated by FDA for all manufacturers, e.g. federal pre-emption. The U.S. Supreme Court decided in favor of the generic companies in June 2011 in what is known now as the Mensing decision. While many cases since have been dismissed by state courts, several judges, including in Pennsylvania and California, have allowed the plaintiffs to resubmit their complaints.

At the present time, ANI's management is unable to assess the likely outcome of the remaining cases. ANI's insurance company has assumed the defense of this matter. In addition, ANI's insurance company renewed ANI's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. ANI cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial

condition and cash flow. Furthermore, like all pharmaceutical manufacturers, ANI in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

***ANI may experience declines in the sales volume and prices of its products as the result of the continuing trend toward consolidation of certain customer groups, such as the wholesale drug distribution and retail pharmacy industries, as well as the emergence of large buying groups. These developments could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations, has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. For example, ANI's net revenues are concentrated among three customers representing 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled \$3.6 million, or approximately 64 percent of ANI's net accounts receivable. Drug wholesalers and retail pharmacy chains, which represent an essential part of the distribution chain of generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing ANI's business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on ANI's products. The result of these developments may have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

***Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could affect adversely the market for ANI's hormone products.***

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. The markets for female hormone therapies for menopausal symptoms declined as

a result of these published studies, although the market now seems to have stabilized. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to ANI's products, also could affect adversely ANI's business.

***ANI has a limited number of manufacturing facilities producing a substantial portion of its products. Production at any one of these facilities could be interrupted, which could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

A substantial portion of ANI's capacity as well as its current production is attributable to a limited number of manufacturing facilities and certain third party suppliers. During the nine months ended September 30, 2012, ANI purchased approximately 43 percent of total costs of goods sold from two suppliers. A significant disruption at any one of the facilities within ANI's internal supply chain, even on a short-term basis, whether due to a labor strike, failure to reach acceptable agreement with labor and unions, adverse quality or compliance observation, act of God, civil or political unrest, or other events could impair ANI's ability to produce and ship products to the market on a timely basis and, among other consequences, could subject ANI to exposure to claims from customers. Any of these events could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.

Virtually all contracts for the supply of pharmaceutical products by ANI to customers contain "failure to supply" clauses. Under these clauses, if ANI is unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and ANI must reimburse its customer for the difference between ANI's contract price and the price the customer was forced to pay to procure the substitute product. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements, and can be far in excess of the revenue that ANI would otherwise have received on the sale of its own product. The ability to produce and ship a sufficient quantity of product is therefore critical to ANI.

***ANI depends on a limited number of suppliers for active pharmaceutical ingredients.***

ANI's ability to manufacture and distribute drug products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the United States. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect ANI's ability to manufacture and distribute drug product and could result in legal liabilities that could materially affect ANI's ability to realize profits or otherwise harm ANI's business, financial, and operating results. ANI sources the raw materials for its products, including active pharmaceutical ingredients (API) from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

As described above, virtually all contracts for the supply of pharmaceutical products by ANI to customers contain "failure to supply" clauses. The ability to source sufficient quantities of active pharmaceutical ingredients for manufacturing is therefore critical to ANI. For Opium Tincture, this ability to source adequate amounts of raw material is in turn dependent on the quota set by the DEA. See also "Risks Related to ANI—ANI is entirely dependent on periodic approval by the DEA for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, ANI is subject to strict regulation by the DEA and is subject to sanctions if it is unable to comply with related regulatory requirements."

***Legislative or regulatory programs that may influence prices of pharmaceutical products could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

Current or future federal, state or foreign laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that ANI receives for its products. For example, programs in existence in certain states in the U.S. seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the prices ANI receives for its products and could have a material adverse effect on its business, financial position, results of operations and cash flows.

***Healthcare reform legislation could have a material adverse effect on ANI's business, financial position, results of operations and cash flows.***

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States, and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education and Reconciliation Act, which amends the PPACA (collectively the Health Reform Laws), were signed into law in March 2010. While the Health Reform Laws may increase the number of patients who have insurance coverage for ANI's products, they also include provisions such as the assessment of a pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent ANI from maintaining prices for its products that are sufficient for ANI to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that ANI's approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent ANI from maintaining prices for such products that are sufficient for ANI to realize profits and may otherwise significantly harm its business, financial condition and operating results.

ANI is unable to predict the future course of federal or state healthcare legislation. The Health Reform Laws and further changes in the law or regulatory framework that reduce ANI's revenues or increase its costs could have a material adverse effect on its business, financial condition, results of operations and cash flows.

***If third-party payers deny coverage or offer inadequate levels of reimbursement, ANI or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.***

Third-party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, ANI or any of its strategic partners may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

*ANI is subject to federal, state and local laws and regulations, and complying with these may cause ANI to incur significant costs.*

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration, and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act of 1970 and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of ANI's products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

ANI's research, product development and manufacturing activities have involved the controlled use of hazardous materials, and ANI may incur significant costs as a result of the need to comply with numerous laws and regulations. ANI is subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (OSHA), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of ANI's products, materials used to develop and manufacture such products, and resulting waste products. For example, certain of ANI's products, including Esterified Estrogen with Methyltestosterone, must be manufactured in a fully contained environment due to their potency and/or toxicity, and compliance with related OSHA requirements is costly.

ANI cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts from these materials. In the event of an accident, ANI could be held liable for any damages that result, and any resulting liability could exceed its resources. ANI may also be required to incur significant costs to comply with environmental laws and regulations in the future. ANI is also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to its business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm ANI's business, results of operations, financial condition, cash flow and future prospects.



## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This joint proxy statement/prospectus contains "forward-looking statements" of BioSante within the meaning of the Private Securities Litigation Reform Act of 1995, which is applicable to BioSante, but not ANI, because BioSante, unlike ANI, is a public company subject to the reporting requirements of the Exchange Act. For this purpose, any statements contained herein regarding BioSante, other than statements of historical fact, may be forward-looking statements under the provisions of the Private Securities Litigation Reform Act of 1995. In addition, any statements contained herein regarding ANI, other than statements of historical fact, should be considered forward-looking statements. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. Statements that include words such as "expect," "believe," "will," "may," "might," "anticipate," "continue," "plan," "estimate," "intend," "should," "can," "likely," "could," "predict," "project," "forecast," "potential," "possible" or the negative of these words or other words or expressions of similar meaning may identify forward-looking statements. These forward-looking statements are found at various places throughout this joint proxy statement/prospectus and relate to a variety of matters, including but not limited to:

- the timing and anticipated completion of the proposed merger between BioSante and ANI;
- the expected benefits of and potential value created by the proposed merger for the stockholders of BioSante and ANI;
- the amount of cash and cash equivalents that will be available to fund the combined company's business after the merger and the length of time that the combined company anticipates such cash and cash equivalents will be available to fund the combined company's operating plan after the merger;
- the likelihood of the satisfaction of certain conditions to completion of the merger and whether and when the merger will be completed;
- the amount of shares of BioSante common stock that BioSante expects to issue in the proposed merger and the post-capitalization of the combined company after the merger;
- BioSante's and ANI's respective results of operations, financial condition and businesses and their respective objectives, plans and expectations; and
- information about the combined company and the expected impact of the proposed merger on the combined company and its future business, operating results and financial condition.

These statements are subject to risks and uncertainties, including the risks described in this joint proxy statement/prospectus under the section "Risk Factors," that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements in this joint proxy statement/prospectus. Forward-looking statements are not guarantees of performance. These statements are based upon the current beliefs and expectations of management of BioSante and ANI and are subject to a number of factors that could cause actual outcomes and results to be materially different from those projected or anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date hereof. Except to the extent required by applicable law or regulation, neither BioSante nor ANI undertakes any obligation to update or publish revised forward-looking statements to reflect events or circumstances after the date hereof or the date of the forward-looking statements or to reflect the occurrence of unanticipated events.

## THE SPECIAL MEETING OF BIOSANTE STOCKHOLDERS

### General

This joint proxy statement/prospectus is being furnished to stockholders of BioSante on or about January 25, 2013. BioSante is sending this joint proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by the BioSante board of directors for use at the BioSante special meeting and any adjournments or postponements of the meeting.

### Date, Time and Place

The special meeting of BioSante stockholders will be held at 8:00 a.m., local time, on Friday, March 15, 2013, at BioSante's corporate office located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069.

### Purposes of the BioSante Special Meeting

The purposes of the BioSante special meeting are to consider and act upon the following matters:

1. To consider and vote upon a proposal to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.
2. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.
3. To consider and vote upon a proposal to approve an amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc."
4. To consider and vote upon a proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.
5. To consider and vote upon a proposal to approve an adjournment of the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and 3.

BioSante stockholders also will consider and act on any other matters as may properly come before the BioSante special meeting or any adjournment or postponement of the meeting, including any procedural matters incident to the conduct of the meeting.

### Recommendations of the BioSante Board of Directors

The BioSante board of directors has determined and believes that the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

The BioSante board of directors has determined and believes that the amendment to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C

special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, as described in this joint proxy statement/prospectus, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors recommends unanimously that BioSante stockholders vote "**FOR**" BioSante Proposal No. 2 to approve the amendment to BioSante's certificate of incorporation to effect the reverse stock split.

The BioSante board of directors has determined and believes that the amendment to BioSante's certificate of incorporation to change the name of BioSante from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc.", as described in this joint proxy statement/prospectus, is advisable, fair to, and in the best interests of BioSante and its stockholders and unanimously has approved such proposal. The BioSante board of directors recommends unanimously that BioSante stockholders vote "**FOR**" BioSante Proposal No. 3 to approve the amendment to BioSante's certificate of incorporation to effect the corporate name change.

The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 4 to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.

The BioSante board of directors unanimously recommends that BioSante stockholders vote "**FOR**" BioSante Proposal No. 5 to adjourn the BioSante special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and 3.

### **Record Date and Voting Power**

The close of business on January 17, 2013 has been fixed as the BioSante record date for the determination of BioSante stockholders entitled to notice of, and to vote at, the BioSante special meeting or any adjournments or postponements of the meeting. Only holders of record of BioSante common stock and BioSante class C stock at the close of business on the BioSante record date are entitled to notice of, and to vote at, the BioSante special meeting. At the close of business on the record date, BioSante had 24,422,240 shares of common stock and 65,211 shares of class C special stock outstanding and entitled to vote. Each share of BioSante common stock and BioSante class C special stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See "Principal Stockholders of BioSante" for information regarding persons known to management of BioSante to be the beneficial owners of more than five percent of the outstanding shares of BioSante common stock and BioSante class C special stock.

### **Voting and Revocation of Proxies**

The proxy accompanying this joint proxy statement/prospectus is solicited on behalf of the BioSante board of directors for use at the BioSante special meeting. If you are a BioSante stockholder of record as of the record date for the BioSante special meeting, you may vote in person at the BioSante special meeting or vote by proxy over the Internet, by telephone or by using the enclosed proxy card. Whether or not you plan to attend the BioSante special meeting, BioSante urges you to vote by proxy to ensure your vote is counted. You still may attend the BioSante special meeting and vote in person if you already have voted by proxy. BioSante stockholders of record as of the close of business on January 17, 2013 may submit their proxies:

- **through the Internet**, by visiting the website established for that purpose at <https://www.proxyvote.com> and following the instructions (please note you must type an "s" after http); or

- **by telephone**, by calling the toll-free number 1-800-690-6903 in the United States, Canada or Puerto Rico on a touch-tone phone, providing the unique 10-digit control number shown on the enclosed proxy card and following the recorded instructions; or
- **by mail**, by marking, signing and dating the enclosed proxy card and returning it in the postage-paid envelope provided or returning it pursuant to the instructions provided in the proxy card.

If your shares are held in "street name," you must request a legal proxy from your nominee as proof of ownership in order to vote in person at the BioSante special meeting. **If you hold your shares in "street name," please refer to your proxy card or the information forwarded by your bank, broker or other holder of record to see which options are available to you.**

All properly executed proxies that are not revoked will be voted at the BioSante special meeting and at any adjournments or postponements of the meeting in accordance with the instructions contained in the proxy. If a holder of BioSante capital stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted **"FOR"** BioSante Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger; **"FOR"** BioSante Proposal No. 2 to approve an amendment to BioSante's certificate of incorporation to effect the reverse stock split described in this joint proxy statement/prospectus; **"FOR"** BioSante Proposal No. 3 to approve an amendment to BioSante's certificate of incorporation to effect the corporation name change; **"FOR"** BioSante Proposal No. 4 to approve on an advisory basis the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger; and **"FOR"** BioSante Proposal No. 5 to adjourn the BioSante special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and 3 in accordance with the recommendation of the BioSante board of directors.

Any BioSante stockholder of record voting by proxy, other than those stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the BioSante special meeting by sending a written notice stating that it would like to revoke its proxy to the corporate secretary of BioSante, by voting again over the Internet or by telephone, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the BioSante special meeting and voting in person. Attendance alone at the BioSante special meeting will not revoke a proxy. A beneficial owner of BioSante common stock that holds shares in "street name" must follow directions received from the bank, broker or other nominee that holds the shares to change its voting instructions.

#### **Quorum and Required Vote**

The presence at the BioSante special meeting, in person or by proxy, of the holders of one-third (8,162,484 shares) of the outstanding shares of BioSante capital stock as of the record date will constitute a quorum for the transaction of business at the BioSante special meeting. In general, shares of BioSante common stock and shares of BioSante class C special stock represented by a properly signed and returned proxy card will be counted as shares present and entitled to vote at the BioSante special meeting for purposes of determining a quorum. Shares represented by proxies marked "Abstain" or "Withheld" are counted in determining whether a quorum is present. In addition, a "broker non-vote" is considered in determining whether a quorum is present. A "broker non-vote" is a proxy returned by a broker on behalf of its beneficial owner customer that is not voted on a particular matter because voting instructions have not been received by the broker from the customer, and the broker does not have discretionary authority to vote on behalf of such customer on such matter. If a quorum is not present at the BioSante special meeting, BioSante expects that the BioSante special meeting will be adjourned or postponed to solicit additional proxies.

A description of the vote required to approve each proposal being submitted to a vote of BioSante stockholders is included with the description of each proposal. For BioSante Proposals No. 1, 2 and 3, a failure to vote by proxy or in person at the BioSante special meeting, or an abstention, vote withheld or "broker non-vote" for such proposals, will have the same effect as a vote against the approval of such proposals. For BioSante Proposals No. 4 and 5, a failure to submit a proxy card or vote at the BioSante special meeting, or an abstention, vote withheld or "broker non-votes" will have no effect on the outcome of such proposals.

The approval of the merger agreement and the transactions contemplated by it is not conditioned upon approval of the amendments to BioSante's certificate of incorporation to effect the reverse stock split or corporation name change. However, the approval of the amendments to BioSante's certificate of incorporation is conditioned upon approval of the merger agreement. Therefore, the proposals to amend BioSante's certificate of incorporation will only be effected if the merger agreement is approved by the stockholders of BioSante and ANI.

In connection with the execution of the merger agreement, all of BioSante's directors and officers, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into a voting agreement with ANI, pursuant to which each stockholder agreed to vote all of their shares of BioSante capital stock in favor of adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, in favor of the charter amendments and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated thereby.

#### **Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of BioSante may solicit proxies from BioSante stockholders by personal interview, telephone, telegram or other electronic means. BioSante will bear the costs of the solicitation of proxies by BioSante from BioSante stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of BioSante common stock for the forwarding of solicitation materials to the beneficial owners of BioSante common stock and BioSante class C special stock. BioSante will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials. BioSante has retained Phoenix Advisory Partners, a proxy solicitation firm, to assist in the solicitation of proxies for the merger for a fee of approximately \$8,000.

#### **Delivery of Proxy Materials to Households Where Two or More Stockholders Reside**

Some banks, brokers and other nominee record holders may be participating in the practice of "householding" proxy statements. This means that only one copy of this joint proxy statement/prospectus to any BioSante stockholder may have been sent to multiple stockholders in each household. BioSante will promptly deliver a separate copy of this joint proxy statement/prospectus to any BioSante stockholder upon written or oral request to BioSante's Investor Relations Department, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, telephone: (847) 478-0500 ext. 120; e-mail: [info@biosantepharma.com](mailto:info@biosantepharma.com).

#### **Other Matters**

As of the date of this joint proxy statement/prospectus, the BioSante board of directors does not know of any business to be represented at the BioSante special meeting other than as set forth in the notice accompanying this joint proxy statement/prospectus. If any other matters should properly come before the BioSante special meeting, or any adjournment or postponement of the BioSante special meeting it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the person voting the proxies.

## MATTERS BEING SUBMITTED TO A VOTE OF BIOSANTE STOCKHOLDERS

### **BioSante Proposal No. 1—Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, including the Merger and the Issuance of Shares of BioSante Common Stock in the Merger**

#### ***General***

At the BioSante special meeting, BioSante stockholders will be asked to adopt the agreement and plan of merger dated as of October 3, 2012 by and between BioSante and ANI, as amended, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is \$18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of approximately 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger (as determined prior to an anticipated reverse stock split of BioSante common stock), assuming BioSante's net cash as of the determination date was \$18.0 million.

The terms of, reasons for and other aspects of the merger agreement, the merger and the issuance of shares of BioSante common stock in the merger are described in detail in the other sections of this joint proxy statement/prospectus. The full text of the merger agreement is attached to this joint proxy statement/prospectus as Annex A.

#### ***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 1.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 1.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante's Proposal No. 1 to adopt the agreement and plan of merger and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.**

**BioSante Proposal No. 2—Approval of Amendment to BioSante's Certificate of Incorporation to Effect a Reverse Split of BioSante Common Stock and Class C Special Stock at the Discretion of BioSante and ANI at a Ratio of Either One-for-Two, One-for-Three, One-for-Four or One-for-Five.**

**General**

The BioSante board of directors has approved unanimously a proposal to amend BioSante's certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, with the exact ratio to be determined by BioSante and ANI prior to completion of the merger. The BioSante board of directors has recommended that this proposal be presented to the BioSante stockholders for approval. The text of the form of proposed amendment to BioSante's certificate of incorporation to effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock is attached to this joint proxy statement/prospectus as Annex I.

The proposed amendment to BioSante's certificate of incorporation will effect a reverse stock split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, with the exact ratio to be determined by BioSante and ANI prior to completion of the merger. The BioSante board of directors believes that stockholder approval of an amendment granting this discretion, rather than approval of one specified ratio, provides BioSante and ANI the appropriate flexibility to react to then-current market conditions and, therefore, is in the best interests of BioSante and its stockholders.

By approving this amendment, BioSante stockholders will (i) approve a series of amendments to BioSante's certificate of incorporation pursuant to which a one-for-two, one-for-three, one-for-four or one-for-five reverse split of BioSante common stock and BioSante class C special stock will be effected, and (ii) authorize the BioSante board of directors to (a) file only one such amendment, as determined immediately prior to completion of the merger in the manner described herein and (b) abandon each amendment not selected. In addition, BioSante may elect not to undertake a reverse stock split.

If, following approval by the BioSante stockholders, it is determined that an amendment to BioSante's certificate of incorporation to effect a reverse stock split is in the best interests of BioSante and its stockholders, the reverse stock split will become effective upon filing one such amendment with the Secretary of State of the State of Delaware. Such amendment will effect either a one-for-two, one-for-three, one-for-four or one-for-five reverse split of BioSante common stock or BioSante class C special stock.

If, following approval by the BioSante stockholders, a reverse stock split is undertaken, the number of issued and outstanding shares of BioSante common stock and BioSante class C special stock will be reduced in accordance with a reverse stock split ratio determined by BioSante and ANI immediately prior to completion of the merger. Except for adjustments that may result from the treatment of fractional shares, as described below, each BioSante stockholder will hold the same percentage of BioSante common stock and BioSante class C special stock outstanding immediately following the reverse stock split as such stockholder held immediately prior to the reverse stock split and immediately prior to completion of the merger. The par value of BioSante common stock and BioSante class C special stock will remain unchanged at \$0.0001 per share.

***Reasons for the Reverse Stock Split***

The BioSante board of directors approved the proposal authorizing the reverse stock split because it believes that a reverse stock split may allow the shares of BioSante common stock to be issued in connection with the merger to become listed on The NASDAQ Global Market or The NASDAQ

Capital Market, which listing is a condition to completion of the merger. In addition, the BioSante board of directors believes that the increased market price of BioSante common stock expected to result from the implementation of a reverse stock split will improve the marketability and liquidity of BioSante common stock.

*NASDAQ Requirements for Listing on The NASDAQ Global Market*

BioSante common stock currently is listed on The NASDAQ Global Market. According to the listing rules of The NASDAQ Stock Market, in a transaction in which an issuer combines with a non-NASDAQ entity, resulting in a change of control of the issuer and potentially allowing the non-NASDAQ entity to obtain a NASDAQ listing, the issuer must apply for initial inclusion on the applicable NASDAQ market.

The merger agreement requires that BioSante use its reasonable best efforts to cause the shares of BioSante common stock to be issued in the merger to be approved, at or prior to completion of the merger, for listing (subject to notice of issuance) on The NASDAQ Global Market or The NASDAQ Capital Market, and the listing of the shares of BioSante common stock issuable pursuant to the merger agreement is a condition to ANI's obligation to complete the merger.

The listing standards of The NASDAQ Global Market and The NASDAQ Capital Market require, among other things, a \$4.00 per share minimum bid upon completion of the merger. As of the date of the mailing of this joint proxy statement/prospectus, BioSante has filed an initial listing application for The NASDAQ Global Market in connection with the merger. The BioSante board of directors expects that a reverse stock split of BioSante common stock will increase the market price of BioSante common stock so that the combined company is able to achieve the initial listing requirements for The NASDAQ Global Market upon completion of the merger and thereafter maintain compliance with the NASDAQ minimum bid price listing standard of \$4.00 per share. In determining the exact ratio for the reverse stock split, BioSante and ANI intend to use either a one-for-two, one-for-three, one-for-four or one-for-five ratio that would result in a per share price of greater than \$4.00 per share following the reverse stock split. Notwithstanding the foregoing, there can be no assurance that the market price per share following the merger and the reverse stock split will remain in excess of the minimum bid price for a sustained period of time. In addition, there can be no assurance that the BioSante common stock, or the common stock of the combined company following completion of the merger, will not be delisted due to a failure to meet other continued listing requirements even if the market price per share of BioSante common stock on a post-reverse-stock-split basis remains in excess of the minimum bid requirement.

Additionally, the BioSante board of directors believes that a listing on The NASDAQ Global Market for the shares of common stock of the combined company may provide a broad market for the common stock of the combined company and facilitate the use of the common stock of the combined company in financing and other transactions.

*Potential Increased Investor Interest*

On January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, the closing sale price of BioSante common stock was \$1.36 per share. An investment in BioSante common stock may not appeal to brokerage firms that are reluctant to recommend lower-priced stocks to their clients. Investors also may be dissuaded from purchasing lower-priced stocks because the brokerage commissions, as a percentage of the total transaction, tend to be higher for such stocks. Moreover, analysts at many brokerage firms do not monitor the trading activity or otherwise provide coverage of lower-priced stocks. Also, the BioSante board of directors believes that most investment funds are reluctant to invest in lower-priced stocks.



There are risks associated with the reverse stock split, including that the reverse stock split may not result in an increase in the per share price of BioSante common stock. There is no assurance that (i) the market price per share of BioSante common stock following the reverse stock split will rise in proportion to the reduction in the number of shares of BioSante common stock outstanding before the reverse stock split; (ii) the reverse stock split will result in a market price per share of BioSante common stock that will attract brokers and investors who do not trade in lower-priced stocks; (iii) the market price per share of BioSante common stock will either exceed or remain in excess of the \$4.00 minimum bid price as required for initial listing on The NASDAQ Global Market or The NASDAQ Capital Market; or (iv) BioSante otherwise will meet the initial listing requirements for The NASDAQ Global Market or The NASDAQ Capital Market.

The market price per share of BioSante common stock also will be based on the performance of BioSante and other factors, some of which are unrelated to the number of shares of BioSante common stock outstanding. If the reverse stock split is affected and the market price per share of BioSante common stock declines, the percentage decline as an absolute number and as a percentage of the overall market capitalization of BioSante may be greater than would occur in the absence of a reverse stock split. Furthermore, the liquidity of BioSante common stock could be adversely affected by the reduced number of shares of BioSante common stock that will be outstanding following the reverse stock split.

### ***Effects of the Reverse Stock Split***

If approved and implemented, the principal effects of the reverse stock split would include the following, all of which have been considered by the BioSante board of directors in approving the reverse stock split amendment:

- The number of outstanding shares of BioSante common stock and BioSante class C special stock will be reduced and each BioSante stockholder will own fewer shares than they currently own.
- The number of authorized shares of BioSante common stock and BioSante class C special stock will not be affected, thereby resulting in an increase in the authorized but unissued shares of BioSante common stock and BioSante class C special stock. This could result in BioSante or the combined company having the ability to issue more shares without further stockholder approval. Neither BioSante nor ANI has any current plan, commitment, arrangement, understanding or agreement, written or oral, to issue shares of BioSante common stock or BioSante class C special stock, other than in connection with the merger and to satisfy obligations under outstanding options and warrants to purchase shares of BioSante common stock.
- The number of shares of BioSante common stock reserved and available for issuance under BioSante's equity-based compensation plans and the number of shares of BioSante common stock issuable upon exercise of outstanding options and warrants will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the exercise price of all outstanding options and warrants will be increased proportionately. The reverse stock split will not in and of itself change the value of a BioSante stock option or warrant. The number of shares of BioSante common stock issuable upon conversion of BioSante's convertible senior notes will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the conversion price of such notes will be increased proportionately. The number of shares of BioSante common stock issuable upon conversion of BioSante class C special stock will be reduced proportionately based on the reverse stock split ratio selected by BioSante and ANI and the per share conversion or purchase price of such shares will be increased proportionately.
- Except for adjustments that may result from the treatment of fractional shares resulting from the reverse stock split, which are explained below under the heading "—Fractional Shares," each

BioSante stockholder will hold the same percentage of BioSante outstanding common stock or BioSante class C special stock immediately following the reverse stock split as the stockholder held immediately prior to the reverse stock split.

- The voting rights, rights to dividends and distributions and other rights of BioSante common stock and BioSante class C special stock will not be changed as a result of the reverse stock split, except for the per share conversion or purchase price of the BioSante class C special stock as described above.
- The number of BioSante stockholders of record will not be affected by the reverse stock split, except to the extent that any BioSante stockholder holds only a fractional share following the reverse stock split and receives cash for such fractional share following the reverse stock split as described below under the heading "—Fractional Shares."
- Because the number of outstanding shares of BioSante common stock will be reduced, the liquidity of BioSante common stock could be adversely affected as a result of the reverse stock split. This effect, however, may be mitigated to some extent by the additional shares of BioSante common stock that would be issued in connection with the merger between BioSante and ANI.

The following tables show the number of shares of BioSante common stock and BioSante class C special stock that would be (1) issued and outstanding prior to completion of the merger; (2) authorized and reserved for issuance upon the exercise of outstanding stock options and warrants and conversion of convertible senior notes and in the case of BioSante common stock, conversion of the BioSante class C special stock prior to completion of the merger; (3) authorized and unreserved for issuance prior to completion of the merger; and (4) authorized, in each case upon the implementation of the reverse stock split at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five based on BioSante's capitalization at December 31, 2012 but prior to completion of the merger:

**BioSante Common Stock**

<u>Reverse Stock Split Ratio</u>	<u>BioSante Common Stock Issued and Outstanding</u>	<u>BioSante Common Stock Authorized and Reserved for Issuance</u>	<u>BioSante Common Stock Authorized and Unreserved for Issuance</u>	<u>Total Shares of BioSante Common Stock Authorized</u>
Pre-split	24,422,240	6,302,837	169,274,923	200,000,000
1-for-2	12,211,120	3,151,418	184,637,462	200,000,000
1-for-3	8,140,746	2,100,945	189,758,309	200,000,000
1-for-4	6,105,560	1,575,709	192,318,731	200,000,000
1-for-5	4,884,448	1,260,567	193,854,985	200,000,000

**BioSante Class C Special Stock**

<u>Reverse Stock Split Ratio</u>	<u>BioSante Class C Special Stock Issued and Outstanding</u>	<u>BioSante Class C Special Stock Authorized and Reserved for Issuance</u>	<u>BioSante Class C Special Stock Authorized and Unreserved for Issuance</u>	<u>Total Shares of BioSante Class C Special Stock Authorized</u>
Pre-split	65,211	0	4,622,473	4,687,684
1-for-2	32,605	0	4,655,079	4,687,684
1-for-3	21,737	0	4,665,947	4,687,684
1-for-4	16,302	0	4,671,382	4,687,684
1-for-5	13,042	0	4,674,642	4,687,684

In addition, if approved and implemented, other possible effects of the reverse stock split include the following, all of which have been considered by the BioSante board of directors in approving the reverse stock split amendment:

- It is anticipated that the reduction in outstanding shares of BioSante common stock will result in an increase in the per share price of BioSante common stock. However, there is no assurance that such a result will occur. Similarly, there is no assurance that if the per share price of BioSante common stock increases as a result of the reverse stock split, such increase in the per share price will be permanent, which will be dependent on several factors.
- One of the purposes for the proposed reverse stock split is to comply with the initial listing requirements for The NASDAQ Global Market and The NASDAQ Capital Market so that the shares of BioSante common stock issued in the merger will be listed on one of such markets. However, there can be no assurance that the reverse stock split alone will guarantee the initial or continual listing of BioSante common stock on The NASDAQ Global Market or The NASDAQ Capital Market. The listing of the shares of BioSante common stock issued pursuant to the merger on The NASDAQ Global Market or The NASDAQ Capital Market is a condition to ANI's obligation to complete the merger. If the shares of BioSante common stock issued pursuant to the merger are not listed on The NASDAQ Global Market or The NASDAQ Capital Market, ANI may decide not to complete the merger.
- The reverse stock split could be viewed negatively by the market and, consequently, could lead to a decrease in BioSante's overall market capitalization. It is often the case that the reverse-split adjusted stock price and market capitalization of companies that effect a reverse stock split decline. Should the per share price of BioSante common stock decline after implementation of the reverse stock split, the percentage decline may be greater than would occur in the absence of the reverse stock split.
- The anticipated resulting increase in per share price of BioSante common stock due to the reverse stock split is expected to encourage greater interest in BioSante common stock by brokers and investors and possibly promote greater liquidity for BioSante stockholders. However, there is no assurance that such greater interest will occur.
- Since the reverse stock split will decrease the number of shares held by BioSante stockholders, the reverse stock split may increase the number of BioSante stockholders who hold less than a "round lot," or 100 shares. Typically, the transaction costs to stockholders selling "odd lots" are higher on a per share basis. Consequently, the reverse stock split could increase the transaction costs to existing BioSante stockholders in the event they wish to sell all or a portion of their shares.

BioSante common stock is currently registered under Section 12(b) of the Exchange Act, and BioSante is subject to the periodic reporting and other requirements of the Exchange Act. The reverse stock split will not affect the registration of BioSante common stock under the Exchange Act nor affect BioSante continuing to be subject to the periodic reporting requirements of the Exchange Act. The reverse stock split is not intended as, and will not have the effect of, a "going private transaction" covered by Rule 13e-3 under the Exchange Act. If the reverse stock split is implemented, and the combined company's initial listing application with The NASDAQ Global Market is approved, BioSante common stock will continue to be listed on The NASDAQ Global Market under the symbol "BPAX" (although NASDAQ likely will add the letter "D" to the end of the trading symbol for a period of 20 trading days to indicate that the reverse stock split has occurred). It is expected that following the merger, the combined company will change its name to "ANI Pharmaceuticals, Inc." and that its trading symbol will be changed. ANI has reserved the ticker symbol "ANIP" for this purpose.

Upon completion of the merger, each share of ANI capital stock will be converted into the right to receive that number of shares of BioSante common stock equal to the applicable exchange ratio. As

of January 15, 2013, the last practicable date before the printing of this joint proxy statement/prospectus, 24,422,240 shares of BioSante common stock were outstanding and 2,375,312 shares of ANI series D preferred stock were outstanding and it is anticipated that an additional 321,737 shares of ANI series D preferred stock will be issued to ANI's executive officers and an additional ANI employee immediately prior to the merger, assuming BioSante's net cash is \$18.0 million and an exchange ratio of 10.3502 for each share of ANI series D preferred stock and an exchange ratio of zero for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock. The exchange ratios depend upon the reverse stock split ratio. If the merger had been completed as of December 31, 2012, assuming a reverse stock split ratio of one-for-two, each share of ANI series D preferred stock would have converted into and been exchanged for the right to receive 5.1751 shares of BioSante common stock and each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would not have been entitled to receive any payment and would have been cancelled in connection with the merger, which would have resulted in an aggregate issuance of 14.0 million shares of BioSante common stock. If the merger had been completed as of December 31, 2012, assuming a reverse stock split ratio of one-for-five, each share of ANI series D preferred stock would have converted into and been exchanged for the right to receive 2.0700 shares of BioSante common stock and each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been cancelled in connection with the merger, which would have resulted in an aggregate issuance of 5.6 million shares of BioSante common stock.

#### ***Procedures for Effecting the Reverse Stock Split and Filing the Reverse Stock Split Amendment***

If the BioSante stockholders approve the reverse stock split amendment and BioSante and ANI subsequently determines that it is in the best interests of BioSante and its stockholders to effect a reverse stock split, BioSante and ANI, in their sole discretion, at any time prior to completion of the merger, will determine the ratio of the reverse stock split to be implemented. BioSante and ANI believe that BioSante stockholder approval of four potential exchange ratios (rather than a single exchange ratio) is in the best interests of BioSante and its stockholders because it provides BioSante and ANI with the flexibility to achieve the desired results of the reverse stock split and because it is not possible to predict market conditions at the time the reverse stock split would be implemented. The ratio to be selected by BioSante and ANI will be either one-for-two, one-for-three, one-for-four or one-for-five and the numbers in the ratio will consist only of whole numbers. The decision of BioSante and ANI as to whether and when to effect the reverse stock split, and the decision of BioSante and ANI regarding the final split ratio will be based, in part, on existing and expected trading prices for BioSante common stock, the combined company's ability to meet the initial listing requirements of The NASDAQ Global Market, and prevailing general market and economic conditions. BioSante and ANI intend to select a reverse split ratio that they believe would be most likely to achieve the anticipated benefits of the reverse stock split as described above.

After BioSante and ANI determine to effect a reverse stock split and have determined the split ratio, BioSante and ANI will determine the effective date of the reverse stock split and will announce publicly such information. Any such split will become effective upon the filing of the reverse stock split amendment with the Secretary of State of the State of Delaware or such later date as indicated in the reverse stock split amendment. It is currently anticipated that the reverse stock split would be effective on the closing date of the merger, prior to the effectiveness of the merger.

#### ***Fractional Shares***

No fractional shares of BioSante common stock or BioSante class C special stock would be issued as a result of the reverse stock split, if any. Each holder of BioSante common stock at the effective time of the reverse stock split, if any, who otherwise would be entitled to a fractional share will, in lieu thereof,

be entitled receive a cash payment equal to: (1) the fractional share amount multiplied by (2) the product of (a) the closing sale price of a share of BioSante common stock as reported on The NASDAQ Global Market or other principal market of BioSante common stock, as applicable, on the effective date of the reverse stock split and (b) the reverse stock split ratio, as determined by BioSante and ANI. Each holder of BioSante class C special stock at the effective time of the reverse stock split, if any, who otherwise would be entitled to a fractional share will, in lieu thereof, be entitled receive a cash payment equal to the cash payment that a holder of BioSante common stock would receive minus \$15.00. Except for the right to receive the cash payment in lieu of fractional shares, BioSante stockholders will not have any voting, dividend or other rights with respect to the fractional shares they otherwise would be entitled to receive.

BioSante stockholders should be aware that, under the escheat laws of the various jurisdictions where stockholders reside, where BioSante is domiciled, and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective date of the reverse stock split may be required to be paid to the designated agent for each such jurisdiction, unless correspondence has been received by BioSante or the exchange agent concerning ownership of such funds within the time permitted in such jurisdiction. Thereafter, BioSante stockholders otherwise entitled to receive such funds will have to seek to obtain them directly from the state to which they were paid.

#### ***Exchange of Pre-Reverse Stock Split Shares with Post-Reverse Stock Split Shares***

If the BioSante stockholders approve and BioSante and ANI implement a reverse stock split, BioSante's transfer agent will act as exchange agent for purposes of implementing the exchange of pre-reverse stock split shares of BioSante common stock for post-reverse stock split shares of BioSante common stock, and BioSante will act as exchange agent for purposes of implementing the exchange of pre-reverse stock split shares of BioSante class C special stock for post-reverse stock split shares of BioSante class C special stock.

*Registered Book Entry Stockholder.* Holders of BioSante common stock holding all of their shares electronically in book-entry form with BioSante's transfer agent do not need to take any action (the exchange will be automatic) to receive post-reverse stock split shares.

*Registered Certificated Stockholder.* Some of the holders of BioSante common stock hold their shares in certificate form or a combination of certificate and book-entry form and all of the holders of BioSante class C special stock hold their shares in certificate form. If any of your shares of BioSante common stock are held in certificate form, you will receive a transmittal letter from BioSante's transfer agent as soon as practicable after the effective date of the reverse stock split. The letter of transmittal will contain instructions on how to surrender your certificate(s) representing your pre-reverse stock split shares to the transfer agent. Upon receipt of your pre-reverse stock split certificate(s), you will be issued the appropriate number of shares of BioSante common stock electronically in book-entry form under the Direct Registration System (DRS). No new shares in book-entry form will be reflected until you surrender your outstanding pre-reverse stock split certificate(s), together with the properly completed and executed letter of transmittal, to BioSante's transfer agent. At any time after receipt of your DRS statement, you may request a stock certificate representing your ownership interest. Holders of BioSante class C special stock will receive a transmittal letter from BioSante as soon as practicable after the effective date of the reverse stock split. The letter of transmittal will contain instructions on how to surrender your certificate(s) representing your pre-reverse stock split shares to BioSante and upon receipt of your pre-reverse stock split certificate(s), you will be issued the appropriate number of shares of BioSante class C special stock in certificate form.

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**BIOSANTE STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATES AND SHOULD NOT SUBMIT ANY CERTIFICATES UNTIL REQUESTED TO DO SO.**

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## **Accounting Matters**

The reverse stock split is not expected to affect stockholders' accumulated deficit on BioSante's balance sheet. However, because the par value of BioSante common stock and BioSante class C special stock will remain unchanged on the effective date of the reverse stock split, the components that make up stockholders' accumulated deficit will change by offsetting amounts. The stated common stock and BioSante class C special stock components will be reduced, and the additional paid-in capital component will be increased by the amount by which the stated common stock and BioSante class C special stock component is reduced. The per share net loss and net book value of BioSante common stock and BioSante class C special stock will be increased because there will be fewer shares of BioSante common stock and BioSante class C special stock outstanding. Net loss per share amounts in prior periods will be restated to reflect the reverse stock split. BioSante does not anticipate that any other accounting consequences would arise as result of the reverse stock split.

## **Potential Anti-Takeover Effect; Possible Dilution**

Because the reverse stock split would increase the number of authorized but unissued shares of BioSante common stock and BioSante class C special stock available for issuance, the reverse stock split could be construed as having an anti-takeover effect, since BioSante could use the increased available shares to frustrate persons seeking to effect a takeover or otherwise gain control of BioSante. For example, BioSante could use the additional authorized but unissued shares to resist or frustrate a third-party transaction providing an above-market premium that is favored by a majority of the BioSante stockholders. The reverse stock split proposal is not being proposed in response to any effort of which BioSante is aware to accumulate shares of BioSante common stock or obtain control of BioSante, other than as contemplated by the merger agreement, nor is it part of a plan by management to recommend a series of similar amendments to the BioSante stockholders.

In addition to the increased number of shares of BioSante common stock and BioSante class C special stock that would be available for issuance as a result of the reverse stock split, other provisions of BioSante's certificate of incorporation and bylaws could delay or prevent a merger, tender offer or proxy contest to take control of BioSante. Specifically, BioSante's certificate of incorporation and bylaws contain provisions which:

- authorize the issuance of "blank check" preferred stock, which is preferred stock that can be created and issued by the BioSante board of directors without prior stockholder approval, with rights senior to BioSante common stock or BioSante class C special stock;
- prohibit BioSante stockholders to call a special meeting; and
- prohibit cumulative voting for directors of BioSante.

BioSante's bylaws require advance written notice to BioSante of any stockholder-proposed business or of a stockholder's intention to make a nomination for director at an annual meeting of stockholders and limit the business that may be conducted at any special meeting of stockholders to business brought by the BioSante board of directors.

The holders of BioSante common stock and BioSante class C special stock do not have preemptive rights to subscribe for additional securities that may be issued by BioSante, which means that current BioSante stockholders do not have a prior right to purchase any additional shares from time to time issued by BioSante. Accordingly, if the BioSante board of directors elects to issue additional shares of BioSante common stock or BioSante class C special stock, such issuance could have a dilutive effect on the earnings (if any) per share, voting power and equity ownership of current BioSante stockholders.

## **Material U.S. Federal Income Tax Consequences of the Reverse Stock Split**

The following discussion describes the anticipated material U.S. federal income tax consequences to "U.S. holders" of BioSante capital stock relating to the reverse stock split. For purposes of this discussion, a "U.S. holder" is an owner of BioSante capital stock who is (i) a citizen or individual resident of the U.S., including an individual who is resident in the U.S. by reason of a physical presence here during the year or by virtue of lawful permanent residence; (ii) a corporation or other entity treated as a corporation which is created or organized under the laws of the U.S., any state thereof or the District of Columbia; (iii) an estate, the income of which is subject to U.S. federal income tax without regard to its source; or (iv) a trust if (A) a court within the U.S. is able to exercise primary supervision over the administration of the trust, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (B) the trust was in existence on August 20, 1996, and has a valid election in effect under applicable Regulations to be treated as a domestic trust for U.S. federal income tax purposes. A holder of BioSante capital stock that is not a U.S. holder is urged to consult his, her or its own tax advisor regarding the U.S. federal income tax consequences of the reverse stock split.

This discussion is based upon the current provisions of the existing Treasury Regulations promulgated under the Internal Revenue Code of 1986, as amended (Code), and current administration rulings and court decisions, all as currently in effect and all of which are subject to change or differing interpretations, possibly with retroactive effect. BioSante has not obtained, and does not intend to obtain, a ruling from the IRS or an opinion of legal or tax counsel with respect to the tax consequences of the reverse stock split. The following discussion is for information purposes only and is not intended as tax or legal advice.

This discussion assumes that a U.S. holder holds BioSante capital stock as a capital asset within the meaning of Code Section 1221. This discussion does not address all of the tax consequences that may be relevant to a particular stockholder or to stockholders that are subject to special treatment under U.S. federal income tax laws including, but not limited to, financial institutions, tax-exempt organizations, insurance companies, regulated investment companies, persons that are broker-dealers, traders in securities who elect the mark-to-market method of accounting for their securities, or stockholders holding their shares of BioSante capital stock as part of a "straddle," "hedge," "conversion transaction," or other integrated transaction. This discussion also does not address the tax consequences to BioSante, or to BioSante stockholders that own five percent or more of BioSante capital stock, are affiliates of BioSante, or are not U.S. holders. In addition, this discussion does not address other U.S. federal taxes (such as gift or estate taxes or alternative minimum taxes), the tax consequences of the reverse stock split under state, local or foreign tax laws or certain tax reporting requirements that may be applicable with respect to the reverse stock split. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences set forth below.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a stockholder of BioSante, the tax treatment of a partner in the partnership, or any equity owner of such other entity will generally depend upon the status of the person and the activities of the partnership or other entity treated as a partnership for U.S. federal income tax purposes.

### *Tax Consequences of the Reverse Stock Split Generally*

BioSante believes that the reverse stock split will qualify as a "reorganization" under Section 368(a)(1)(E) of the Code. Accordingly, provided that the fair market value of the post-reverse stock split shares is equal to the fair market value of the pre-reverse stock split shares surrendered in the reverse stock split:

- A U.S. holder will not recognize any gain or loss as a result of the reverse stock split (except to the extent of cash received in lieu of a fractional share).

- A U.S. holder's aggregate tax basis in his, her or its post-reverse stock split shares will be equal to the aggregate tax basis in the pre-reverse stock split shares exchanged therefor, reduced by the amount of the adjusted basis of any pre-reverse stock split shares exchanged for such post-reverse stock split shares that is allocated to any fractional share for which cash is received.
- A U.S. holder's holding period for the post-reverse stock split shares will include the period during which such stockholder held the pre-reverse stock split shares surrendered in the reverse stock split.

#### *Cash Received Instead of a Fractional Share*

A U.S. holder who receives cash instead of a fractional share of post-reverse stock split shares will be treated as having received the fractional share of post-reverse stock split shares pursuant to the reverse stock split and then as having exchanged the fractional share of post-reverse stock split shares for cash in a redemption by BioSante. In general, this deemed redemption will be treated as a sale or exchange, provided the redemption is not essentially equivalent to a dividend as discussed below. Gain or loss generally will be recognized based on the difference between the amount of cash received and the portion of the U.S. holder's adjusted tax basis of the pre-reverse stock split shares exchanged in the reverse stock split which is allocable to such fractional share. Such gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for such pre-reverse stock split shares is more than one year as of the effective date of the reverse stock split, and otherwise will be short-term capital gain or loss. The deductibility of capital losses is subject to limitations.

The receipt of cash is "not essentially equivalent to a dividend" if the reduction in a U.S. holder's proportionate interest in BioSante resulting from the reverse stock split (taking into account for this purpose shares of BioSante common stock and BioSante class C special stock which such holder is considered to own under certain attribution rules) is considered a "meaningful reduction" given such U.S. holder's particular facts and circumstances. The IRS has ruled that a small reduction by a minority stockholder whose relative stock interest is minimal and who exercises no control over the affairs of a corporation can satisfy this test. If the receipt of cash in lieu of a fractional share is not treated as capital gain or loss under the test just described, it will be treated first as ordinary dividend income to the extent of a U.S. holder's ratable share of BioSante's current and accumulated earnings and profits, then as a tax-free return of capital to the extent of the portion of the U.S. holder's adjusted tax basis of the pre-reverse stock split shares which is allocable to such fractional share, and any remaining amount will be treated as capital gain.

#### *Information Reporting and Backup Withholding*

Cash payments received by a U.S. holder of BioSante capital stock pursuant to the reverse stock split are subject to information reporting, and may be subject to backup withholding at the applicable rate specified by the IRS (currently at a rate of 28 percent) if the holder fails to provide a valid taxpayer identification number and comply with certain certification procedures or otherwise establish an exemption from backup withholding. Backup withholding is not an additional U.S. federal income tax. Rather, the U.S. federal income tax liability of the person subject to backup withholding will be reduced by the amount of the tax withheld. If backup withholding results in an overpayment of taxes, a refund may be obtained provided that the required information is timely furnished to the IRS.

#### *No Appraisal Rights*

No appraisal rights are available under the Delaware General Corporation Law or under BioSante's certificate of incorporation or bylaws to any BioSante stockholder who dissents from the proposal to approve the amendment to BioSante's certificate of incorporation to effect the reverse stock split.



***Discretion to Implement the Reverse Stock Split***

If the proposed reverse stock split is approved by the BioSante stockholders, BioSante and ANI, in their discretion, at any time prior to completion of the merger, may determine to implement the reverse stock split. Notwithstanding the approval of the form of the reverse stock split amendment, BioSante and ANI, in their discretion, may determine not to implement the reverse stock split.

***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 2.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 2.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 2 to approve the amendment to BioSante's certificate of incorporation to effect a reverse split of the issued and outstanding shares of BioSante common stock and BioSante class C special stock at the discretion of the BioSante board of directors at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.**

## **BioSante Proposal No. 3—Approval of Amendment to BioSante's Certificate of Incorporation to Change Corporate Name**

### **General**

At the BioSante special meeting, BioSante stockholders will be asked to approve an amendment to BioSante's certificate of incorporation to change the name of the corporation from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." immediately following completion of the merger. The full text of the form of proposed amendment is attached to this joint proxy statement/prospectus as Annex J.

The primary reason for the corporate name change is that ANI's senior management believes this will allow for recognition of the combined company's business following completion of the merger. ANI's senior management believes that the current name will no longer accurately reflect the business of the combined company and the mission of the combined company subsequent to the completion of the merger.

Insofar as the proposed new corporate name will reflect the combined company's business following completion of the merger, the proposed name change and the amendment to BioSante's certificate of incorporation, even if approved by the BioSante stockholders at the BioSante special meeting, will only be filed with the office of the Secretary of State of the State of Delaware and, therefore become effective, if the merger is completed.

### ***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, having voting power outstanding on the record date for the BioSante special meeting is required for approval of BioSante Proposal No. 3.

A failure to submit a proxy card or vote at the BioSante special meeting, or an abstention or "broker non-vote" will have the same effect as a vote against the approval of BioSante Proposal No. 3.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 3 to approve the amendment to BioSante's certificate of incorporation to change the name of the corporation from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc." immediately following completion of the merger.**

## **BioSante Proposal No. 4—Advisory Vote on Golden Parachute Compensation**

### **General**

As required by Section 14A of the Exchange Act and the SEC's rules thereunder, BioSante is asking its stockholders to cast an advisory (non-binding) vote on the compensation that may be payable to its named executive officers under existing agreements in connection with the merger, as described in this joint proxy statement/prospectus under "The Merger—Interests of BioSante's Directors and Officers in Connection with the Merger—Golden Parachute Compensation," including in the associated narrative discussion. In accordance with these requirements, BioSante is asking its stockholders to vote on the adoption of the following resolution:

"RESOLVED, that the compensation that may be payable to BioSante's named executive officers in connection with the merger, as disclosed in the table captioned "Golden Parachute Compensation" beginning on page 147 of this joint proxy statement/prospectus under "The Merger—Interests of BioSante's Directors and Officers in Connection with the Merger—Golden Parachute Compensation," including the associated narrative discussion, and the agreements or understandings pursuant to which such compensation may be payable, are hereby APPROVED."

The vote on the compensation payable in connection with the merger is a vote separate and apart from the votes on the other BioSante proposals described in this joint proxy statement/prospectus. BioSante stockholders may vote to approve this proposal and vote not to approve another proposal, or may vote against this proposal and vote to approve some or all of the other proposals.

Because the vote on this BioSante Proposal No. 4 is advisory in nature only, it will not be binding on BioSante. Accordingly, because BioSante is obligated contractually to pay the compensation covered by this proposal, such compensation will be payable, subject only to the applicable conditions, if the merger is approved and regardless of the outcome of the advisory vote.

### ***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting is required for approval of BioSante Proposal No. 4.

A failure to submit a proxy card or vote at the BioSante special meeting or a "broker non-vote" will have no effect on the outcome of BioSante Proposal No. 4. For purposes of the vote on this BioSante Proposal No. 4, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 4 to approve the compensation that may be payable to BioSante's named executive officers in connection with the merger, as disclosed in the table captioned "Golden Parachute Compensation" beginning on page 147 of this joint proxy statement/prospectus under "The Merger—Interests of BioSante's Directors and Officers in Connection with the Merger—Golden Parachute Compensation," including the associated narrative discussion, and the agreements or understandings pursuant to which such compensation may be payable.**

## **BioSante Proposal No. 5—Approval of Possible Adjournment of the BioSante Special Meeting**

### **General**

BioSante is asking its stockholders to consider and vote upon a proposal to approve one or more adjournments of the BioSante special meeting, if necessary or appropriate, including adjournments to permit further solicitation of proxies in favor of approval of BioSante Proposals No. 1, 2 and 3.

If the number of shares of BioSante capital stock present in person or represented by proxy at the BioSante special meeting voting in favor of BioSante Proposal No. 1, BioSante Proposal No. 2 or BioSante Proposal No. 3 is insufficient to approve one or more of such proposals at the time of the BioSante special meeting, then BioSante may move to adjourn the BioSante special meeting in order to enable the BioSante board of directors to solicit additional proxies in respect of the applicable proposal. In that event, BioSante stockholders will be asked to vote only upon the adjournment proposal, BioSante Proposal No. 5, and not on any other proposal.

In this proposal, BioSante is asking its stockholders to authorize the holder of any proxy solicited by the BioSante board of directors to vote in favor of granting discretionary authority to the proxy or attorney-in-fact to adjourn the BioSante special meeting one or more times for the purpose of soliciting additional proxies. If BioSante stockholders approve this BioSante Proposal No. 5, BioSante could adjourn the BioSante special meeting and any adjourned session of the BioSante special meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from BioSante stockholders that previously have returned properly executed proxies or authorized a proxy by using the Internet or telephone. Among other things, approval of BioSante Proposal No. 5 could mean that, even if BioSante has received proxies representing a sufficient number of votes against the approval of BioSante Proposals No. 1, BioSante Proposal No. 2 or BioSante Proposal No. 3 that such proposal would be defeated, BioSante could adjourn the BioSante special meeting without a vote on such proposal and seek to obtain sufficient votes in favor of such proposal to obtain approval of that proposal.

BioSante currently does not intend to propose adjournment at the BioSante special meeting if there are sufficient votes to approve BioSante Proposals No. 1, 2 and 3.

### ***Vote Required; Recommendation of BioSante Board of Directors***

The affirmative vote of holders of a majority of the BioSante common stock and BioSante class C special stock, voting together as a single class, present in person or represented by proxy at the BioSante special meeting is required for approval of BioSante Proposal No. 5.

A failure to submit a proxy card or vote at the BioSante special meeting or a "broker non-vote" will have no effect on the outcome of BioSante Proposal No. 5. For purposes of the vote on this BioSante Proposal No. 5, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The BioSante board of directors unanimously recommends that BioSante stockholders vote "FOR" BioSante Proposal No. 5 to adjourn the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of BioSante Proposals No. 1, 2 and 3.**

## THE SPECIAL MEETING OF ANI STOCKHOLDERS

### General

This joint proxy statement/prospectus is being furnished to stockholders of ANI on or about January 25, 2013. ANI is sending this joint proxy statement/prospectus to its stockholders in connection with the solicitation of proxies by the ANI board of directors for use at the ANI special meeting and any adjournments or postponements of the special meeting.

### Date, Time and Place

The special meeting of ANI stockholders will be held at 9:00 a.m., local time, on Friday, March 15, 2013, at the offices of MVP Capital Partners located at 259 N. Radnor-Chester Road, Suite 130, Radnor, Pennsylvania 19087.

### Purposes of the ANI Special Meeting

The purposes of the ANI special meeting are to consider and act upon the following matters:

1. To consider and to vote upon a proposal to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger.
2. To consider and to vote upon a proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

ANI stockholders also will consider and act on any other matters as may properly come before the ANI special meeting or any adjournment or postponement thereof, including any procedural matters incident to the conduct of the special meeting.

### Recommendations of the ANI Board of Directors

The ANI board of directors has determined and believes that the merger agreement and the transactions contemplated thereby, including the merger, is advisable, fair to, and in the best interests of ANI and its stockholders and has unanimously approved such proposal. The ANI board of directors recommends unanimously that ANI stockholders vote "**FOR**" ANI Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger.

The ANI board of directors recommends unanimously that ANI stockholders vote "**FOR**" ANI Proposal No. 2 to adjourn the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.

### Record Date and Voting Power

The close of business on January 17, 2013 has been fixed as the ANI record date for the determination of ANI stockholders entitled to notice of, and to vote at, the ANI special meeting or any adjournments or postponements of the ANI special meeting. Only holders of record of ANI capital stock at the close of business on the ANI record date are entitled to notice of, and to vote at, the ANI special meeting. At the close of business on the record date, ANI had 2,375,312 shares of ANI series D preferred stock, 34,810 shares of ANI series C preferred stock, 78,491 shares of ANI series B preferred stock, 102,774 shares of ANI series A preferred stock and 23,613 shares of ANI common stock outstanding and entitled to vote. Each share of ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock entitles the holder thereof to one vote on each matter submitted for stockholder approval. See "Principal

Stockholders of ANI" for information regarding persons known to management of ANI to be the beneficial owners of more than five percent of the outstanding shares of ANI capital stock.

### **Voting and Revocation of Proxies**

The proxy accompanying this joint proxy statement/prospectus is solicited on behalf of the ANI board of directors for use at the ANI special meeting.

If you are a stockholder of record of ANI as of the applicable record date referred to above, you may vote in person at the ANI special meeting or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the ANI special meeting, ANI urges you to vote by proxy to ensure your vote is counted. You still may attend the ANI special meeting and vote in person if you already have voted by proxy. ANI stockholders of record as of the close of business on January 17, 2013 may submit their proxies by marking, signing and dating the enclosed proxy card and returning it in the postage-paid envelope provided or returning it pursuant to the instructions provided in the proxy card.

All properly executed proxies that are not revoked will be voted at the ANI special meeting and at any adjournments or postponements of the ANI special meeting in accordance with the instructions contained in the proxy. If a holder of ANI capital stock executes and returns a proxy and does not specify otherwise, the shares represented by that proxy will be voted **"FOR"** ANI Proposal No. 1 to approve the merger agreement and the transactions contemplated thereby, including the merger; **"FOR"** ANI Proposal No. 2 to adjourn the ANI special meeting, if necessary, if a quorum is present, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1 in accordance with the recommendation of the ANI board of directors.

Any ANI stockholder of record voting by proxy, other than those stockholders who have executed a voting agreement and irrevocable proxy, has the right to revoke the proxy at any time before the polls close at the ANI special meeting by sending a written notice stating that it would like to revoke its proxy to the Secretary of ANI, by providing a duly executed proxy card bearing a later date than the proxy being revoked or by attending the ANI special meeting and voting in person. Attendance alone at the ANI special meeting will not revoke a proxy.

### **Quorum and Required Vote**

The presence at the ANI special meeting, in person or by proxy, of the holders of a majority of the voting power of the issued and outstanding shares of ANI capital stock entitled to vote will constitute a quorum for the transaction of business at the ANI special meeting. In general, shares of ANI capital stock represented by a properly signed and returned proxy card will be counted as shares present and entitled to vote at the ANI special meeting for purposes of determining a quorum. Shares represented by proxies marked "Abstain" or "Withheld" are counted in determining whether a quorum is present. If a quorum is not present at the ANI special meeting, ANI expects that the ANI special meeting will be adjourned or postponed to solicit additional proxies.

A description of the vote required to approve each proposal being submitted to a vote of ANI stockholders is included with the description of each proposal. For ANI Proposal No. 1, a failure to vote by proxy or in person at the ANI special meeting, or an abstention or vote withheld for such proposal, will have the same effect as a vote against the approval of such proposal. For ANI Proposal No. 2, a failure to submit a proxy card or vote at the ANI special meeting, or an abstention or vote withheld will have no effect on the outcome of such proposal.

In connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D

preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

As of the record date for the ANI special meeting, the shares of ANI capital stock owned by all of ANI's directors, executive officers and affiliated entities constituted approximately 92 percent of the outstanding shares of ANI capital stock, on an as-converted basis, and approximately 94 percent of the outstanding shares of the ANI series D preferred stock on that date.

#### **Solicitation of Proxies**

In addition to solicitation by mail, the directors, officers, employees and agents of ANI may solicit proxies from ANI stockholders by personal interview, telephone, telegram or other electronic means. ANI will bear the costs of the solicitation of proxies by ANI from ANI's stockholders. Arrangements also will be made with brokerage firms and other custodians, nominees and fiduciaries who are record holders of ANI capital stock for the forwarding of solicitation materials to the beneficial owners of ANI capital stock. ANI will reimburse these brokers, custodians, nominees and fiduciaries for the reasonable out-of-pocket expenses they incur in connection with the forwarding of solicitation materials.

#### **Other Matters**

As of the date of this joint proxy statement/prospectus, the ANI board of directors does not know of any business to be represented at the ANI special meeting other than as set forth in the notice accompanying this joint proxy statement/prospectus. If any other matters should properly come before the ANI special meeting, or any adjournment or postponement of the ANI special meeting it is intended that the shares represented by proxies will be voted with respect to such matters in accordance with the judgment of the person voting the proxies.

## MATTERS BEING SUBMITTED TO A VOTE OF ANI STOCKHOLDERS

### **ANI Proposal No. 1—Adoption of Agreement and Plan of Merger and the Transactions Contemplated Thereby, Including the Merger**

#### ***General***

At the ANI special meeting, ANI stockholders will be asked to adopt the merger agreement, a copy of which is attached as Annex A to this joint proxy statement/prospectus, and the transactions contemplated thereby, including the merger.

If the merger is completed, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. Following completion of the merger, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. If the merger had been completed on January 17, 2013, the record date for the BioSante special meeting, an aggregate of 27.9 million shares of BioSante common stock would have been issuable to ANI stockholders upon completion of the merger, assuming BioSante's net cash is \$18.0 million as of the determination date.

The terms of, reasons for and other aspects of the merger agreement and the merger are described in detail in the other sections of this joint proxy statement/prospectus. The full text of the merger agreement is attached as Annex A to this joint proxy statement/prospectus.

#### ***Vote Required; Recommendation of ANI Board of Directors***

The affirmative vote of holders of a majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis and voting together as a single class, and 65 percent of the shares of ANI series D preferred stock entitled to vote, in each case outstanding on the record date for the ANI special meeting, is required for approval of ANI Proposal No. 1.

A failure to submit a proxy card or vote at the ANI special meeting, or an abstention will have the same effect as a vote against the approval of ANI Proposal No. 1.

**The ANI board of directors unanimously recommends that ANI stockholders vote "FOR" ANI Proposal No. 1 to adopt the agreement and plan of merger and the transactions contemplated thereby, including the merger.**



## **ANI Proposal No. 2—Approval of Possible Adjournment of the ANI Special Meeting**

### **General**

ANI is asking its stockholders to consider and vote upon a proposal to approve one or more adjournments of the ANI special meeting, if necessary or appropriate, including adjournments to permit further solicitation of proxies in favor of approval of ANI Proposal No. 1.

If the number of shares of ANI capital stock present in person or represented by proxy at the ANI special meeting voting in favor of ANI Proposal No. 1 is insufficient to approve such proposal at the time of the ANI special meeting, then ANI may move to adjourn the ANI special meeting in order to enable the ANI board of directors to solicit additional proxies in respect of the applicable proposal. In that event, ANI stockholders will be asked to vote only upon the adjournment proposal, ANI Proposal No. 2, and not on any other proposal.

In this proposal, ANI is asking its stockholders to authorize the holder of any proxy solicited by the ANI board of directors to vote in favor of granting discretionary authority to the proxy or attorney-in-fact to adjourn the ANI special meeting one or more times for the purpose of soliciting additional proxies. If ANI stockholders approve this ANI Proposal No. 2, ANI could adjourn the ANI special meeting and any adjourned session of the ANI special meeting and use the additional time to solicit additional proxies, including the solicitation of proxies from ANI stockholders that previously have returned properly executed proxies. Among other things, approval of ANI Proposal No. 2 could mean that, even if ANI has received proxies representing a sufficient number of votes against the approval of ANI Proposal No. 1 that such proposal would be defeated, ANI could adjourn the ANI special meeting without a vote on such proposal and seek to obtain sufficient votes in favor of such proposal to obtain approval of that proposal.

ANI currently does not intend to propose adjournment at the ANI special meeting if there are sufficient votes to approve ANI Proposal No. 1.

### ***Vote Required; Recommendation of ANI Board of Directors***

The affirmative vote of holders of a majority of the shares of ANI capital stock entitled to vote, calculated on an as-converted basis, present in person or represented by proxy and voting together as a single class is required for approval of ANI Proposal No. 2.

A failure to submit a proxy card or vote at the ANI special meeting will have no effect on the outcome of ANI Proposal No. 2. For purposes of the vote on ANI Proposal No. 2, an abstention will have the same effect as a vote "AGAINST" such proposal.

**The ANI board of directors unanimously recommends that ANI stockholders vote "FOR" ANI Proposal No. 2 to adjourn the special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of ANI Proposal No. 1.**

## THE MERGER

*This section and the section entitled "The Merger Agreement" describe the material aspects of the merger, including the merger agreement. While BioSante and ANI believe that this description covers the material terms of the merger and the merger agreement, it may not contain all of the information that is important to you. You should read carefully this entire joint proxy statement/prospectus for a more complete understanding of the merger and the merger agreement, including the attached Annexes, and the other documents to which you are referred herein. See "Where You Can Find More Information."*

### General

The merger agreement provides that, at the effective time, ANI will be merged with and into BioSante, with BioSante surviving the merger.

Pursuant to the terms of the merger agreement, upon completion of the merger, ANI stockholders will have the right to receive, for each share of ANI capital stock they hold, that number of shares of BioSante common stock equal to the applicable exchange ratio, as such ratio is calculated pursuant to the terms of the merger agreement, such that immediately following completion of the merger, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding capital stock of the combined company and current stockholders of BioSante are expected to own approximately 47 percent of the outstanding capital stock of the combined company, assuming BioSante's net cash as of the determination date is \$18.0 million.

BioSante stockholders will continue to own their existing shares of BioSante common stock or BioSante class C special stock after the merger. Each share of BioSante common stock will represent one share of common stock in the combined company, and each share of BioSante class C special stock will represent one share of class C special stock in the combined company, subject to adjustment for any reverse stock split effective immediately prior to the merger.

The closing of the merger will take place as promptly as practicable after the day on which the last of the conditions to the merger set forth in the merger agreement has been satisfied or waived (if permissible), unless BioSante and ANI agree to a different date. However, because the merger is subject to a number of conditions, neither BioSante nor ANI can predict exactly when the closing will occur or if it will occur at all. See "The Merger Agreement—Conditions to Completion of the Merger" for a more complete description of the conditions that must be satisfied or, if permissible, waived before closing.

### Background of the Merger

As a part of its corporate strategy, BioSante over the past several years actively has sought and implemented strategic alternatives with respect to its products and its company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies.

In 2008, BioSante engaged a financial advisor to assist BioSante in exploring a possible exclusive license of LibiGel to a third party or a possible sale of BioSante. During 2008, BioSante's then financial advisor contacted approximately 100 public and private companies regarding their interest in licensing LibiGel or acquiring BioSante. Approximately 10 of these companies received management presentations from BioSante and/or performed limited due diligence on BioSante. However, almost all of these companies indicated that they were not interested in licensing LibiGel or acquiring BioSante. Of the companies that indicated an interest, none of them submitted a formal bid. BioSante's management, nonetheless, continued to pursue the companies that indicated informally an interest in licensing LibiGel or acquiring BioSante and other third parties that were subsequently identified by BioSante as possible candidates for a possible business combination, license transaction or other

transaction with BioSante. However, no transaction to license LibiGel or acquire BioSante was ever negotiated or completed.

In October 2009, BioSante acquired Cell Genesys, Inc., a company that was focused on the development and commercialization of novel biological therapies for patients with cancer. Although the primary purpose of BioSante's acquisition of Cell Genesys was to acquire Cell Genesys's cash to use to fund BioSante's LibiGel clinical development program, BioSante also acquired Cell Genesys's rights to its GVAX cancer vaccine portfolio.

Subsequent to BioSante's acquisition of Cell Genesys, BioSante continued its development of LibiGel, including its two Phase III efficacy trials and its Phase III cardiovascular events and breast cancer safety study. BioSante also facilitated further studies and commercialization of its GVAX cancer vaccine portfolio in order to bring important cancer therapies to patients in need and maximize the value of the GVAX cancer vaccine portfolio to the BioSante stockholders. BioSante was successful in coordinating the further development of the GVAX cancer vaccine portfolio, including vaccines for the treatment of several different cancers including melanoma, leukemia, pancreatic, breast and prostate cancer, and obtaining FDA orphan drug designations for four of these vaccines—to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing.

In an attempt to monetize the GVAX cancer vaccine portfolio, in July 2010, BioSante engaged a consulting and advisory firm that specializes in transactions in the biopharmaceutical and life sciences industries to assist BioSante in exploring strategic alternatives with respect to the GVAX cancer vaccine portfolio. BioSante's management and this consulting and advisory firm contacted over 80 companies to determine their interest in licensing some or all of BioSante's GVAX cancer vaccine portfolio. Through management's efforts, BioSante was successful in implementing licensing transactions during 2011 with Aduro BioTech, Inc. and The John P. Hussman Foundation covering certain aspects of the GVAX cancer vaccine portfolio. BioSante retains rights to substantially all of the GVAX cancer vaccine portfolio, other than those licensed to Aduro BioTech, Inc. and The John P. Hussman Foundation.

In 2010, BioSante again engaged a management consulting company to assist BioSante in exploring a possible exclusive license of LibiGel to a third party. During 2010 and 2011, BioSante's then advisor contacted over 60 public and private companies regarding their interest in the further development and marketing of LibiGel. Approximately 10 of these companies received management presentations from BioSante and/or performed limited due diligence on BioSante regarding LibiGel. Several of these companies expressed interest in a licensing transaction and potential terms were discussed with at least one of these companies. However, based on the passage of time and the then approaching completion of the LibiGel efficacy trials, all of these companies determined that they would wait until BioSante's receipt of the results from its LibiGel Phase III efficacy trials. Although some companies indicated that they may be interested in LibiGel after BioSante's receipt of the results from its LibiGel Phase III efficacy trials, none of these companies or any other companies indicated any such interest after BioSante's announcement of the results from the LibiGel Phase III efficacy trials in December 2011.

In December 2011, BioSante announced the results from its two LibiGel Phase III efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from use of placebo.

Subsequent to BioSante's announcement of the results from its two LibiGel Phase III efficacy trials, BioSante implemented several operating expense reduction measures, explored potential new product development projects through in-licensing and mergers and acquisitions, and analyzed further the data from the LibiGel Phase III efficacy trials in an attempt to understand whether to continue to allocate resources to the development of LibiGel and the LibiGel Phase III safety study.

In January 2012, in order to reduce its operating expenses and conserve cash, BioSante implemented several cost-saving measures, including reducing substantially the number of its independent contractors, resulting in a 25 percent total reduction in BioSante's personnel.

In February 2012, in order to reduce its then outstanding debt of approximately \$20.8 million in aggregate principal amount, and ongoing interest obligations, BioSante issued an aggregate of 1,868,055 shares of BioSante common stock in exchange for the cancellation of \$9.0 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 and the related accrued and unpaid interest of \$79,024. After these securities exchange transactions, BioSante had \$11.8 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 outstanding.

From mid-December 2011 through May 2012, BioSante's management contacted over 50 public and private companies regarding their interest in a possible strategic transaction with BioSante, including in-licensing transactions and other business combinations or transactions. Of these companies, 12 engaged in management presentations with BioSante and/or limited due diligence investigations with BioSante, and approximately 10 of these companies entered into confidentiality agreements with BioSante, including the companies referred to as Company A, Company B and Company C in this section.

At the same time, from mid-December 2011 through May 2012, BioSante's management continued to analyze further the data from its LibiGel Phase III efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA in an attempt to understand whether to continue to allocate resources to the development of LibiGel and the LibiGel Phase III safety study. In addition, during such time period, BioSante's management also explored other alternative potential uses for its LibiGel Phase III safety study data.

On May 30, 2012, the BioSante board of directors held a regular meeting at BioSante's corporate offices in Lincolnshire, Illinois. At this meeting, the BioSante board of directors discussed whether it would be in the best interest of BioSante and its stockholders for BioSante to continue to allocate its resources to the development of LibiGel or allocate its resources to other biopharmaceutical product areas through in-licensing or acquisitions, or combine with or be acquired by a public or private company. After careful consideration of these strategic alternatives, the BioSante board of directors decided to proceed with a plan to continue the development of LibiGel, including continuing the then ongoing LibiGel Phase III safety study and initiating two new LibiGel Phase III efficacy trials. The BioSante board of directors determined that while such a plan was not without risk, it represented the best alternative then available to BioSante and its stockholders. However, the BioSante board of directors also directed BioSante's management to continue its pursuit to seek strategic alternatives and to keep the BioSante board of directors apprised of the status of such efforts so that the BioSante board of directors could revisit from time-to-time as appropriate its decision to continue the development of LibiGel.

On June 11, 2012, BioSante announced its plan to initiate two new LibiGel Phase III efficacy trials. BioSante subsequently continued to develop a protocol for the two new efficacy trials and to seek an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials.

On June 12, 2012, the day after BioSante announced its plan to initiate two new LibiGel Phase III efficacy trials, BioSante received an unsolicited indication of interest from a private specialty pharmaceutical company referred to as Company A to engage in a stock-for-stock transaction pursuant to which 50 percent of the surviving entity would be owned by the BioSante stockholders and the remaining 50 percent of which would be owned by Company A stockholders. The indication of interest contemplated that the surviving entity would be managed by Company A's management and would complete development of and submit new drug applications for two of Company A's drug candidates, and, based on statements in the indication of interest, would not pursue any further development of LibiGel.

On June 18, 2012, the BioSante board of directors held a special meeting to discuss the receipt of the indication of interest from Company A, to engage possible financial advisors to assist BioSante and the BioSante board of directors in evaluating a response to the indication of interest from Company A and other strategic alternatives that may be available for BioSante, and BioSante's recently announced plan to initiate two new LibiGel Phase III efficacy trials. A representative of BioSante's legal counsel, Oppenheimer Wolff & Donnelly LLP (OWD) summarized the fiduciary duties and responsibilities of the BioSante board of directors both generally and specifically in considering an all-stock transaction of the type proposed by Company A. After extensive discussion, it was the consensus of the BioSante board of directors that although the board remained committed to BioSante's current business plan and strategy, including the plan to initiate two new LibiGel Phase III efficacy trials, the board also was committed to increasing stockholder value for the BioSante stockholders and thus remained open minded as to other strategic alternatives that would increase stockholder value and be in the best interests of the BioSante stockholders. The BioSante board of directors directed BioSante's management to request from Company A additional information, including its business plan and strategy, historical and projected financial information, and valuation information, in order to enable the BioSante board of directors to review and analyze the proposal.

Subsequent to the BioSante board of directors meeting on June 18, 2012, BioSante's president and chief executive officer, Stephen M. Simes, responded to Company A's June 12, 2012 indication of interest requesting additional information from Company A.

On June 20, 2012, the president and chief executive officer of Company A requested a meeting with Mr. Simes, and BioSante's senior vice president, finance, chief financial officer and secretary, Phillip B. Donenberg, to discuss Company A's indication of interest, BioSante's corporate strategy and general aspects of a possible transaction between the two companies.

On June 21, 2012, BioSante's management reiterated to Company A BioSante's need for additional information from Company A in order to enable BioSante to review and analyze Company A's offer.

On June 27, 2012, the president and chief executive officer of Company A responded that prior to responding to BioSante's information request, he would like to meet with BioSante's management to discuss Company A's indication of interest.

On July 3, 2012, the president and chief executive officer of Company A visited BioSante's corporate offices in Lincolnshire, Illinois and met with Mr. Simes and Mr. Donenberg. The parties discussed Company A's corporate strategy, BioSante's corporate strategy, Company A's indication of interest and general aspects of a possible transaction between the two companies. Subsequent to July 3, 2012, BioSante commenced a due diligence investigation of Company A, including its proposed products, regulatory matters and intellectual property, and gave access to Company A and its advisors to BioSante's electronic data room, which contained legal, regulatory, financial and other documents relating to BioSante and its business. Also subsequent to July 3, 2012, BioSante's management and Company A's management discussed on several occasions in person and via telephone the status of each other's respective due diligence investigations, the material terms of a possible transaction between the two parties and the status and timing of a possible transaction between the two parties.

On July 9, 2012, BioSante received a non-binding draft term sheet from a public biopharmaceutical company referred to as Company B proposing a stock-for-stock transaction pursuant to which the exchange ratio would be based on BioSante's market capitalization immediately prior to the signing of a definitive agreement. Under the term sheet, 30 percent of the Company B shares to be issued to the BioSante stockholders in connection with the transaction would be held back and offset against BioSante's transaction expenses, the remaining principal amount of BioSante's convertible senior notes and certain other costs and expenses, and the completion of the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing. The term sheet also provided for

contingent value rights that would entitle the BioSante stockholders to 75 percent of any fees received by Company B from the sale or license of LibiGel and certain milestone payments with respect to products in BioSante's GVAX cancer vaccine portfolio. The term sheet contemplated that Company B's management team would manage the surviving entity and the surviving entity would focus primarily on the further development and commercialization of Company B's products and technologies.

From July 10, 2012 to July 12, 2012, Mr. Simes and Mr. Donenberg attended the annual JMP Securities 7th Annual Healthcare Conference in New York. During the conference, Mr. Simes and Mr. Donenberg met with five investment banking firms which focused on the biopharmaceutical industry and that BioSante had worked with in the past regarding their interest in acting as a financial advisor for BioSante and assisting BioSante in responding to the indication of interest from Company A and the term sheet from Company B and in raising additional financing to fund the two new LibiGel efficacy trials. In addition, during the conference, Mr. Simes and Mr. Donenberg met with three institutional investors to discuss their interest in a possible equity investment in BioSante to fund the two new LibiGel Phase III efficacy trials.

Subsequent to BioSante's announcement of the two new LibiGel Phase III efficacy trials, the trading price of BioSante common stock decreased significantly from a closing sale price of \$2.58 per share as of June 8, 2012 to a closing sale price of \$2.01 as of July 12, 2012, a decrease of over 20 percent.

In part, as a result of the significant decrease in the trading price of BioSante common stock since the public announcement of the two new LibiGel Phase III efficacy trials, the input from the five investment banking firms and three institutional investors regarding BioSante's ability to raise the additional financing required to fund the two new LibiGel Phase III efficacy trials and the likely terms of such financing, the Listing Rules of The NASDAQ Global Stock Market which limit the ability of NASDAQ listed companies to raise additional financing in discounted equity offerings, the volatility of the stock market in general and the uncertainty of the capital markets environment to raise additional financing, BioSante's management began to recognize the significant risks and uncertainties involved in raising the substantial additional financing that would be required to fund the two new LibiGel efficacy trials. BioSante's management estimated that the two new LibiGel Phase III efficacy trials would cost approximately \$15 to \$18 million each, or a combined \$30 to \$36 million spread over 18 months.

On July 16, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. At the meeting, BioSante's management presented financial scenarios of BioSante as an ongoing independent publicly traded company, assuming the continuation of the LibiGel Phase III safety study and the initiation of the two new LibiGel Phase III efficacy trials, but no other clinical development, licensing revenues or equity financings, and assuming a conclusion of the LibiGel Phase III safety study, a decision not to pursue the two new LibiGel Phase III efficacy trials, no other clinical development, licensing revenues or equity financings and certain restructuring activities to downsize BioSante's organization. BioSante's management described analyst and investor response to BioSante's June 2012 announcement of the two new LibiGel Phase III efficacy trials based on management's several meetings with investment banking firms and investors and the significant decrease in the trading price of BioSante common stock since the announcement. BioSante's management informed the board that raising the substantial additional financing required to fund the new LibiGel Phase III efficacy trials would be challenging in light of investor reaction to BioSante's announcement of the new LibiGel Phase III efficacy trials, BioSante's then current stock price and NASDAQ's limitations on discounted offerings. After extensive discussion, the BioSante board of directors authorized BioSante's management to continue to explore whether there were any strategic alternatives available to BioSante that likely would increase stockholder value more than BioSante's current business plan and strategy. In so directing BioSante's management, the BioSante board of directors recognized that since no cash buyers had emerged over the last five years during BioSante's

efforts to seek strategic alternatives, a cash buyer was unlikely to emerge at this time and thus directed BioSante's management not to expend significant time and resources in pursuing a cash sale of BioSante and to focus on those companies that previously had expressed an interest in a potential business combination with BioSante or otherwise would be likely to be interested in a potential business combination with BioSante.

On July 18, 2012, Mr. Simes contacted the president and chief executive officer of Company B and informed him that BioSante was undertaking a process to evaluate strategic alternatives for BioSante and that he would discuss Company B's term sheet with the BioSante board of directors.

On July 19, 2012, Mr. Simes, Mr. Donenberg, Michael C. Snabes, M.D., Ph.D., BioSante's Senior Vice President of Medical Affairs, Joanne Zborowski, BioSante's Vice President of Clinical Development, and Jeff Winkelman, Ph.D., BioSante's Vice President of Intellectual Property and Contracts, met with representatives of another private biotechnology company referred to as Company C. At this meeting, the parties discussed each other's businesses and the possible terms of a potential transaction between the two companies.

On July 19, 2012, BioSante and ANI entered into a mutual confidentiality agreement in order to allow the parties to explore and evaluate a possible transaction and conduct initial due diligence.

On July 23, 2012, ANI sent an exploratory initial indication of interest letter to BioSante that proposed an acquisition of 100 percent of the equity securities of BioSante for total consideration of up to 50 percent of the equity securities of the combined company and additional contingent cash payments of 66 percent of any net cash payments received in connection with BioSante's LibiGel program, up to an aggregate of \$40 million.

On July 26, 2012, BioSante received a written non-binding initial term sheet from Company C proposing a stock-for-stock transaction pursuant to which BioSante as the surviving company would be owned 51 percent by Company C stockholders and 49 percent by the BioSante stockholders, but would be managed by Company C's management team and focus primarily on Company C's business. The term sheet also provided for contingent value rights that would entitle the BioSante stockholders to 75 percent of any fees received by Company C from the sale or license of LibiGel for a period of two years from the closing date. The term sheet indicated that the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing of the transaction.

On July 31, 2012, BioSante received a written non-binding letter of intent from Company A proposing a stock-for-stock merger transaction pursuant to which BioSante as the surviving entity would be owned 50 to 60 percent by the Company A stockholders and 40 to 50 percent by the BioSante stockholders, with the exact ownership percentages determined based on BioSante's net cash as of closing. The letter of intent indicated that the board of directors of the surviving entity would be comprised of three members selected by Company A, three members selected by BioSante and one member selected by both Company A and BioSante. The letter of intent contemplated that the surviving entity would focus on Company A's business and terminate all clinical development activities relating to LibiGel. The letter of intent contemplated that BioSante's management team would manage the merged company. The letter of intent stated that it would be valid only if executed by BioSante by August 9, 2012.

During July 2012, in order to reduce further the outstanding principal amount of its convertible senior notes and ongoing interest obligations, BioSante issued an aggregate of 1,784,070 shares of BioSante common stock in exchange for the cancellation of \$3.5 million in aggregate principal amount of its convertible senior notes and the related accrued and unpaid interest of \$20,686. After these securities exchange transactions, BioSante had \$8.3 million in aggregate principal amount of its convertible senior notes outstanding.

On August 3, 2012, Mr. Simes and Mr. Donenberg of BioSante met with Arthur S. Pryzbyl, ANI's president and chief executive officer, and Charlotte C. Arnold, ANI's vice president and chief financial officer, and representatives of Oppenheimer & Co. Inc. by telephone to discuss further a potential transaction between BioSante and ANI. Each of ANI's and BioSante's management team gave a corporate presentation on such call.

On August 7, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. At the meeting, BioSante's management presented updated and revised financial scenarios of BioSante as an ongoing independent publicly traded company, assuming the continuation of the LibiGel Phase III safety study and the two new LibiGel Phase III efficacy trials, but no other clinical development, licensing revenues or equity financings, and assuming a conclusion of the LibiGel Phase III safety study, a decision not to pursue the two new LibiGel Phase III efficacy trials, no other clinical development, licensing revenues or equity financings and certain restructuring activities to downsize BioSante's organization. BioSante's management summarized for the board the four indications of interest that BioSante had received to date and the possibility that BioSante may receive additional indications of interest based on discussions between BioSante's management and other parties. BioSante's management described the companies that had submitted indications of interest, their businesses, the status of negotiations with each of the companies, and, at a high level, the likely terms of a possible transaction with BioSante. The BioSante board of directors authorized management to continue to explore whether there were any strategic alternatives available to BioSante that likely would increase stockholder value more than BioSante's current business plan and strategy. BioSante's management also informed the board regarding the various investment banking firms with whom it had met and the material terms of an engagement if BioSante were to engage such firms. The BioSante board of directors authorized BioSante's management to enter into an engagement letter with Oppenheimer & Co. Inc., pursuant to which Oppenheimer & Co. Inc. would act as exclusive financial advisor to BioSante in connection with a possible strategic transaction. The BioSante board of directors selected Oppenheimer & Co. Inc. based on its familiarity with BioSante's business and the biopharmaceutical industry in general, its ability to access companies potentially interested in a transaction with BioSante and the financial terms of the engagement. The BioSante board of directors authorized BioSante's management to direct Oppenheimer & Co. Inc. to solicit indications of interest regarding a possible business combination transaction with BioSante and to focus those efforts on companies in the biopharmaceutical industry with a commercial or near-commercial stage product or products in development that coincide with BioSante's products in development.

On August 8, 2012, BioSante formally engaged the investment banking firm, Oppenheimer & Co. Inc., in connection with BioSante's evaluation of alternatives.

On August 8, 2012, the president and chief executive officer of Company A contacted Mr. Simes and indicated that Company A was no longer interested in pursuing a stock-for-stock transaction with BioSante primarily because of BioSante's refusal prior to such time to engage in exclusive negotiations with Company A regarding the transaction proposed by Company A in its July 31, 2012 letter of intent.

On August 8, 2012, a representative of Oppenheimer & Co. Inc., on behalf of BioSante, contacted Company B and indicated that BioSante was conducting a formal process to seek strategic alternatives and would keep Company B informed as the process continued.



On August 8, 2012, BioSante received a written indication of interest from a public biotechnology company referred to as Company D to engage in a possible business transaction. Prior to proposing the material terms of such a transaction, Company D insisted that BioSante enter into a written confidentiality agreement and that the parties commence a due diligence review of each other's operations, assets, liabilities, books, records, facilities and capital structure. On August 14, 2012, BioSante and Company D entered into a written confidentiality agreement and subsequently commenced their respective due diligence investigations. In furtherance of Company D's due diligence of BioSante, BioSante gave access to BioSante's electronic data room to Company D and its advisors. Based on conversations between representatives of BioSante and of Oppenheimer & Co. Inc. and representatives of Company D, Company D contemplated a stock-for-stock merger transaction pursuant to which the BioSante stockholders would own up to 50 percent of the parent or surviving entity.

On August 8, 2012, ANI's management and legal advisors were granted access to BioSante's electronic data room and immediately commenced a due diligence review of BioSante and its business.

On August 16, 2012, BioSante entered into a placement agent agreement with Rodman & Renshaw, LLC, pursuant to which Rodman & Renshaw, LLC agreed to use its reasonable best efforts to arrange for the sale of shares of BioSante common stock and warrants to purchase shares of BioSante common stock in a registered direct public offering. Later on August 16, 2012, BioSante and a certain institutional investor entered into a securities purchase agreement, pursuant to which BioSante agreed to sell 2,359,932 shares of its common stock and warrants to purchase a total of 1,179,966 shares of its common stock to such investor for gross proceeds of \$3.475 million. The common stock and warrants were sold in units, with each unit consisting of one share of BioSante common stock and a warrant to purchase 0.50 of a share of BioSante common stock. The purchase price per unit was \$1.4725. On August 20, 2012, BioSante completed the offering.

On August 22, 2012, BioSante received a revised non-binding written letter of intent from Company B proposing a reverse triangular stock-for-stock merger pursuant to which BioSante would be the surviving entity and a wholly owned subsidiary of Company B and the exchange ratio used to determine the number of Company B shares to be issued to the BioSante stockholders would be based on BioSante's market capitalization immediately prior to the signing of the definitive agreement. Under the letter of intent, 30 percent of the Company B shares to be issued to the BioSante stockholders in connection with the transaction would be held back and offset against BioSante's transaction expenses, the remaining principal amount of BioSante's convertible senior notes and certain other costs and expenses, and completion of the transaction would be conditioned upon BioSante having a specified minimum net cash as of closing. Unlike the initial term sheet provided by Company B to BioSante on July 9, 2012, the letter of intent did not contemplate the issuance of contingent value rights to the BioSante stockholders. The letter of intent contemplated that Company B's management team would manage the surviving entity going forward and the surviving entity would focus primarily on the further development and commercialization of Company B's products and technologies.

On August 24, 2012, BioSante and a public pharmaceutical oncology company referred to as Company E entered into a mutual confidentiality agreement. Shortly thereafter, BioSante gave access to BioSante's electronic data room to Company E and its advisors. On August 27, 2012 BioSante received from Company E a written non-binding term sheet describing the general terms of a proposed business combination transaction between BioSante and Company E. The term sheet contemplated a reverse triangular stock-for-stock merger pursuant to which Company E would be the surviving entity and the number of Company E shares to be issued to the BioSante stockholders would be based on BioSante's market capitalization at the time of the execution of the definitive merger agreement. The term sheet indicated that the transaction would be conditioned upon BioSante having a specified minimum amount of net cash at closing. Subsequent to August 27, 2012, representatives of BioSante and Company E conducted due diligence on each other and met in person and via telephone and discussed the general terms of a proposed business combination transaction between the two parties.

During July and August 2012, in addition to the various companies previously mentioned BioSante conducted limited due diligence on a private oncology company and another private pharmaceutical company to decide whether to engage in more formal discussions regarding a potential business combination transaction with such companies. After BioSante's due diligence investigation of the two companies, BioSante's management decided that neither of the two companies would be a good fit for BioSante largely due to the fact that both companies' businesses were at too early a stage of development and would require significant additional investment for the foreseeable future.

On August 27, 2012, the BioSante board of directors held a special meeting for management to update the board with respect to BioSante's business, including the LibiGel clinical development program, and discuss strategic alternatives. With respect to the LibiGel clinical development program, the BioSante board of directors determined that in light of the independent Data Monitoring Committee's most recent unblinded review of the LibiGel safety study adequate safety data of LibiGel use in menopausal women had been obtained and determined to conclude the safety study. BioSante's management and representatives of Oppenheimer & Co. Inc. summarized for the board management's review and assessment of BioSante's alternatives, including a review of whether it would be in the best interest of BioSante and its stockholders for BioSante to continue as an independent company and continue to allocate its resources to the development of LibiGel or allocate its resources to other biopharmaceutical product areas through in-licensing or acquisitions, combine with or be acquired by a public or private company, sell BioSante's assets or liquidate BioSante. After an extensive discussion on the potential alternatives and the various companies that had submitted indications of interest and remained interested in a transaction with BioSante, it was the consensus of the BioSante board of directors that a combination of BioSante and ANI would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, and the uncertain capital markets, which BioSante historically had relied upon to raise additional financing to fund its product development efforts. In addition, the BioSante board of directors concluded that a potential transaction with ANI was superior to a liquidation of BioSante since ANI's proposal represented a premium to BioSante's estimated cash available to distribute to the BioSante stockholders and also included considerable upside through a continued equity investment in the combined business. The BioSante board of directors directed management to proceed with negotiations with ANI since ANI's proposal appeared to offer the most attractive terms for a transaction with BioSante out of the indications of interest that had been received by BioSante and such a transaction with ANI would give the BioSante stockholders an opportunity to participate in the potential future value of the combined company, including future potential value from ANI's established contract manufacturing operations, niche generic prescription products and products in development, as well as give the BioSante stockholders the right to potentially receive certain future cash payments in the event of a subsequent sale, transfer, license or similar transaction relating to BioSante's LibiGel program. In addition to ANI, the BioSante board of directors also directed management to explore further a potential transaction with Company B, Company D and Company E since discussions with those companies had not matured as quickly as with ANI.

On August 31, 2012, a representative of Oppenheimer & Co. Inc. sent to ANI's management a draft merger agreement and a due diligence request for purposes of assisting BioSante in performing a due diligence investigation of ANI.

On August 31, 2012, ANI's management communicated to Oppenheimer & Co. Inc. that ANI was not interested in spending significant resources on a potential transaction without an exclusivity letter and sent a draft exclusivity letter to BioSante's management.

On September 4, 2012, the representative of Oppenheimer & Co. Inc. informed ANI's management that BioSante would not grant exclusivity to ANI prior to September 14, 2012, the date of

the next regular meeting of the BioSante board of directors, and that in the meantime, the parties should continue to perform their respective due diligence investigations of each other in order to move the transaction forward and enable BioSante's management to present a proposed transaction with ANI to the BioSante board of directors at its meeting on September 14, 2012.

On September 5, 2012, ANI's management sent to Oppenheimer & Co. Inc. and BioSante's management a draft non-binding letter of intent pursuant to which ANI proposed a merger with BioSante following which the holders of ANI capital stock and in-the-money dilutive securities would hold 55 percent of the issued and outstanding common stock of the combined company and the holders of BioSante common stock and in-the-money dilutive securities would hold 45 percent of the issued and outstanding common stock of the combined company. The letter of intent contemplated contingent cash payments to the BioSante stockholders of 65 percent of any net cash proceeds received for BioSante's LibiGel program, up to a maximum of \$40 million in the aggregate. The letter of intent contemplated that the executive officers of ANI would be the executive officers of the combined company and that the board of directors of the combined company would consist of seven individuals, one of whom would be the combined company's chief executive officer, four of whom would be designated by ANI and two of whom would be designated by BioSante. The letter of intent also contained other provisions, including a minimum net cash closing requirement for BioSante, a net cash definition, termination right and fee provisions and a 15-day exclusivity provision

Between September 5, 2012 and September 14, 2012, representatives of BioSante and ANI exchanged drafts of the letter of intent and negotiated the terms and conditions of the letter of intent, including the post-merger ownership percentages, potential adjustments to the post-merger ownership percentages, the minimum net cash closing requirement for BioSante, the net cash definition, the composition of the board of directors of the combined company, termination right and fee provisions and the term of the exclusivity provision.

On September 13, 2012, Mr. Pryzbyl and Ms. Arnold and a representative of ANI's outside legal counsel, SNR Denton US LLP (Dentons) met with Mr. Simes and Mr. Donenberg of BioSante and a representative of OWD at BioSante's corporate offices in Lincolnshire, Illinois to engage in further negotiations and discussions regarding the letter of intent and conduct due diligence. By the end of the day on September 13th, the parties had negotiated the terms of the letter of intent, subject to the final approval of the letter of intent by the parties' respective boards of directors.

On September 14, 2012, a regular meeting of the BioSante board of directors took place at BioSante's corporate offices in Lincolnshire, Illinois. At the meeting, BioSante's management updated the board as to BioSante's business, including the status of the LibiGel clinical development program, and strategic alternatives. The representative of Oppenheimer & Co. Inc. described the process that Oppenheimer & Co. Inc. had engaged in since August 2012 to respond to companies that previously had indicated an interest in a possible strategic transaction with BioSante and to reach out to other companies that may have an interest in a strategic transaction with BioSante. The representative of Oppenheimer & Co. Inc. summarized the six indications of interest received by BioSante, and noted the other three parties that had engaged in discussions regarding a possible strategic business combination transaction with BioSante. The representative of Oppenheimer & Co. Inc. also discussed the potential terms of a transaction with each of these parties as evident by their respective indications of interest and, in some cases, subsequent conversations between representatives of Oppenheimer & Co. Inc. and such companies. The representative of Oppenheimer & Co. Inc. described the management teams, businesses, prospects, operating results and financial position of three of the companies with whom Oppenheimer & Co. Inc. and BioSante's management considered to be the most likely parties to a transaction with BioSante, and in much greater detail, the management team, business, prospects, operating results of ANI. BioSante's management summarized the material terms of the proposed non-binding letter of intent with ANI. After an extensive discussion, the BioSante

board of directors authorized BioSante's management to enter into the non-binding letter of intent with ANI, on substantially the terms as described to the board at the meeting.

After the meeting of the BioSante board of directors, on September 14, 2012, and after further negotiation regarding the circumstances under which a termination of the merger agreement would give rise to the payment of a termination fee by BioSante, the letter of intent was executed by BioSante and ANI. Pursuant to the terms of the letter of intent, BioSante and ANI agreed to negotiate exclusively with one another until September 28, 2012, unless either party earlier notified the other of its decision to terminate discussions.

From September 14, 2012 to October 3, 2012, BioSante's and ANI's respective managements performed additional due diligence. During such period, several telephone conference calls were held between BioSante's management and advisors and ANI's management and advisors to discuss various aspects of their respective due diligence investigations.

On September 19, 2012, ANI's legal counsel sent BioSante's legal counsel a mark-up of the draft merger agreement.

On September 20, 2012, representatives of OWD and Dentons held a telephone conference call to discuss the terms of the merger agreement, including in particular the definition of net cash, various adjustments to net cash and the effect of potential future payments to BioSante on the determination of net cash for purposes of the merger agreement, certain representations and warranties, and certain covenants, including the non-solicitation covenant, the employee benefit covenant and the ability of BioSante and ANI to take certain actions during the period after the execution of the merger agreement and prior to the closing of the merger, and closing conditions.

Between September 20, 2012 and September 28, 2012, representatives from OWD and Dentons exchanged drafts of the merger agreement, contingent value rights agreement, form of voting agreements and form of lock-up agreement and continued to negotiate the terms and conditions of the merger agreement, the contingent value rights agreement and the other ancillary agreements.

On September 28, 2012, representatives of BioSante, ANI, OWD and Dentons held a telephone conference call to discuss the remaining open business terms of the merger agreement, including the definition of net cash, various adjustments to net cash and the effect of potential future payments to BioSante on the determination of net cash for purposes of the merger agreement, the ability of BioSante and ANI to enter into certain agreements during the period after the execution of the merger agreement and the closing of the merger, and certain conditions to the obligation of ANI to close the merger. The parties also discussed the remaining open business terms of the contingent value rights agreement. After such call, although BioSante and ANI did not enter into a written amendment to their letter of intent extending the exclusivity provision beyond September 28, 2012, the parties and their advisors committed to negotiate and finalize the merger agreement, the contingent value rights agreement and the other related ancillary agreements as soon as reasonably practicable.

Between September 28, 2012 and October 3, 2012, representatives from OWD and Dentons continued to exchange drafts of the merger agreement, the contingent value rights agreement and the other related ancillary agreements and negotiate the terms and conditions of such agreements.

On October 3, 2012, the BioSante board of directors held a special meeting to consider the proposed transaction with ANI. A representative of OWD reviewed with the BioSante board of directors its fiduciary duties applicable to the proposed transaction. A representative of OWD summarized the principal deal terms focusing, in particular, on changes to those terms since the meeting held by the BioSante board of directors on September 14, 2012 and the letter of intent executed on that date. A draft of the merger agreement and the contingent value rights agreement, a memorandum describing the principal terms of the transaction documents and proposed resolutions were provided to the members of the BioSante board of directors in advance of the meeting. Also at

this meeting, Oppenheimer & Co. Inc. reviewed with the BioSante board of directors its financial analyses and rendered to the BioSante board of directors an oral opinion, which was confirmed by delivery of a written opinion dated October 3, 2012, to the effect that, as of that date and based on and subject to the matters described in the opinion, the exchange ratios provided in the merger agreement were fair, from a financial point of view, to BioSante. A representative of OWD summarized the proposed resolutions for the BioSante board of directors. After an extensive discussion and consideration of the financial and legal aspects of the proposed transaction and the other matters described under "—BioSante Reasons for the Merger" beginning on page 128 of this joint proxy statement/prospectus, the directors unanimously determined that the merger and the other transactions contemplated thereby were fair to, and in the best interests of, BioSante and its stockholders. The directors voted unanimously to approve and adopt all of the resolutions, including the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, the approval of the contingent value rights agreement and other related ancillary agreements and the approval of the amendments to BioSante's certificate of incorporation to effect a reverse split of BioSante common stock and BioSante class C special stock in the discretion of BioSante and ANI at a ratio of either one-to-two, one-to-three, one-to-four or one-to-five and to change the corporate name of BioSante to "ANI Pharmaceuticals, Inc."

On October 3, 2012, the ANI board of directors held a special meeting to consider the proposed transaction with BioSante. A representative of Dentons summarized the principal deal terms focusing, in particular, on changes to the terms since the letter of intent was executed on September 14, 2012. A draft of the merger agreement and the contingent value rights agreements were provided to the members of the ANI board of directors in advance of the meeting. After an extensive discussion and consideration of the financial and legal aspects of the proposed transaction and the other matters described under "—ANI Reasons for the Merger" beginning on page 132 of this joint proxy statement/prospectus, the directors voted unanimously to approve the merger agreement and the transactions contemplated thereby, including the merger, and related matters.

During the evening of October 3, 2012, all of BioSante's directors and officers entered into voting agreements with ANI to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger, and the approval of the amendments to BioSante's certificate of incorporation. In addition, certain stockholders of ANI entered into a voting agreement with BioSante pursuant to which they agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger, and one of ANI's stockholders, Meridian Venture Partners II, L.P., agreed in its voting agreement with BioSante to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders of the combined company following completion of the merger.

Also during the evening of October 3, 2012, representatives of ANI and Dentons and BioSante and OWD finalized the merger agreement, and BioSante and ANI entered into the merger agreement.

On October 4, 2012, BioSante and ANI issued a joint news release announcing the proposed merger of ANI and BioSante.

On November 13, 2012, BioSante and ANI entered into an amendment to the merger agreement to change the date upon which the parties must agree to the amount of the current class action and shareholder derivative litigation reserve for purposes of the net cash definition from November 15, 2012 to November 30, 2012. BioSante and ANI subsequently agreed upon zero as the amount of the current class action and shareholder derivative litigation reserve for purposes of the net cash definition.

## BioSante Reasons for the Merger

In evaluating the merger, the BioSante board of directors consulted with BioSante's management and legal, financial and other advisors and, in reaching its decision to approve the merger and enter into the merger agreement, the BioSante board of directors considered a number of factors, including the following material factors which the BioSante board of directors viewed as generally supporting its decision to approve the merger and the merger agreement.

- The consideration of BioSante's anticipated near- and long-term operations and performance on an independent, stand-alone basis, the substantial additional financing that would be needed to sustain such operations assuming BioSante continued its LibiGel clinical development program or in-licensed or acquired additional technologies or product candidates, and the risk that such substantial additional financing could not be obtained on terms favorable to BioSante, or at all, in light of a volatile economy, uncertain capital markets and limitations on BioSante's ability to effect equity offerings.
- The consideration of other strategic alternatives to the proposed merger with ANI, including other merger transactions with other companies, continuing to operate BioSante on an independent, stand-alone basis, in-licensing or acquiring additional technologies or product candidates and undertaking a liquidation of BioSante, and the belief that the proposed merger with ANI would permit the BioSante stockholders with a greater potential opportunity to realize a return on their investment than any other alternative reasonably available to BioSante and the BioSante stockholders.
- The belief that the combination of BioSante's and ANI's businesses would create more value for the BioSante stockholders in the long-term than BioSante could create as an independent, stand-alone company, given the anticipated costs, timing and risks associated with continuing the development of LibiGel and other BioSante products in development and/or in-licensing or acquiring additional technologies or product candidates, the uncertain capital markets, which BioSante historically has relied upon to raise additional financing to fund its product development efforts, and limitations on BioSante's ability to effect equity offerings.
- Historical and current information concerning ANI's business, financial performance, financial condition, operations and management and the results of a due diligence investigation of ANI conducted by BioSante's management and advisors.
- The opportunity for the BioSante stockholders to participate in the potential future value of the combined company, including potential future value from ANI's established contract manufacturing operations, niche generic prescription products and products in development.
- The fact that the cash resources of the combined company expected to be available at the closing of the merger would provide the combined company sufficient capital to execute its near-term business strategy, obtain regulatory approvals for several of its products in development and maintain its projected business operations beyond 2013.
- BioSante's ability, under the terms of the merger agreement, to issue CVRs to the holders of BioSante common stock prior to completion of the merger, which would give such BioSante stockholders the right to potentially receive certain cash payments in the event BioSante receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, subject to the terms and conditions contained in the CVR agreement.
- The significant costs of liquidating BioSante, the operational challenges of maintaining a liquidating trust to administer any royalty and other future payments BioSante expects to receive from Teva, the licensee of BioSante's male testosterone gel, and may receive from other

licensees of BioSante's products and technologies, the likelihood that BioSante would not be able to distribute immediately all of its remaining cash to the BioSante stockholders in the event of a liquidation and dissolution of the company, given the fact that BioSante would need to set aside a reserve to pay, and make provisions for, existing and future contingent and potential claims and liabilities, and the likelihood that any amount ultimately distributed to the BioSante stockholders would be minimal.

- Historical and current information concerning BioSante's business, financial performance, financial condition, operations and management, including financial projections of BioSante under various scenarios and its short- and long-term strategic objectives and the risks associated therewith.
- Historical and current financial market conditions and stock prices and historical stock prices and trading volumes of BioSante common stock.
- The exchange ratios in the merger, which are subject to adjustment for changes in BioSante's net cash, and are intended to result in the BioSante stockholders holding approximately 47 percent of the outstanding shares of the combined company after the merger, assuming BioSante's net cash as of the determination date is \$18.0 million.
- The fact that the exchange ratios will not fluctuate based upon changes in the price of BioSante common stock or the value of ANI capital stock prior to completion of the merger, which protects the BioSante stockholders from any materially negative trends in the price of BioSante common stock and any materially positive trends in the value of ANI capital stock.
- The all-stock nature of the merger and the intent that the merger be tax-free to the BioSante stockholders.
- The terms and conditions of the merger agreement, including without limitation the following:
  - The structure of the merger and the level of certainty as to the percentage of the total shares of common stock of the combined company that current BioSante and ANI stockholders will own after the merger provided by the exchange ratios which may be adjusted based on BioSante's net cash as of the determination date, but will not be adjusted to reflect changes in the market value of BioSante common stock or ANI common stock, and the determination that the relative percentage ownership of the combined company by the BioSante and ANI stockholders was consistent with BioSante's perceived valuation of each company at the time the BioSante board of directors approved the merger agreement.
  - The provisions in the merger agreement that limit the ability of BioSante to solicit and respond to offers for alternative transactions, but which allow BioSante to respond to a bona fide acquisition proposal that the BioSante board of directors determines is or is reasonably likely to lead to a superior proposal, subject to certain restrictions imposed by the merger agreement, which such provisions the BioSante board of directors believes are reasonable under the circumstances.
  - The requirement to hold a special meeting of BioSante stockholders to vote on the merger agreement even if the BioSante board of directors subsequently changes its recommendation, but the ability of the BioSante board of directors, in accordance with its fiduciary duties, to withdraw, modify or amend its recommendation that the BioSante stockholders vote in favor the adoption of the merger agreement and the transactions contemplated thereby, including the merger, which such provisions the BioSante board of directors believes are reasonable under the circumstances.

- The relatively limited nature of the closing conditions, the net cash closing condition and the inclusion of an exchange ratio adjustment for certain changes in BioSante's net cash rather than requiring a higher net cash closing condition requirement.
  - The ability of BioSante to effect other transactions with respect to its products in development during the pendency of the merger with ANI.
  - The conditions under which the merger agreement may be terminated by either party and the conclusion of the BioSante board of directors that the potential termination fee of \$1.0 million or the reimbursement of certain transaction expenses incurred in connection with the merger of up to \$500,000, payable by BioSante to ANI and the potential termination fee of \$750,000 payable by ANI to BioSante and the circumstances when such fee or expense reimbursement may be payable or received by BioSante, are reasonable.
  - The restrictions on the ability of certain ANI stockholders to freely trade the shares of BioSante common stock that they receive in connection with the merger for a period of 180 days following completion of the merger.
  - The belief that the parties' respective representations, warranties and covenants, and conditions to their respective obligations, are reasonable under the circumstances.
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- The voting agreements entered into by certain stockholders of ANI representing approximately 90 percent of the outstanding shares of ANI common stock, on an as-converted basis, and 86 percent of the outstanding ANI series D preferred stock as of October 3, 2012, pursuant to which such stockholders agreed, solely in their capacity as stockholders, to vote all of their shares of ANI capital stock in favor of adoption of the merger agreement and against any alternative acquisition proposal.
  - The fact that two directors of BioSante will continue as directors of the combined company after the merger.
  - Oppenheimer & Co.'s opinion, and its financial presentation, dated October 3, 2012, to the BioSante board of directors as to the fairness, from a financial point of view and as of the date of the opinion, to BioSante of the exchange ratios, as described more fully below under the caption "Opinion of Oppenheimer & Co. Inc."

The BioSante board of directors weighed the factors described above which the BioSante board of directors viewed generally as supporting its decision to approve the merger and the merger agreement against a number of other factors identified in its deliberations weighing negatively against the merger, including without limitation the following material factors:

- The fact that the shares of BioSante common stock to be issued in the merger will represent approximately 53 percent of the outstanding common stock of the combined company immediately after completion of the merger, assuming BioSante's net cash as of the determination date is \$18.0 million, thus causing existing BioSante stockholders to experience immediate and significant dilution in their equity interests and voting power of BioSante upon completion of the merger.
- The fact that, while BioSante expects the merger to be completed, there can be no assurance that all conditions to the parties' obligations to complete the merger, including BioSante obtaining stockholder approval of the merger and related merger proposals and BioSante's net cash being at least \$17.0 million (as calculated and as adjusted pursuant to the terms of the merger agreement) as of the closing date of the merger, will be satisfied within the time frames contemplated by the merger agreement, especially since some of the conditions are outside the control of BioSante, and, as a result, the merger may not be completed.



- The amount of time required to complete the merger and the possibility that the merger may not be completed and the potential adverse consequences to BioSante if the merger is not completed, including the potential adverse effect on the reputation of BioSante, the potential to depress the values offered by others to BioSante in a business combination or other alternative transaction and the ability of BioSante to obtain financing in the future.
- The possibility that the merger might be unduly delayed and the potential of such a delay to reduce or eliminate the expected benefits of the transaction, especially since a delay would cause BioSante's net cash to decrease thereby potentially resulting in a decrease in the percentage ownership of the BioSante stockholders in the combined company after the merger.
- The possible negative effect of the public announcement of the merger on BioSante's stock price and the possible volatility in BioSante common stock that may occur during the pendency of the merger.
- The possibility that the anticipated benefits of the merger may not be realized or that they may be lower than expected.
- The risk that the per share value of the consideration to be paid in the merger to the ANI stockholders could increase significantly from the value prior to the announcement of the merger agreement because the exchange ratios will not be adjusted for changes in the market price of BioSante common stock or the value ANI capital stock.
- The risk that sales of substantial amounts of BioSante common stock immediately after the closing of the merger and after the lapsing of lock-up restrictions 180 days after completion of the merger could adversely affect the market price of BioSante common stock.
- The substantial charges to be incurred in connection with the merger, including transaction expenses that would be incurred whether or not the merger is completed, and change of control and severance payments to BioSante executive officers triggered by the closing of the transaction.
- The risk of diverting the attention of BioSante's management from other strategic priorities to implement the merger and make arrangements for the integration of each company's operations and infrastructure following the merger.
- The risk that ANI's revenue forecasts are not attained at the level or within the timeframe expected.
- The risks, challenges and costs associated with successfully integrating two companies, with separate operations and locations.
- The potential loss of key ANI employees critical to the ongoing success of the combined company's business.
- The requirement under the merger agreement that BioSante call and hold a vote of the BioSante stockholders to approve the merger and related proposals, even in circumstances where the BioSante board of directors has withdrawn or adversely changed its recommendation to the BioSante stockholders with respect to such proposals in response to a superior proposal.
- The ability of the ANI stockholders and management to significantly influence the combined company's business following completion of the merger.
- The restrictions on the conduct of BioSante's business prior to completion of the merger, which require BioSante to carry on its business in the ordinary course and consistent with past practice, subject to specific additional restrictions, which may delay or prevent BioSante from pursuing

business opportunities that otherwise would be in its best interests as an independent, stand-alone company.

- The requirement that BioSante receive approval from The NASDAQ Global Market for the re-listing of BioSante common stock in connection with the merger based on The NASDAQ Global Market's initial listing requirements.
- The risk of stockholder lawsuits that may be filed against BioSante and/or the BioSante board of directors in connection with the merger agreement.
- The substantial transaction costs and expenses that have been incurred to date and are expected to be incurred in connection with the merger.
- The provisions of the merger agreement that require BioSante to reimburse ANI for certain transaction expenses incurred in connection with the merger in the amount of up to \$500,000 and pay a \$1.0 million fee if the merger agreement is terminated by BioSante or ANI due to specified reasons.
- The other risks of the type and nature described under "Risk Factors" and the matters described under "Cautionary Statement Regarding Forward-Looking Statements."

After consideration of these factors, the BioSante board of directors determined that these risks could be mitigated or managed by BioSante or ANI or by the combined company following the merger, were reasonably acceptable under the circumstances or, in light of the anticipated benefits, the risks were unlikely to have a materially adverse impact on the merger or on the combined company following the merger, and that, overall, these risks were significantly outweighed by the potential benefits of the merger.

Although this discussion of the information and factors considered by the BioSante board of directors is believed to include the material factors considered by the BioSante board of directors, it is not intended to be exhaustive and may not include all of the factors considered by the BioSante board of directors. In reaching its determination to approve the merger and approve and adopt the merger agreement, the BioSante board of directors did not find it useful and did not attempt to quantify or assign any relative or specific weights to the various factors that it considered in reaching its determination that the merger and the merger agreement are advisable and fair to and in the best interests of BioSante and its stockholders. Rather, the BioSante board of directors based its position and determination on the totality of the information presented to and factors considered by it. In addition, individual members of the BioSante board of directors may have given differing weights to different factors.

In considering the determination by the BioSante board of directors that the merger and the merger agreement are advisable and fair to and in the best interests of BioSante and its stockholders, you should be aware that certain BioSante directors and officers have arrangements that may cause them to have interests in the transaction that are different from, in addition to, or may conflict with the interests of the BioSante stockholders generally. See "—Interests of BioSante's Directors and Officers in the Merger."

#### **ANI Reasons for the Merger**

In addition to its ongoing discussions and negotiations with the BioSante board of directors, the ANI board of directors discussed the potential merger with members of its management team, as well as its legal, financial and other advisors. The ANI board of directors also considered a number of

factors which it believed supported its decision to approve the merger and the merger agreement, including, without limitation, the following:

- That the existing BioSante product lines fit well within the ANI platform of hormone-based products.
- That ANI would be able to leverage its knowledge of the hormone-based products market to further the existing BioSante product lines.
- The fact that the remaining cash resources expected to be available at the closing of the merger would provide the combined company with enough capital to enable it to meet its operational needs beyond 2013.
- The belief that the combination of the two businesses will result in accelerated growth and more value for the ANI stockholders than the ANI business could create on its own, given the combination of the product lines of the two companies, ANI's need for additional capital and the well-capitalized balance sheet that the combined company will have after completion of the merger.
- The belief that potential future license and other royalty fees due to BioSante for its FDA-approved male testosterone gel and other products could generate significant future cash flow for the combined company.
- The belief that the combined company will have access to a greater number of capital market opportunities as a public company than ANI would have as a privately held company.
- That the exchange ratios in the merger will result in the ANI stockholders owning approximately 53 percent of the outstanding shares of common stock of the combined company following completion of the merger, assuming BioSante's net cash as of the determination date is \$18.0 million.
- The tax-free nature of the combination of ANI and BioSante in the merger.
- The terms and conditions of the merger agreement, including, without limitation, the following:
  - The relatively limited number of closing conditions.
  - The ability of ANI to effect certain other transactions prior to completion of the merger.
  - The termination provisions and the potential for ANI to receive a termination fee of \$1.0 million or the reimbursement of up to \$500,000 of transaction expenses in the event of a termination by BioSante for certain specified reasons.
  - The reasonable nature of the representations and warranties of ANI and BioSante in the merger agreement.
  - The fact that the board of directors of the combined company will initially be controlled by persons appointed by ANI.

The ANI board of directors also considered certain factors that generally weighed against the merger, including, without limitation, the following:

- The significant costs of concluding the LibiGel safety study and the risk that if such costs exceeded the estimates of BioSante's management, BioSante would not meet the \$17.0 million net cash threshold closing condition.
- The significant costs associated with the merger and the possibility that the merger will not close, with no certainty that any or all of such costs will be reimbursed by BioSante.

- The restrictions on the ability of certain of the ANI stockholders to freely trade their shares of BioSante common stock for a period of 180 days following completion of the merger.
- The possibility that the merger may not result in the benefits the ANI board of directors expects or that such benefits could be lower than anticipated.
- The risk that the per share value of the shares of BioSante common stock being issued in the merger to the ANI stockholders could be higher than the trading price of the combined company's common stock following completion of the merger.
- The risk that the remaining BioSante products do not achieve the revenue currently anticipated by the ANI board of directors.
- The risks, challenges and significant costs associated with integrating two companies with separate operations and locations.
- The potential loss of key ANI employees critical to the performance of the combined company following completion of the merger.
- The restrictions on the operation of the ANI business prior to completion of the merger, which generally require ANI to operate in the ordinary course, consistent with its past practice, which may restrict ANI from taking certain actions that the ANI board of directors otherwise believes to be in the best interest of the ANI stockholders.
- The risk that ANI may be named in stockholder suits filed against BioSante in connection with the merger agreement.
- The provision in the merger agreement that requires ANI to pay BioSante a \$750,000 termination fee if the merger agreement is terminated by BioSante due to specified reasons.
- Certain other risks of the type and nature described under "Risk Factors."

After considering all of the information, risks and concerns set forth above, the ANI board of directors determined that each of them was manageable or could otherwise be mitigated by ANI, BioSante or the combined company following the merger and that taken as a whole, such risks and concerns were reasonably acceptable when the benefits of the merger also were considered. Overall, the ANI board of directors did not believe that the risks outweighed the significant potential benefits of the merger.

In reaching its determination to approve the merger and approve and adopt the merger agreement, the ANI board of directors did not find it useful and did not attempt to quantify or assign any relative or specific weights to the various factors that it considered in reaching its determination that the merger and the merger agreement are advisable and fair to and in the best interests of ANI and its stockholders. Rather, the ANI board of directors based its position and determination on the totality of the information presented to and factors considered by it. In addition, individual members of the ANI board of directors may have given differing weights to different factors.

In considering the determination by the ANI board of directors that the merger and the merger agreement are advisable and fair to and in the best interests of ANI and its stockholders, you should be aware that certain ANI directors and officers have arrangements that may cause them to have interests in the transaction that are different from, in addition to, or may conflict with the interests of the ANI stockholders generally. See "—Interests of ANI's Directors and Officers in the Merger."

#### **Opinion of Oppenheimer & Co. Inc.**

On August 8, 2012, BioSante engaged Oppenheimer & Co. Inc. (Oppenheimer & Co.) as its financial advisor in connection with the merger. In connection with this engagement, the BioSante

board of directors requested that Oppenheimer & Co. evaluate the fairness, from a financial point of view, to BioSante of the exchange ratios, as provided in and as calculated pursuant to the terms of the merger agreement. On October 3, 2012, at a meeting of the BioSante board of directors held to evaluate the merger, Oppenheimer & Co. rendered to the BioSante board of directors an oral opinion, confirmed by delivery of a written opinion dated October 3, 2012, to the effect that, as of that date and based on and subject to the matters described in its opinion, the exchange ratios were fair, from a financial point of view, to BioSante.

The full text of Oppenheimer & Co.'s written opinion, dated October 3, 2012, which describes the assumptions made, procedures followed, matters considered and limitations on the review undertaken, is attached to this proxy statement/prospectus as Annex G and is incorporated by reference in its entirety. **Oppenheimer & Co.'s opinion was provided for the use of the BioSante board of directors (in its capacity as such) in connection with its evaluation of the exchange ratios from a financial point of view and did not address any other terms, aspects or implications of the merger, including, without limitation, the form or structure of the merger or any term, aspect or implication of any voting agreements or other agreement, arrangement or understanding entered into in connection with the merger or otherwise. Oppenheimer & Co. expressed no view as to, and its opinion did not address, the underlying business decision of BioSante to proceed with or effect the merger or the relative merits of the merger as compared to any alternative business strategies that might exist for BioSante or the effect of any other transaction in which BioSante might engage. Oppenheimer & Co.'s opinion does not constitute a recommendation to any BioSante or ANI stockholder as to how such stockholder should vote or act with respect to any matters relating to the merger or otherwise.** This summary of Oppenheimer & Co.'s opinion is qualified in its entirety by reference to the full text of its opinion.

In arriving at its opinion, Oppenheimer & Co.:

- reviewed the draft, dated October 2, 2012, of the merger agreement;
- reviewed publicly available financial statements of BioSante for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of BioSante for the six months ended June 30, 2012;
- reviewed audited financial statements of ANI for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of ANI for the eight months ended August 31, 2012, and other relevant financial and operating data furnished to Oppenheimer & Co. by ANI;
- reviewed financial forecasts and estimates relating to BioSante prepared by the management of BioSante;
- reviewed financial forecasts and estimates relating to ANI prepared by the management of ANI;
- held discussions with the senior managements of BioSante and ANI with respect to the businesses and prospects of BioSante and ANI, respectively;
- reviewed the historical market prices and trading volumes of BioSante common stock;
- reviewed and analyzed certain publicly available financial data for companies Oppenheimer & Co. deemed relevant in evaluating ANI;
- analyzed the estimated present value of the future cash flows of ANI based on financial forecasts and estimates prepared by the management of ANI;
- reviewed other public information concerning BioSante; and
- performed such other analyses, reviewed such other information and considered such other factors as Oppenheimer & Co. deemed appropriate.

In rendering its opinion, Oppenheimer & Co. relied upon and assumed, without independent verification or investigation, the accuracy and completeness of all of the financial and other information publicly available or provided to or discussed with Oppenheimer & Co. by BioSante and ANI and their respective employees, representatives and affiliates or otherwise reviewed by Oppenheimer & Co. With respect to the financial forecasts and estimates relating to BioSante and ANI utilized in Oppenheimer & Co.'s analyses, at the direction of the respective management and with BioSante's consent, Oppenheimer & Co. assumed, without independent verification or investigation, that such forecasts and estimates were reasonably prepared on bases reflecting the best available information, estimates and judgments of the respective managements of BioSante and ANI as to the future financial condition and operating results of BioSante and ANI and the other matters covered thereby and that the financial results reflected in such forecasts and estimates would be achieved at the times and in the amounts projected. Oppenheimer & Co. also assumed, at BioSante's direction, the final terms of the merger agreement would not vary materially from those set forth in the draft reviewed by Oppenheimer & Co. Oppenheimer & Co. further assumed, with BioSante's consent, that the merger would qualify for federal income tax purposes as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended. Oppenheimer & Co. also assumed, with the consent of BioSante, that the merger would be consummated in accordance with its terms without waiver, modification or amendment of any material term, condition or agreement and in compliance with all applicable laws and other requirements and that, in the course of obtaining the necessary regulatory or third party approvals, consents and releases with respect to the merger, no delay, limitation, restriction or condition would be imposed that would have an adverse effect on BioSante or the contemplated benefits of the merger.

Oppenheimer & Co. is not a legal, tax, regulatory or accounting advisor and relied on the assessments made by BioSante and its advisors with respect to such issues. The opinion of Oppenheimer & Co. did not constitute a solvency opinion or a fair value opinion, and Oppenheimer & Co. did not evaluate the solvency or fair value of BioSante under any federal or state laws relating to bankruptcy, insolvency or similar matters. Oppenheimer & Co. neither made nor obtained any independent evaluations or appraisals of the assets or liabilities (contingent or otherwise) of BioSante or ANI. Oppenheimer & Co. expressed no view as to, and its opinion did not address, any terms or other aspects or implications of the merger (other than the exchange ratios to the extent expressly specified in its opinion) or any aspect or implication of any other agreement, arrangement or understanding entered into in connection with the merger or otherwise, including, without limitation, the fairness of the amount or nature of the compensation resulting from the merger to any individual officers, directors or employees of BioSante, or class of such persons, relative to the exchange ratios. Oppenheimer & Co. also expressed no view as to, and its opinion did not address, the issuance by BioSante of a distribution to the holders of BioSante common stock prior to the consummation of the merger consisting of contingent value rights with respect to certain payments arising from the sale, transfer, license or a similar transaction relating to BioSante's LibiGel program in accordance with the terms of a form of contingent value rights agreement in the form agreed to by BioSante and ANI.

The opinion of Oppenheimer & Co. was based on the information available to it and general economic, financial and stock market conditions and circumstances as they existed and could be evaluated by Oppenheimer & Co. on the date of delivery of such opinion. Although subsequent developments may affect its opinion, Oppenheimer & Co. does not have any obligation to update, revise or reaffirm its opinion, provided that Oppenheimer & Co. has agreed to deliver one update of its opinion, subject to certain conditions.

This summary is not a complete description of Oppenheimer & Co.'s opinion or the financial analyses performed and factors considered by Oppenheimer & Co. in connection with its opinion, but is a description of their material terms. The preparation of a financial opinion is a complex analytical process involving various determinations as to the most appropriate and relevant methods of financial

analysis and the application of those methods to the particular circumstances and, therefore, a financial opinion is not readily susceptible to summary description. Oppenheimer & Co. arrived at its ultimate opinion based on the results of all analyses undertaken by it and assessed as a whole, and did not draw, in isolation, conclusions from or with regard to any one factor or method of analysis for purposes of its opinion. In addition, Oppenheimer & Co. may have given various analyses and factors more or less weight than other analyses and factors, and may have deemed various assumptions more or less probable than other assumptions. As a result, the ranges of valuations resulting from any particular analysis described below should not be taken to be Oppenheimer & Co.'s view of the actual value of ANI or BioSante. Accordingly, Oppenheimer & Co. believes that its analyses and this summary must be considered as a whole and that selecting portions of its analyses and factors or focusing on information presented in tabular format, without considering all analyses and factors or the narrative description of the analyses, could create a misleading or incomplete view of the processes underlying Oppenheimer & Co.'s analyses and opinion.

In performing its analyses, Oppenheimer & Co. considered industry performance, general business, economic, market and financial conditions and other matters existing as of the date of its opinion, many of which are beyond ANI's control. No company or business used in the analyses is identical to ANI, and an evaluation of the results of those analyses is not entirely mathematical. Rather, the analyses involve complex considerations and judgments concerning financial and operating characteristics and other factors that could affect the acquisition, public trading or other values of the companies or business segments analyzed.

The assumptions and estimates contained in Oppenheimer & Co.'s analyses and the ranges of valuations resulting from any particular analysis are not necessarily indicative of actual values or future results, which may be significantly more or less favorable than those suggested by its analyses. In addition, analyses relating to the value of businesses or securities do not purport to be appraisals or to reflect the prices at which businesses or securities actually may be sold or acquired. Accordingly, the assumptions and estimates used in, and the results derived from, Oppenheimer & Co.'s analyses are inherently subject to substantial uncertainty.

Oppenheimer & Co. was not requested to, and it did not, recommend the specific consideration payable in the merger. The type and amount of consideration payable in the merger was determined through negotiation between BioSante and ANI and was approved by the BioSante board of directors. Oppenheimer & Co. provided advice to BioSante during these negotiations. Oppenheimer & Co. did not, however, recommend any specific consideration to BioSante or the BioSante board of directors or that any specific consideration constituted the only appropriate consideration for the merger. The decision to enter into the merger agreement was solely that of the BioSante board of directors. Oppenheimer & Co.'s opinion and financial analysis were only one of many factors considered by the BioSante board of directors in its evaluation of the merger and should not be viewed as determinative of the views of the BioSante board of directors or management with respect to the merger or the exchange ratios or of whether the BioSante board of directors would have been willing to agree to different consideration.

The following is a summary of the material financial analyses reviewed with the BioSante board of directors in connection with Oppenheimer & Co.'s opinion dated October 3, 2012. **The financial analyses summarized below include information presented in tabular format. In order to fully understand Oppenheimer & Co.'s financial analyses, the tables must be read together with the text of each summary. The tables alone do not constitute a complete description of the financial analyses. Considering the data in the tables below without considering the full narrative description of the financial analyses, including the methodologies and assumptions underlying the analyses, could create a misleading or incomplete view of Oppenheimer & Co.'s financial analyses.**

### ***Implied Equity Value of ANI Based on BioSante's Share Price***

Based on BioSante fully diluted shares outstanding and value of equity implied from the five-day volume-weighted average share price of BioSante common stock of \$1.87 as of October 1, 2012, and the 47 percent equity ownership percentage of the combined company to be held by BioSante's equity holders, Oppenheimer & Co. calculated an implied value of the equity of the combined company and an implied value of the equity of ANI of \$54 million.

### ***Implied Equity Value of ANI Based on BioSante's Net Cash and Other Assets***

Based on dividing BioSante's estimated net cash and other assets of \$39 million to \$43 million at the closing of the merger by the 47 percent equity ownership percentage of the combined company to be held by BioSante's equity holders, Oppenheimer & Co. calculated an implied value of the equity of the combined company and an implied value of the equity of ANI in the range of \$44 million to \$49 million.

### ***Valuation of Net Cash and Other Assets of BioSante***

Net cash and other assets of BioSante range was calculated based on the sum of four following components, each based on information provided by BioSante's management: (i) estimated net cash at the time of closing of the merger of \$18 million, (ii) estimated value range of \$1.8 million to \$3.6 million for BioSante's 10.9 percent equity investment in Ceregene, Inc., (iii) the present value of the estimated free cash flows with respect to BioSante's male testosterone gel, and (iv) the estimated value range of \$1.0 million to \$2.0 million for BioSante's GVAX assets.

Oppenheimer & Co. performed a discounted cash flow analysis of BioSante's male testosterone gel by calculating the estimated present value of the after-tax free cash flows that the product was forecasted to generate during fiscal years ending December 31, 2012 through 2019 based on internal estimates of BioSante's management. The cash flows were then discounted to present value as of September 30, 2012 using discount rates ranging from 16.9 percent to 18.9 percent, reflecting estimates of BioSante's weighted average cost of capital calculated using the capital asset pricing model and assuming that the selected companies' average capital structure represents the optimal capital structure. This analysis indicated an implied valuation range for BioSante's male testosterone gel of approximately \$18 million to \$20 million.

### ***ANI Comparable Company Analysis***

Oppenheimer & Co. performed a comparable company analysis, which attempts to provide a range of implied aggregate values for ANI's equity and the combined company's net cash at the closing of the merger, which is referred to as the implied pro forma equity value for ANI, by comparing it to similar companies. Oppenheimer & Co. reviewed financial information of ANI and the following eight selected publicly-held specialty pharmaceutical companies:

- Mylan Inc.
- Watson Pharmaceuticals Inc.
- Perrigo Co.
- Hospira Inc.
- Akorn Inc.
- Impax Laboratories Inc.
- Hi-Tech Pharmacal Co. Inc.
- Lannett Co. Inc.



All multiples were based on closing stock prices on October 1, 2012. Estimated financial data for the selected companies were based on public filings, information available through FactSet, and publicly available equity research analyst estimates. Estimated financial data for ANI were based on ANI management projections.

For each of the selected companies, Oppenheimer & Co. calculated the following:

- Equity Value, which is defined as market capitalization on a fully-diluted basis.
- Enterprise Value, which is defined as market capitalization on a fully-diluted basis plus debt and preferred equity, less cash, adjusted for in-the-money options, warrants and convertible debt.
- Enterprise Value/Revenue 2015E, which is defined as the ratio of Enterprise Value to calendar year 2015 estimated revenue, as adjusted to reflect calendar year-end and pro-forma adjustments for acquisitions.
- Enterprise Value/EBITDA 2015E, which is defined as the ratio of Enterprise Value to calendar year 2015 estimated earnings before interest, taxes, depreciation and amortization, referred to as EBITDA, as adjusted to reflect calendar year-end and pro-forma adjustments for acquisitions.

Based on the analysis of the relevant metrics for each of the selected companies, Oppenheimer & Co. selected representative ranges of financial multiples of the selected companies and applied these ranges of multiples to determine the implied equity value of ANI. The median revenue multiple observed for the selected companies for estimated calendar year 2015 was 2.0x and the median EBITDA multiple observed for the selected companies for estimated calendar year 2015 was 7.1x. The selected ranges represent plus and minus 15 percent around each applicable median multiple. Financial data for the selected companies were based on publicly available research analyst estimates, public filings and other publicly available information. Financial data for ANI were based on information provided by the managements of ANI and BioSante. Based on the combined company's expected capitalization as a result of the merger, Oppenheimer & Co. calculated the estimated implied equity value of ANI as of October 1, 2012 as follows:

<u>Financial Statistic</u>	<u>Selected Company Representative Multiple Range</u>	<u>Implied Pro Forma Equity Value of ANI (\$ millions)</u>
2015E Revenue	1.7x - 2.3x	\$82.2 - \$112.4
2015E EBITDA	6.0x - 8.2x	\$67.1 - \$92.0

Oppenheimer & Co. noted that based on BioSante's fully diluted value of equity implied from the five-day volume-weighted average share price of BioSante common stock of \$1.87 as of October 1, 2012, the implied value of the equity of ANI is \$54 million and based on BioSante's estimated net cash and other assets at the closing of the merger, the implied value of the equity of ANI is in the range of \$44 million to \$49 million.

Although the foregoing companies were compared to ANI for purposes of this analysis, Oppenheimer & Co. noted that no company used in the comparable companies analysis is identical to ANI because of differences between the private company/public company nature, business mix, markets served, operations, and other characteristics of ANI and the selected companies. In evaluating the selected companies, Oppenheimer & Co. relied on publicly available research analyst estimates, which estimates are based in part on judgments and assumptions with regard to industry performance, general business, economic, market and financial conditions, and other matters, many of which are beyond the control of ANI, such as the impact of competition on the business of ANI, as well as on the industry generally, industry growth, and the absence of any adverse material change in the financial condition and prospects of ANI or the industry or in the markets generally.

### ***ANI Discounted Cash Flow Analysis***

Oppenheimer & Co. performed a discounted cash flow analysis of ANI by calculating the estimated present value of the standalone unlevered, after-tax free cash flows that ANI was forecasted to generate during fiscal years ending December 31, 2012 through 2020 based on internal estimates of ANI's management. Oppenheimer & Co. calculated terminal values for BioSante by applying a range of perpetuity growth rates to BioSante's fiscal year 2020 estimated free cash flow of 2 percent to 4 percent and a range of discount rates of 16.9 percent to 18.9 percent. The cash flows and terminal values were then discounted to present value as of September 30, 2012 using discount rates ranging from 16.9 percent to 18.9 percent, reflecting estimates of ANI's weighted average cost of capital calculated using the capital asset pricing model and assuming that the selected companies' average capital structure represents the optimal capital structure. This analysis indicated an implied equity valuation range for ANI of approximately \$99 million to \$136 million.

Oppenheimer & Co. noted that based on BioSante's fully diluted value of equity implied from the five-day volume-weighted average share price of BioSante common stock of \$1.87 as of October 1, 2012, the implied value of the equity of ANI is \$54 million and based on BioSante's estimated net cash and other assets at the closing of the merger, the implied value of the equity of ANI is in the range of \$44 million to \$49 million.

### ***Miscellaneous***

In connection with the review by the BioSante board of directors of the merger and the issuance of shares of BioSante common stock to ANI stockholders, Oppenheimer & Co. performed a variety of financial and comparative analyses for purposes of rendering its opinion. Oppenheimer & Co. conducted the analyses described above solely as part of its analysis of the fairness of the exchange ratios pursuant to the merger agreement from a financial point of view to BioSante and in connection with the delivery of its opinion dated October 3, 2012 to the BioSante board of directors. These analyses do not purport to be appraisals or to reflect the prices at which shares of BioSante common stock might naturally trade. The foregoing summary describes the material analyses performed by Oppenheimer & Co. but does not purport to be a complete description of the analyses performed by Oppenheimer & Co.

BioSante selected Oppenheimer & Co. to act as its financial advisor in connection with the merger based on Oppenheimer & Co.'s reputation and experience. Oppenheimer & Co. is an internationally recognized investment banking firm and, as a part of its investment banking business, is regularly engaged in valuations of businesses and securities in connection with acquisitions and mergers, underwritings, secondary distributions of securities, private placements and valuations for other purposes. In the ordinary course of business, Oppenheimer & Co. and its affiliates may actively trade securities of BioSante for Oppenheimer & Co.'s and its affiliates' own accounts and for the accounts of customers and, accordingly, at any time may hold a long or short position in such securities. In addition, a senior member of the Oppenheimer & Co. investment banking team assisting BioSante in connection with the merger currently owns approximately 1,400 shares of BioSante common stock, which were acquired in 2009.

BioSante has agreed to pay Oppenheimer & Co. for its financial advisory services in connection with the merger a customary fee, \$500,000 of which was payable upon delivery of Oppenheimer & Co.'s opinion and \$100,000 of which is contingent upon consummation of the merger. BioSante also has agreed to reimburse Oppenheimer & Co. for its expenses, including fees and expenses of its legal counsel, and to indemnify Oppenheimer & Co. and related parties against liabilities, including liabilities under the federal securities laws, relating to, or arising out of, its engagement. In the two years prior to the date hereof, Oppenheimer & Co. has provided financial advisory services for BioSante unrelated to the merger and has received fees in the aggregate amount of \$100,000 from BioSante in connection

with certain of such services. During the same period, Oppenheimer & Co. provided certain private placement and/or arranger services for ANI unrelated to the merger; however, the related transaction was not consummated and Oppenheimer & Co. did not receive any compensation therefor. Oppenheimer & Co. also may seek to provide financial advisory services to BioSante in the future and expects to receive fees for the rendering of these services.

The issuance of Oppenheimer & Co.'s opinion was approved by an authorized committee of Oppenheimer & Co. Oppenheimer & Co. has consented to the use of its written opinion in this joint proxy statement/prospectus and such consent is an exhibit to the registration statement of which this joint proxy statement/prospectus is a part.

#### **Certain Financial Forecasts of ANI Used in Connection with the Merger**

ANI does not, as a matter of course, publicly disclose long-term forecasts or internal projections as to future performance, earnings or other results, and ANI is particularly concerned with making such forecasts and projections due to the unpredictability of the underlying assumptions and estimates. In connection with its due diligence process and evaluation of the merger, ANI's management prepared financial forecasts regarding certain items of its projected operating results, including ANI's forecasted revenues and EBITDA for its 2012 through 2020 fiscal years. ANI's financial forecasts were not prepared with a view toward public disclosure. However, ANI has included below a summary of its financial forecasts to provide its stockholders and investors access to certain non-public information that was furnished to third parties in connection with the merger.

ANI's financial forecasts included assumptions with respect to general business, economic, competitive, regulatory, market and financial conditions, and other future events, as well as matters specific to ANI's business, such as the following, all of which are difficult to predict and many of which are beyond ANI's control:

- the time required to obtain FDA approval for ANDAs;
- the number of competitors, including authorized generics, for ANI's products;
- the prices at which ANI will be able to sell its products;
- the impact of new therapies on the sale of ANI's products;
- changes affecting ANI's contract manufacturing customers; and
- changes in the cost or availability of ANI's raw materials.

ANI's financial forecasts also assume the following:

- ANI will be able to continue to market all of its existing products, including its unapproved pharmaceutical products Opium Tincture and Esterified Estrogen with Methyltestosterone;
- ANI will be able to continue to contract manufacture, and earn royalties on, a group of unapproved pharmaceutical products marketed by its contract manufacturing customer;
- ANI will be able to obtain the raw materials necessary to support the ongoing commercial sales of its existing products, and the development, launch and commercial sales of its pipeline products, including obtaining a sufficient quota from the Drug Enforcement Administration to purchase raw materials to support the production and sales of its existing and future narcotic products;
- increases in the cost of raw materials for existing or pipeline products will not have a material negative effect on ANI's business;

- ANI will be able to develop and obtain FDA approval of and commercialize the products in its pipeline on a timely basis;
- recent trends in unit sales and pricing for each of ANI's pipeline products are a reasonable basis for forecasting total market size upon product launch;
- the number of competitors for ANI's existing products will remain stable;
- ANI's expectations regarding the number of potential competitors for each of its pipeline products are reasonable.

ANI's financial forecasts presented below were provided to Oppenheimer & Co. Inc. in connection with its financial analysis of the exchange ratios. In addition, ANI's financial forecasts also were provided to BioSante by Oppenheimer & Co. Inc. and reviewed with the BioSante board of directors and were utilized by BioSante in connection with its financial analysis of the exchange ratios.

The inclusion of ANI's financial forecasts in this joint proxy statement/prospectus should not be regarded as an indication that ANI or the ANI board of directors considered, or now considers, these forecasts to be material to the ANI or BioSante stockholders or necessarily indicative of actual future results. You should not place undue reliance on the unaudited financial forecasts of ANI contained in this joint proxy statement/prospectus. Please read the information set forth below under the heading "Important Information About ANI's Financial Forecasts."

The following table presents the financial forecasts of ANI that were provided by ANI to Oppenheimer & Co. Inc.

(\$ in millions)	Projected								
	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue	\$ 19.9	\$ 20.3	\$ 26.0	\$ 49.8	\$ 106.4	\$ 143.6	\$ 171.3	\$ 178.5	\$ 181.1
EBITDA	1.9	(2.0)	(2.3)	11.7	35.6	51.6	62.2	65.1	66.3

### **Important Information About ANI's Financial Forecasts**

While ANI's financial forecasts were prepared in good faith, no assurance can be made regarding future events. The estimates and assumptions underlying ANI's financial forecasts involve judgments with respect to, among other things, future economic, competitive, regulatory and financial market conditions and future business decisions that may not be realized and that are inherently subject to significant business, economic, competitive and regulatory uncertainties and contingencies, including, among others, the risks and uncertainties described under the sections entitled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" beginning on pages 38 and 91, respectively, all of which are difficult to predict and many of which are beyond the control of ANI and/or BioSante and will be beyond the control of the combined company. There can be no assurance that the underlying assumptions will prove to be accurate or that the forecasted results will be realized, and actual results likely will differ, and may differ materially, from those reflected in ANI's financial forecasts, whether or not the merger is completed.

ANI's financial forecasts summarized in this section were prepared solely for internal use by ANI. This prospective financial information was not prepared with a view toward compliance with published guidelines of the SEC or the guidelines established by the American Institute of Certified Public Accountants for preparation and presentation of prospective financial information. ANI's management believes the forecasts were prepared in good faith and on a reasonable basis based on the best information available to ANI's management at the time of their preparation. ANI's financial forecasts, however, are not fact and should not be relied upon as being necessarily indicative of actual future results, and readers of this joint proxy statement/prospectus are cautioned not to place undue reliance

on this information. None of ANI's financial forecasts reflects any synergies or costs related to or that may arise from the merger.

The prospective financial information of ANI included in this section has been prepared by, and is the responsibility of, ANI's management. ANI's independent registered public accounting firm has neither examined, compiled nor performed any procedures with respect to the accompanying ANI prospective financial information and, accordingly, does not express an opinion or any other form of assurance with respect thereto. The report of ANI's independent registered public accounting firm included in this joint proxy statement/prospectus relates to the historical financial information of ANI. It does not extend to the prospective financial information of ANI and should not be read to do so.

By including in this joint proxy statement/prospectus a summary of ANI's financial forecasts, neither ANI nor any of its representatives has made or makes any representation to any person regarding the ultimate performance of ANI compared to the information contained in ANI's financial forecasts. ANI has made no representation to BioSante, in the merger agreement or otherwise, concerning ANI's financial forecasts. ANI's financial forecasts summarized in this section were prepared during the periods described above and have not been updated to reflect any changes since the date of this joint proxy statement/prospectus or any actual results of operations of ANI, as set forth under the section entitled "Selected Historical Financial Data of ANI" beginning on page 31. Neither ANI, BioSante nor, after completion of the merger, the combined company undertakes any obligation, except as required by law, to update or otherwise revise ANI's financial forecasts to reflect circumstances existing since their preparation or to reflect the occurrence of unanticipated events, even in the event that any or all of the underlying assumptions are shown to be in error, or to reflect changes in general economic or industry conditions.

The foregoing summary of ANI's financial forecasts is not included in this joint proxy statement/prospectus in order to induce any ANI stockholder to vote in favor of ANI Proposal No. 1 to approve and adopt the merger agreement and the transactions contemplated thereby, including the merger, or any other proposals to be voted on at the ANI special meeting or any BioSante stockholder to vote in favor of BioSante Proposal No. 1 to approve and adopt the merger agreement and the transactions contemplated thereby, including the merger and the issuance of BioSante common stock in connection with the merger, or any other proposals to be voted on at the BioSante special meeting.

### **Interests of BioSante's Directors and Officers in the Merger**

In considering the recommendation of the BioSante board of directors to BioSante stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and the other matters to be acted upon by BioSante stockholders at the BioSante special meeting, BioSante stockholders should be aware that members of the BioSante board of directors and BioSante's officers have interests in the merger that may be different from, in addition to, or may conflict with the interests of BioSante stockholders. These interests relate to or arise from, among other things:

- The fact that Fred Holubow and Ross Mangano, each of whom are current directors of BioSante, will continue to serve on the board of directors of the combined company following completion of the merger and will receive cash and equity compensation in connection with such service as described in more detail below and under "Management of the Combined Company After the Merger—Director Compensation."
- Severance benefits to which each of Stephen M. Simes, Phillip B. Donenberg and Michael C. Snabes, M.D., Ph.D. will become entitled in connection with the completion of the merger, as described in more detail below.

- The accelerated vesting of all BioSante stock options held by the directors and executive officers of BioSante upon completion of the merger as described in more detail below.
- The right to continued indemnification and insurance coverage for directors and executive officers of BioSante following completion of the merger, pursuant to the terms of the merger agreement, as described in more detail below.

The BioSante board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and to recommend that BioSante stockholders approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock, and related matters. Other than full disclosure of these potential conflicts of interest, the BioSante board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock.

### ***Ownership Interests***

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, directors and executive officers of BioSante, together with their respective affiliates, beneficially owned and were entitled to vote 472,335 shares of BioSante common stock and 16,666 shares of BioSante class C special stock, or approximately 1.9 percent of the shares of BioSante common stock and 25.6 percent of the shares of BioSante class C special stock outstanding on that date. Assuming the merger had been completed as of such date, all directors and executive officers of BioSante, together with their respective affiliates, would beneficially own, in the aggregate, less than one percent of the outstanding shares of common stock of the combined company and 25.6 percent of the outstanding shares of BioSante class C special stock of the combined company.

For a more complete discussion of the ownership interests of the directors and executive officers of BioSante, see the sections entitled "Principal Stockholders of BioSante" and "Principal Stockholders of the Combined Company."

### ***Continuing Directors***

Following completion of the merger, Fred Holubow and Ross Mangano are expected to receive cash and equity compensation in accordance with BioSante's equity compensation policies for non-employee directors. Currently, BioSante provides an annual cash retainer of \$25,000 for non-employee board members, pays each non-employee director \$2,000 for board meetings attended in person, \$1,000 for each board meeting attended by telephone and for each board committee meeting attended in person or by telephone, grants options on an annual basis and enters into indemnification agreements with each director, although these policies are subject to change at any time.

### ***Employment Letter Agreements and Severance and Change in Control Agreements***

Upon completion of the merger and the anticipated termination of their employment on the date following completion of the merger, Mr. Simes, Mr. Donenberg and Dr. Snabes will be entitled to receive certain severance payments and other benefits or payments, as applicable, each as more fully described below. BioSante has adopted a rabbi trust to hold funds to pay the severance amounts owed to Mr. Simes and Mr. Donenberg that are subject to the six-month suspension rule under Section 409A of the Internal Revenue Code of 1986.

*Stephen M. Simes.* In January 1998, BioSante entered into an employment letter agreement with Stephen M. Simes. BioSante and Mr. Simes amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Code Section 409A and to make certain changes to the change in control provisions. The agreement has not been amended since July 2008.

As a result of the anticipated termination of his employment immediately after completion of the merger, Mr. Simes will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to the sum of: (1) two times his annual base salary, plus (2) his most recent annual bonus, plus (3) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs;
- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 24 months and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Mr. Simes immediately prior to his termination date to obtain such coverage; and
- provision of outplacement services up to a maximum amount of \$30,000.

*Phillip B. Donenberg.* In June 1998, BioSante entered into an employment letter agreement with Phillip B. Donenberg. BioSante and Mr. Donenberg amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Section 409A of the Internal Revenue Code of 1986 and to make certain changes to the change in control provisions. The agreement has not been amended since July 2008.

As a result of the anticipated termination of his employment immediately after completion of the merger, Mr. Donenberg will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to, the sum of: (1) one and one-half times his annual base salary, plus (2) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs;
- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 18 months and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Mr. Donenberg immediately prior to his termination date to obtain such coverage; and
- provision of outplacement services up to a maximum amount of \$30,000.

*Michael C. Snabes, M.D., Ph.D.* In July 2008, BioSante entered into a change of control and severance agreement with Michael C. Snabes, M.D., Ph.D. However, if Dr. Snabes is terminated without cause or upon a change in control, he will be entitled to certain payments and benefits under the BioSante Pharmaceuticals, Inc. Officer Severance Policy since the severance policy provides for greater severance benefits than Dr. Snabes is currently entitled to receive under his current agreement with BioSante.

As a result of the anticipated termination of his employment immediately after completion of the merger, Dr. Snabes will be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to the sum of: (1) one times his annual base salary, plus (2) 100 percent of his target annual incentive bonus for the year in which the change in control occurs.
- substantially the same health, dental, life and disability insurance benefits he received prior to his termination for a period of up to 12 months and reimbursement for any costs incurred in

securing such continuation coverage that are in excess of costs that would have been incurred by Dr. Snabes immediately prior to his termination date to obtain such coverage; and

- provision of outplacement services up to a maximum amount of \$15,000.

### ***Accelerated Vesting of Stock Options***

The terms of the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan and the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan provide that upon the occurrence of certain corporate transactions, including the merger, the vesting of any stock options outstanding under such plans will be accelerated in full at the effective time of such corporate transaction. As a result, the outstanding unvested stock options held by directors and executive officers of BioSante will vest immediately and become exercisable in full upon completion of the merger. However, if the trading price of BioSante common stock does not trade above the respective per share exercise prices of the options held by such individuals during the terms of the respective options, then no BioSante directors or executive officers will receive any benefit as a result of the option acceleration. As of December 31, 2012, the closing sale price of BioSante common stock was \$1.23 per share, as reported by The NASDAQ Global Market. In addition, since it is anticipated that the employment or other service of all of the directors and officers named below (except Mr. Holubow and Mr. Mangano) will terminate effective as of completion of the merger, all of the options held by such individuals will terminate, if unexercised, three months (one year, in the case of Mr. Simes and Mr. Donenberg) after completion of the merger. These options likely will terminate unexercised in three months (or one year, in the case of Mr. Simes and Mr. Donenberg) after completion of the merger in light of the fact that the exercise prices range from \$4.08 to \$220.92 per share.

The table below sets forth, as of December 31, 2012, information with respect to BioSante stock options held by each of the directors and executive officers of BioSante:

<b>Name</b>	<b>Aggregate Number of Shares of BioSante Common Stock Underlying Options</b>	<b>Aggregate Number of Shares of BioSante Common Stock Underlying Vested Options</b>	<b>Aggregate Number of Shares of BioSante Common Stock Underlying Unvested Options</b>	<b>Per Share Exercise Prices</b>	<b>Aggregate Option Acceleration Value</b>
Stephen M. Simes	396,109	173,192	222,917	\$ 4.11 - 23.97	\$ 0
Louis W. Sullivan, M.D.	33,331	27,498	5,833	4.08 - 26.43	0
Fred Holubow	28,329	24,163	4,166	4.08 - 26.43	0
Ross Mangano	28,329	24,163	4,166	4.08 - 26.43	0
John T. Potts, Jr., M.D.	12,498	7,707	4,791	4.08 - 11.88	0
Edward C. Rosenow III, M.D.	28,329	24,163	4,166	4.08 - 26.43	0
Stephen A. Sherwin, M.D.	32,221	27,430	4,791	4.08 - 220.92	0
Phillip B. Donenberg	180,274	93,468	86,806	4.11 - 23.97	0
Michael C. Snabes, M.D., Ph.D.	84,998	41,109	43,889	4.11 - 26.58	0

### ***Indemnification and Insurance***

The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director or officer of BioSante, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, to the fullest extent permitted under applicable law and BioSante's certificate of incorporation or bylaws. The merger agreement also provides that the combined company will honor all indemnification agreements in place with each present and former director or officer of BioSante.



The merger agreement also provides that, prior to completion of the merger, BioSante will purchase and maintain for a period of six years following completion of the merger, a directors' and officers' liability "tail" insurance policy covering the present and former directors and officers of BioSante for events occurring prior to completion of the merger. Such policy must contain terms no less favorable than the policies maintained by BioSante prior to completion of the merger.

### Golden Parachute Compensation

The following table sets forth the information required by Item 402(t) of Regulation S-K, which requires disclosure of information about compensation for each "named executive officer" of BioSante that is based on or otherwise relates to the merger. This compensation is referred to as "golden parachute" compensation. The "golden parachute" compensation payable to BioSante's named executive officers is subject to a non-binding advisory vote of BioSante stockholders, as described under "Matters Being Submitted to a Vote of BioSante Stockholders—BioSante Proposal No. 4—Advisory Vote on Golden Parachute Compensation" beginning on page 109. Assuming that the merger is completed on January 15, 2013 and the named executive officers are terminated on such date, the executives would receive approximately the amounts set forth in the table below.

In order for BioSante's executives to receive the payments or benefits set forth in the table below as a result of the merger, there must be a termination event, such as a termination by the combined company for any reason other than for cause or a termination by the executive for good reason. For Mr. Simes and Mr. Donenberg, such termination event must occur either within the period beginning on the date of the merger and ending on the last day of the first full calendar month following the second year anniversary date of the merger or prior to the merger if the termination of employment was either a condition of the merger or was at the request or insistence of a person related to the merger. Dr. Snabes has the ability to terminate his employment for good reason if such termination occurs on the date of the merger and ending on the 12 month anniversary of the date of the merger. For purposes of the change in control provisions for Mr. Simes and Mr. Donenberg, the definition of "good reason" is broader than outside the context of change in control and includes: (1) BioSante's failure to obtain from any successor the assent to assume the employment letter agreements; (2) any purported termination by BioSante of the executive's employment that is not properly effected; (3) a requirement that the executive be based at any office or location that is more than 30 miles further from the office or location thereof immediately preceding the change in control; and (4) any termination by the executive of his employment for any reason during the 13th month after the completion of the change in control. For Dr. Snabes, the definition of "good reason" includes: (1) a material diminution in his authority, duties or responsibilities; (2) a material diminution in his base compensation; (3) a material diminution in the authority, duties or responsibilities of the supervisor to whom he reports; (4) a material change in the geographic location at which the company requires him to be based as compared to the location where he was previously based; and (5) any other action or inaction that constitutes a material breach by us under his agreement.

<u>Name</u>	<u>Cash(1)</u>	<u>Perquisites/ Benefits(2)</u>	<u>Total</u>
Stephen M. Simes	\$ 1,490,100	\$ 87,949	\$ 1,578,049
Phillip B. Donenberg	770,000	74,156	844,156
Michael C. Snabes, M.D., Ph.D.	526,400	44,972	571,372

- (1) Represents a severance payment under the executive's employment agreement or, in the case of Dr. Snabes, the BioSante Pharmaceuticals, Inc. Officer Severance Policy, which would be paid in one lump sum equal to, in the case of Mr. Simes, the sum of: (a) two times his annual base salary, plus (b) his most recent annual bonus, plus (c) his maximum annual bonus (100 percent of base salary) for the year in which the change in control

occurs, in the case of Mr. Donenberg, the sum of: (a) 1<sup>1/2</sup> times his annual base salary, plus (b) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs, and in the case of Dr. Snabes, the sum of: (a) one times his annual base salary, plus (b) 100 percent of his target annual incentive bonus for the year in which the change in control occurs. All such benefits are "double trigger" and would only be paid upon completion of the merger and the termination of the executive officer's employment following completion of the merger.

- (2) The amounts above include the estimated value of, in the case of Mr. Simes and Mr. Donenberg, substantially the same health, dental, life and disability insurance benefits the executive received prior to his termination for a period of up to 24 months for Mr. Simes, 18 months for Mr. Donenberg, and in the case of Dr. Snabes, 12 months following the termination date, and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by the executive officer immediately prior to his termination date to obtain such coverage. The value of such benefits is estimated to be the following: Mr. Simes, \$57,949; Mr. Donenberg, \$44,156 and Mr. Snabes, \$29,972. In addition, the above amounts include the provision of outplacement services up to a maximum amount of \$30,000 in the case of Mr. Simes and Mr. Donenberg and \$15,000 in the case of Dr. Snabes. All such benefits are "double trigger" and would only be paid upon completion of the merger and the termination of the executive officer's employment following completion of the merger.

### **Interests of ANI's Directors and Officers in the Merger**

In considering the recommendation of the ANI board of directors to ANI stockholders to vote in favor of the merger agreement and the transactions contemplated thereby, including the merger, and the other matters to be acted upon by the ANI stockholders at the ANI special meeting, ANI stockholders should be aware that members of the ANI board of directors and ANI's officers have interests in the merger that may be different from or in addition to, or may conflict with the interests of ANI stockholders. These interests relate to or arise from, among other things:

- The fact that, Robert E. Brown Jr., Tracy L. Marshbanks, Ph.D., Thomas A. Penn, Arthur S. Przybyl and Robert Schrepfer, each of whom are current directors of ANI, also will continue to serve on the board of directors of the combined company following completion of the merger and such directors, with the exception of Mr. Przybyl, will receive cash and equity compensation for such services, as described in more detail under "Management of the Combined Company After the Merger—Director Compensation."
- The fact that Robert E. Brown, Jr., ANI's chairman of the board, will continue as chairman of the board of the combined company.
- The fact that the executive officers of the combined company will be the current executive officers of ANI and such officers will receive compensation for such service as described in more detail under "Management of the Combined Company After the Merger—Officer Compensation."
- The fact that the executive officers of ANI will receive special transaction bonus payments upon closing of the merger ranging, for each officer, from approximately \$707,705 to \$3,309,410 (assuming BioSante net cash at closing is \$18.0 million) payable in shares of ANI series D preferred stock, which shares will convert into shares of BioSante common stock in the merger, as described in more detail under "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions."

- The fact that MVP Capital and HVC, two firms affiliated with three of ANI's directors, will receive fees of approximately \$350,000 and \$40,000, respectively, upon closing of the merger. This is in addition to unpaid amounts due under existing monitoring arrangements with ANI, which will terminate at closing and which are expected not to exceed \$120,000 for MVP Capital and \$30,000 for HVC, assuming a closing on or before March 31, 2013.
- The right to continued indemnification and insurance coverage for directors and executive officers of ANI following completion of the merger, pursuant to the terms of the merger agreement.

None of ANI's directors or officers has any other interests in the merger that may be different from, or in addition to, the interests of ANI stockholders. The ANI board of directors was aware of these potential conflicts of interest and considered them, among other matters, in reaching its decision to approve the merger agreement and the transactions contemplated thereby, including the merger, and to recommend that ANI stockholders approve the merger agreement and the transactions contemplated thereby, including the merger. Other than full disclosure of these potential conflicts of interest, the ANI board of directors did not take any other steps to alleviate such potential conflicts of interest since it did not consider such potential conflicts of interest to be material in connection with its decision to approve the merger agreement and the transactions contemplated thereby, including the merger.

### ***Ownership Interests***

As of January 15, 2013, the latest practicable date before the printing of this joint proxy statement/prospectus, directors and executive officers of ANI, together with their respective affiliates, beneficially owned and were entitled to vote 28,239 shares of ANI common stock (including warrants to purchase common stock) and 1,902,877 shares of ANI preferred stock, or approximately 68.6 percent of the shares of ANI common stock (including warrants to purchase common stock) and 73.4 percent of the shares of ANI preferred stock outstanding on that date. Assuming the merger had been completed as of such date, all directors and executive officers of ANI, together with their respective affiliates, would beneficially own, in the aggregate, approximately 36.0 percent of the outstanding shares of common stock of the combined company.

For a more complete discussion of the ownership interests of the directors and executive officers of ANI, see the sections entitled "ANI Security Ownership of Certain Beneficial Owners and Management" and "Security Ownership of Certain Beneficial Owners and Management of the Combined Company Following the Merger."

### ***Employment Arrangements with Certain Executive Officers of ANI***

Following completion of the merger, the current executive officers of ANI are expected to be the executive officers of the combined company. The employment arrangements between ANI and such executive officers are expected to remain in place and the terms of such arrangements will be assumed by the combined company. For a discussion of the employment arrangements between ANI and the executive officers of ANI that are expected to become executive officers of the combined company see the section entitled "Management of the Combined Company Following the Merger—Executive Compensation."

### ***Transaction Bonus Agreements and Related Arrangements***

Pursuant to transaction bonus agreements between ANI and certain of its executive officers, such officers are entitled to receive a bonus based on the net proceeds to the ANI stockholders from the consummation of a "change of control" transaction. The agreements acknowledge that the merger between BioSante and ANI qualifies as a change of control. The net proceeds of the merger are calculated as the product of (a) the average closing sale price of the BioSante common stock for the

five trading days prior to the announcement of a signed merger agreement with ANI (which announcement occurred on October 4, 2012) and (b) the aggregate number of shares of BioSante common stock to be issued to the ANI stockholders in the merger.

In connection with the payment of the transaction bonuses to the executive officers of ANI, ANI is required to withhold from such payments amounts sufficient to pay the executives' required tax withholding obligations. ANI and its executive officers expect to enter into arrangements to fund the payment of such withholdings. The transaction bonus agreements and tax withholding arrangements are described in further detail in the section entitled "Management of the Combined Company Following the Merger—Executive Compensation—Transaction Bonus Agreements and Related Arrangements."

### ***Indemnification and Insurance***

The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director, officer, or employee of ANI, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, including advancing expenses, to the fullest extent allowed by applicable law. In addition, all rights to indemnification with respect to acts or omissions occurring at or prior to completion of the merger existing in favor of each present and former director, officer, or employee of ANI as provided in ANI's certificate of incorporation, ANI's bylaws, or indemnification agreements will remain in effect.

The merger agreement also provides that, prior to completion of the merger, ANI will purchase and maintain for a period of six years following completion of the merger, a directors' and officers' liability "tail" insurance policy covering the directors and officers of ANI for events occurring prior to completion of the merger. Such policy must contain terms no less favorable than the policies maintained by ANI prior to completion of the merger.

### **Regulatory Approvals**

Neither BioSante nor ANI is required to make any filings or to obtain approvals or clearances from any antitrust regulatory authorities in the United States or other countries to consummate the merger. In the United States, BioSante must comply with applicable federal and state securities laws in connection with the issuance of shares of BioSante common stock in the merger, including the filing with the SEC of the registration statement of which this joint proxy statement/prospectus is a part. In addition, BioSante must comply with applicable rules of The NASDAQ Stock Market which, as described below, require the preparation and approval of an initial listing application in connection with the transaction.

### **NASDAQ Listing of BioSante Common Stock**

BioSante common stock currently is listed on The NASDAQ Global Market under the symbol "BPAX". BioSante has agreed to use its reasonable best efforts to cause the shares of BioSante common stock issuable in connection with the merger to be approved, at or prior to completion of the merger, for listing (subject to notice of issuance) on The NASDAQ Global Market, and the listing of the shares of BioSante common stock issuable pursuant to the merger agreement is a condition to ANI's obligation to complete the merger.

As of the date of the mailing of this joint proxy statement/prospectus, BioSante has filed an initial listing application for The NASDAQ Global Market in connection with the merger. If such application is approved, BioSante anticipates that its common stock will be listed on The NASDAQ Global Market following completion of the merger under the trading symbol "BPAX". It is expected that following the merger, the combined company will change its name to "ANI Pharmaceuticals, Inc." and that its trading symbol will be changed. ANI has reserved the ticker symbol "ANIP" for this purpose.

## **Restrictions on Sales of BioSante Common Stock Received by ANI Stockholders in the Merger**

Pursuant to the merger agreement, the chief executive officer and chief financial officer of ANI and certain stockholders of ANI have agreed to enter into lock-up agreements with BioSante pursuant to which the shares of BioSante common stock received by ANI stockholders in the merger may not be sold, transferred or encumbered for a 180-day period following completion of the merger, except in limited circumstances.

In addition, shares of BioSante common stock received by ANI stockholders who become affiliates of BioSante for purposes of Rule 144 under the Securities Act may be resold by them only in transactions permitted by Rule 144, or as otherwise permitted under the Securities Act. Persons who may be deemed affiliates of BioSante generally include individuals or entities that control, are controlled by or are under common control with BioSante and may include officers and directors as well as principal stockholders of BioSante. Each director and executive officer of ANI who will serve as a director or executive officer of BioSante following completion of the merger will be deemed an affiliate of BioSante for purposes of Rule 144.

## **Material U.S. Federal Income Tax Consequences of the Merger**

BioSante and ANI intend the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code and have agreed to use reasonable best efforts to structure the merger to qualify as a reorganization and not to take any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Code. For a more complete discussion of the material U.S. federal income tax consequences of the merger, see the section entitled "Material U.S. Federal Income Tax Consequences of the Merger." It is a condition to the completion of the merger that BioSante obtain from Oppenheimer Wolff & Donnelly LLP, and ANI obtain from SNR Denton US LLP, an opinion that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

## **Anticipated Accounting Treatment**

Under U.S. GAAP, the merger will be accounted for as a "reverse acquisition" pursuant to which ANI will be considered the acquiring entity for accounting purposes. As such, ANI will allocate the total purchase consideration to BioSante's tangible and identifiable intangible assets and liabilities based on their relative fair values at the date of the completion of the merger. ANI's historical results of operations will replace BioSante's historical results of operations for all periods prior to the merger; after completion of the merger, the results of operations of both companies will be included in BioSante's financial statements.

BioSante will account for the merger using the acquisition method of accounting under U.S. GAAP. Accounting Standards Codification 805 "*Business Combinations*," referred to as "ASC 805," provides guidance for determining the accounting acquiror in a business combination when equity interests are exchanged between two entities. ASC 805 provides that in a business combination effected through an exchange of equity interests, such as the merger, the entity that issues the equity interests is generally the acquiring entity. Commonly, the acquiring entity is the larger entity. However, the facts and circumstances surrounding a business combination sometimes indicate that a smaller entity acquires a larger one. ASC 805 further provides that in identifying the acquiring entity in a combination effected through an exchange of equity interests, all pertinent facts and circumstances must be considered, including the relative voting rights of the stockholders of the constituent companies in the combined entity, the composition of the board of directors and senior management of the combined company and the terms of the exchange of equity securities in the business combination, including payment of any premium.

Based on the relative voting interests of BioSante and ANI in the combined company whereby the ANI stockholders will have majority voting interest, that the board of directors of the combined entity will be composed of five former-ANI board members and two former-BioSante directors and that the chief executive officer and chief financial officer of the combined entity will be the former chief executive officer and former chief financial officer of ANI, ANI is considered to be the acquirer of BioSante for accounting purposes. This means that the total purchase price will be allocated to BioSante's tangible and identifiable intangible assets and liabilities based on their estimated relative fair market values at the date of the completion of the merger. Final valuations of property, plant and equipment, and intangible and other assets have not yet been completed as management is still reviewing the existence, characteristics and useful lives of BioSante's intangible assets. The completion of the valuation work could result in significantly different amortization expenses and balance sheet classifications. After completion of the merger, the results of operations of both companies will be included in the financial statements of BioSante. For further discussion of the accounting treatment, see "Unaudited Pro Forma Condensed Combined Financial Information."

## **Appraisal Rights**

### ***BioSante***

If the merger is completed, BioSante stockholders are not entitled to appraisal rights under Section 262 of the Delaware General Corporation Law (DGCL).

### ***ANI***

If the merger is completed, ANI stockholders who have not waived such rights are entitled to appraisal rights under Section 262 of the DGCL, referred to as Section 262, provided that they comply with the conditions established by Section 262.

This section is intended to provide a brief summary of the material provisions of the Delaware statutory procedures that a stockholder must follow in order to seek and perfect appraisal rights. However, this summary is not a complete statement of all applicable requirements, and it is qualified in its entirety by reference to the text of the relevant provisions of Delaware law, which are attached to this joint proxy statement/prospectus as Annex H. The following summary does not constitute any legal or other advice, nor does it constitute a recommendation that ANI stockholders exercise their appraisal rights under Section 262. Failure to follow precisely any of the statutory procedures set forth in Annex H may result in a termination or waiver of appraisal rights.

A record holder of shares of ANI capital stock who makes the demand described below with respect to such shares, who continuously holds such shares through the effective time of the merger, who submits a written demand for appraisal to ANI in compliance with the statutory requirements of Section 262, and who does not submit a proxy or vote in favor of the ANI Proposal No. 1 or consent thereto in writing will be entitled to an appraisal by the Delaware Court of Chancery of the fair value of his, her or its shares of ANI capital stock in lieu of the consideration that such stockholder would otherwise be entitled to receive pursuant to the merger agreement. All references in this summary of appraisal rights to a "stockholder" or "holders of shares of ANI capital stock" are to the record holder or holders of shares of ANI capital stock.

Under Section 262, because the merger agreement is to be submitted for adoption at the ANI special meeting, not fewer than 20 days prior to the meeting, ANI must notify each of the holders of its stock for whom appraisal rights are available that such appraisal rights are available and include in such notice a copy of Section 262. This joint proxy statement/prospectus shall constitute such notice to the record holders of ANI capital stock and a copy of Section 262 is attached to this joint proxy statement/prospectus as Annex H.

ANI stockholders who desire to exercise their appraisal rights must satisfy all of the conditions of Section 262. Those conditions include the following:

ANI stockholders electing to exercise appraisal rights must not submit a proxy or vote "for" the ANI Proposal No. 1. Submitting a proxy or voting "for" the ANI Proposal No. 1 will result in the waiver of appraisal rights. Also, because a submitted proxy not marked "against" or "abstain" will be voted "for" the ANI Proposal No. 1, the submission of a proxy not marked "against" or "abstain" will result in the waiver of appraisal rights.

A written demand for appraisal of shares of ANI capital stock must be delivered to ANI before the taking of the vote on the ANI Proposal No. 1 at the ANI special meeting. The written demand for appraisal should specify the ANI stockholder's name and mailing address, and that such stockholder is thereby demanding appraisal of his, her or its shares of ANI capital stock. The written demand for appraisal of shares of ANI capital stock is in addition to and separate from a vote against the ANI Proposal No. 1 or an abstention from such vote. Failure to return your proxy, voting against, or abstaining from voting on, the ANI Proposal No. 1 will not satisfy your obligation to make a written demand for appraisal. Failure to make a written demand for appraisal prior to the taking of the vote on the ANI Proposal No. 1 at the ANI special meeting will constitute a waiver of appraisal rights.

A demand for appraisal must be executed by or for the ANI stockholder of record, fully and correctly, as such stockholder's name appears on the stock certificate. If the shares are owned of record in a fiduciary capacity, such as by a trustee, guardian or custodian, this demand must be executed by or for the fiduciary. If the shares of ANI capital stock are owned by or for more than one person, as in a joint tenancy or tenancy in common, such demand must be executed by or for all joint owners. An authorized agent, including an agent for two or more joint owners, may execute the demand for appraisal for an ANI stockholder of record. However, the agent must identify such record holder and expressly disclose the fact that, in exercising the demand, he is acting as agent for such record holder. A person having a beneficial interest in ANI capital stock held of record in the name of another person, such as a broker or nominee, must act promptly to cause the record holder to follow the steps summarized below in a timely manner to perfect appraisal rights on behalf of the beneficial owners.

An ANI stockholder who elects to exercise appraisal rights should mail or deliver his, her or its written demand to ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota 56623, Attention: Corporate Treasurer.

Within 10 days after the effective time of the merger, ANI must provide notice of the effective time of the merger to all ANI stockholders who have complied with Section 262 and have not voted in favor of the ANI Proposal No. 1.

Within 120 days after the effective time of the merger, either ANI or any ANI stockholder who has complied with the required conditions of Section 262 may file a petition in the Delaware Court of Chancery, with a copy served on ANI in the case of a petition filed by an ANI stockholder, demanding a determination of the fair value of the shares of ANI capital stock held by all ANI stockholders seeking to exercise appraisal rights. There is no present intent on the part of ANI to file an appraisal petition, and ANI stockholders seeking to exercise appraisal rights should not assume that ANI will file such a petition or that ANI will initiate any negotiations with respect to the fair value of such shares. Accordingly, ANI stockholders who desire to have their shares of ANI capital stock appraised should initiate any petitions necessary for the perfection of their appraisal rights within the time periods and in the manner prescribed in Section 262. Failure to file a petition for appraisal within the time period specified in Section 262 could result in a loss of appraisal rights.

Within 120 days after the effective time of the merger, any ANI stockholder who has satisfied the requirements of Section 262 will be entitled, upon written request, to receive from ANI a statement setting forth the aggregate number of shares of ANI common stock and ANI preferred stock not voting

in favor of the ANI Proposal No. 1 and with respect to which demands for appraisal were received by ANI and the aggregate number of holders of such shares. Such statement must be mailed within 10 days after the ANI stockholder's request has been received by ANI or within 10 days after the expiration of the period for the delivery of demands as described above, whichever is later.

If a petition for an appraisal is timely filed and a copy thereof is served upon ANI, ANI will then be obligated, within 20 days after such service, to file in the office of the Register in Chancery (the Register) a duly verified list containing the names and addresses of all ANI stockholders who have demanded an appraisal of their shares of ANI capital stock and with whom agreements as to the value of such shares have not been reached. Upon notice to the ANI stockholders, as required by the Delaware Court of Chancery, at a hearing on such petition, the Delaware Court of Chancery will determine which ANI stockholders are entitled to appraisal rights. The Delaware Court of Chancery may require the ANI stockholders who have demanded an appraisal for their shares of ANI capital stock and who hold such stock represented by certificates to submit their certificates of stock to the Register for notation thereon of the pendency of the appraisal proceedings; and if any ANI stockholder fails to comply with such direction, the Delaware Court of Chancery may dismiss the proceedings as to such stockholder. Where proceedings are not dismissed, the Delaware Court of Chancery will appraise the shares of ANI capital stock owned by such stockholders, determining the fair value of such shares exclusive of any element of value arising from the accomplishment or expectation of the merger. When the fair value has been determined, the Delaware Court of Chancery will direct the payment of such value upon surrender by those stockholders of the certificates representing their shares of ANI capital stock. Unless the Delaware Court of Chancery in its discretion determines otherwise for good cause shown, interest from the effective time of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5 percent over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective time of the merger and the date of payment of the judgment.

Although the board of directors of ANI believes that the merger consideration is fair, no representation is made as to the outcome of the appraisal of fair value as would be determined by the Delaware Court of Chancery, and ANI stockholders should recognize that such an appraisal could result in a determination of a value higher or lower than, or the same as, the consideration they would receive pursuant to the merger agreement. Moreover, ANI does not anticipate offering more than the merger consideration to any ANI stockholder exercising appraisal rights and reserves the right to assert, in any appraisal proceeding, that, for purposes of Section 262, the "fair value" of a share of ANI capital stock is less than the merger consideration. In determining "fair value," the Delaware Court of Chancery is required to take into account all relevant factors. In *Weinberger v. UOP, Inc.*, the Delaware Supreme Court discussed the factors that could be considered in determining fair value in an appraisal proceeding, stating that "proof of value by any techniques or methods which are generally considered acceptable in the financial community and otherwise admissible in court" should be considered and that "fair price obviously requires consideration of all relevant factors involving the value of a company." The Delaware Supreme Court has stated that in making this determination of fair value, the court must consider market value, asset value, dividends, earnings prospects, the nature of the enterprise and any other facts which could be ascertained as of the date of the merger which shed any light on the future prospects of the merged corporation. Section 262 provides that fair value is to be "exclusive of any element of value arising from the accomplishment or expectation of the merger." In *Cede & Co. v. Technicolor, Inc.*, the Delaware Supreme Court stated that such exclusion is a "narrow exclusion that does not encompass known elements of value," but which rather applies only to the speculative elements of value arising from such accomplishment or expectation. In *Weinberger*, the Delaware Supreme Court also stated that "elements of future value, including the nature of the enterprise, which are known or susceptible of proof as of the date of the merger and not the product of speculation, may be considered." In addition, Delaware courts have decided that the statutory



appraisal remedy, depending on factual circumstances, may or may not be a dissenting stockholder's exclusive remedy.

The cost of the appraisal proceeding, which does not include attorneys' or experts' fees, may be determined by the Delaware Court of Chancery and imposed upon the dissenting ANI stockholder(s) and/or ANI as the Delaware Court of Chancery deems equitable under the circumstances. Each dissenting ANI stockholder is responsible for his, her or its attorneys' and expert witness fees and expenses, although, upon application of a dissenting ANI stockholder, the Delaware Court of Chancery may order that all or a portion of the expenses incurred by any dissenting ANI stockholder in connection with the appraisal proceeding, including without limitation reasonable attorneys' fees and the fees and expenses of experts, be charged pro rata against the value of all shares of ANI capital stock entitled to appraisal.

Any ANI stockholder who has duly demanded appraisal in compliance with Section 262 will not, after the effective time of the merger, be entitled to vote for any purpose any shares of ANI capital stock subject to such demand or to receive payment of dividends or other distributions on such shares, except for dividends or distributions payable to ANI stockholders of record at a date prior to the effective time of the merger.

At any time within 60 days after the effective time of the merger, any ANI stockholder will have the right to withdraw his, her or its demand for appraisal and to accept the terms offered in the merger agreement. After this period, an ANI stockholder may withdraw his, her or its demand for appraisal and receive payment for his, her or its shares as provided in the merger agreement only with the consent of ANI. If no petition for appraisal is filed with the Delaware Court of Chancery within 120 days after the effective time of the merger, or if any ANI stockholder otherwise fails to perfect, successfully withdraws, or loses such holder's appraisal rights, then such stockholders' right to appraisal will cease and such stockholder's shares of ANI capital stock will be deemed to have been converted at the effective time of the merger into the right to receive the consideration that such ANI stockholder would otherwise be entitled to receive pursuant to the merger agreement. Inasmuch as ANI has no obligation to file such a petition, any ANI stockholder who desires a petition to be filed is advised to file it on a timely basis. Any ANI stockholder may withdraw such stockholder's demand for appraisal by delivering to ANI a written withdrawal of his, her or its demand for appraisal and acceptance of the merger consideration, except that (i) any such attempt to withdraw made more than 60 days after the effective time of the merger will require written approval of ANI and (ii) no appraisal proceeding in the Delaware Court of Chancery shall be dismissed as to any ANI stockholder who commenced or joined such proceeding as a named party without the approval of the Delaware Court of Chancery, and such approval may be conditioned upon such terms as the Delaware Court of Chancery deems just.

Failure by any ANI stockholder to comply fully with the procedures described above and set forth in Annex H to this joint proxy statement/prospectus may result in the loss of such stockholder's appraisal rights. In view of the complexity of exercising appraisal rights under Delaware law, any ANI stockholder considering exercising these rights should consult with legal counsel.

## THE MERGER AGREEMENT

*BioSante and ANI entered into the merger agreement on October 3, 2012. The full text of this agreement is attached as Annex A to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the merger agreement in its entirety for a more complete description of the terms and conditions of the merger and related matters.*

*The representations and warranties described below and included in the merger agreement were made by BioSante and ANI to each other as of specific dates. The assertions embodied in those representations and warranties were made solely for purposes of the merger agreement and may be subject to important qualifications and limitations agreed to by BioSante and ANI in connection with negotiating the terms of the merger agreement. Moreover, the representations and warranties may be subject to a contractual standard of materiality that may be different from what may be viewed as material to stockholders, or may have been used for the purpose of allocating risk between BioSante and ANI rather than establishing matters as facts. The merger agreement is described in this joint proxy statement/prospectus and included as Annex A only to provide you with information regarding the material terms and conditions of the merger agreement, and not to provide any other factual information regarding BioSante, ANI or their respective businesses. Accordingly, you should not rely on the representations and warranties in the merger agreement as characterizations of the actual state of facts about BioSante or ANI, and you should read the information provided elsewhere in this joint proxy statement/prospectus for information regarding BioSante, ANI and their respective businesses.*

### **Structure of the Merger**

Under the merger agreement, ANI will merge with and into BioSante, with BioSante surviving the merger. At the effective time of the merger, the name of the surviving company will be changed to ANI Pharmaceuticals, Inc., subject to approval of the BioSante stockholders of the amendment to BioSante's certificate of incorporation changing the company's name. The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

### **Completion of the Merger**

The completion of the merger will occur at the time that the parties file the certificate of merger with the Secretary of State of the State of Delaware on the closing date of the merger or on such later date as BioSante and ANI may mutually agree (and set forth in the certificate of merger).

The closing of the merger will take place no later than the second business day after the satisfaction or waiver of the conditions to the completion of the merger contained in the merger agreement, other than the conditions which by their terms can be satisfied only as of the closing of the merger or on such other day as BioSante and ANI may mutually agree. For a more complete discussion of the conditions to the completion of the merger, see the section entitled "The Merger Agreement—Conditions to the Completion of the Merger." Because the completion of the merger is subject to the satisfaction of other conditions, BioSante and ANI cannot predict the exact time at which the merger will become effective and be completed, although it is anticipated to be completed during the first quarter of 2013.

### **Merger Consideration and Adjustment**

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. No fractional shares of BioSante common stock will be issued in connection with the merger. Instead, each ANI stockholder who otherwise would be entitled to receive

a fractional share of BioSante common stock (after aggregating all fractional shares of BioSante common stock issuable to such holder) will be entitled to receive an amount in cash (rounded to the nearest whole cent), without interest, determined by multiplying such fraction of a share of BioSante common stock by the closing price of a share of BioSante common stock on The NASDAQ Global Market on the day on which the merger is completed.

Following the consummation of the transactions contemplated by the merger agreement, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of BioSante are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is \$18.0 million. BioSante will issue to the current stockholders of ANI the aggregate number of shares of BioSante common stock necessary for the current ANI stockholders to own 53 percent of the outstanding shares of common stock of the combined company, subject to adjustment based on BioSante's net cash, as discussed below.

The exchange ratio for each share of ANI capital stock will be determined based on the aggregate number of shares of BioSante common stock that BioSante issues in connection with the merger. The aggregate number of shares of BioSante common stock that BioSante issues in connection with the merger will be determined by multiplying 53 percent (subject to adjustment based on BioSante's net cash) multiplied by a fraction the numerator of which is the number of adjusted outstanding shares of BioSante common stock (as described below) and the denominator of which is 47 percent (subject to adjustment based on BioSante's net cash). The number of adjusted outstanding shares of BioSante common stock will be equal to the sum of the total number of shares of BioSante common stock outstanding immediately prior to the merger plus the product of .32 times the number of remaining shares of BioSante common stock that are issuable upon exercise of warrants to purchase an aggregate of 1,039,254 shares of BioSante common stock issued in or around August 2012. Pursuant to the terms of ANI's certificate of incorporation, before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00 (subject to adjustment as provided in ANI's certificate of incorporation) plus all declared but unpaid dividends. As a result of such provisions, it is likely that holders of shares of other series of ANI preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger. Assuming that only holders of ANI series D preferred stock will receive shares of BioSante common stock in connection with the merger, the exchange ratio for each share of ANI series D preferred stock will be determined by dividing the aggregate number of shares of BioSante common stock issued in connection with the merger by the aggregate number of shares of ANI series D preferred stock outstanding immediately prior to the merger.

For illustrative purposes only, if the merger had been completed on December 31, 2012, and assuming BioSante's net cash as of such date was \$18.0 million, the exchange ratio (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus) for the ANI series D preferred stock (including shares that would have been issued to certain executive officers of ANI immediately prior to completion of the merger) would have been approximately 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio (without giving effect to the proposed reverse stock split described elsewhere in this joint proxy statement/prospectus) for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock would have been zero. Therefore, if the merger had been completed on such date and you owned 1,000 shares of ANI series D preferred stock as of such date, you would have had the right to receive 10,350 shares of BioSante common stock in exchange for your shares of ANI series D preferred stock. If you owned 1,000 shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock as of such date, you would have had the right to receive no

shares of BioSante common stock for such shares of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock or ANI common stock.

The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. For a more complete discussion of the determination of BioSante's net cash, see the section entitled "The Merger Agreement—Determination of BioSante's Net Cash." If BioSante has more than \$18.0 million of net cash as of the determination date, then the percentage ownership of BioSante's current stockholders will be increased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash excess and if BioSante has less than \$18.0 million of net cash as of the determination date, then the percentage ownership of BioSante's current stockholders will be decreased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash shortfall, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than \$17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

The following table illustrates the percentage ownership of the combined company by BioSante and ANI current stockholders assuming various amounts of net cash of BioSante as of the determination date.

<b>BioSante's Net Cash as of Determination Date Calculated Pursuant to Merger Agreement</b>	<b>BioSante Stockholder Ownership of Outstanding Shares of Combined Company</b>	<b>ANI Stockholder Ownership of Outstanding Shares of Combined Company</b>
\$23.0 million or more	49.9%	50.1%
22.0 million	49.4%	50.6%
21.0 million	48.8%	51.2%
20.0 million	48.2%	51.8%
19.0 million	47.6%	52.4%
18.0 million	47.0%	53.0%
17.0 million	46.4%	53.6%

The items that will constitute BioSante's net cash balance at the determination date are subject to numerous factors, many of which are outside of BioSante's control. BioSante will issue a news release after the final determination of the exchange ratios announcing the final exchange ratios and BioSante's net cash balance at the determination date. If BioSante's net cash at the closing date is less than \$17.0 million (as calculated and adjusted pursuant to the terms of the merger agreement), based on the manner of calculating net cash pursuant to the merger agreement, BioSante would be unable to satisfy a closing condition for the merger, and ANI could elect to terminate the merger agreement or waive the condition.

#### **Determination of BioSante's Net Cash**

For purposes of determining the exchange ratios, BioSante's net cash will be calculated as of the date that is 14 days prior to the date of the BioSante special meeting as set forth in this joint proxy statement/prospectus, subject to extension for an adjournment of such meeting. For purposes of determining whether BioSante has satisfied the condition to closing that BioSante have no less than \$17.0 million in net cash as of the closing date (as calculated and as adjusted pursuant to the terms of the merger agreement), BioSante's net cash will be calculated shortly before the closing date of the merger. The closing of the merger could be delayed if BioSante and ANI are not able to agree upon the

amount of BioSante's net cash as of the determination date prior to the BioSante special meeting or as of the closing date.

Under the merger agreement, BioSante's "net cash" is defined as the amount of its cash and cash equivalents minus the aggregate amount of the following liabilities:

- accounts payable, accrued compensation (including accrued paid time off, vacation time, bonuses and payments in respect of benefit plans) and other accrued expenses, including certain amounts payable to BioSante employees as a result of the termination of their employment before or within 30 days after the merger or as a result of the merger constituting a change in control under their employment agreements, including severance costs and continuing insurance coverage;
- indebtedness for borrowed money;
- all remaining lease payments under BioSante's lease for its executive offices;
- all out-of-pocket costs in connection with the merger agreement and the transactions contemplated thereby;
- all remaining costs of BioSante's current LibiGel program, including the completion and/or conclusion of any clinical trials, safety studies or other research studies and the cost of keeping in effect any related product liability or similar insurance policies;
- a reserve yet to be determined by BioSante and ANI and currently expected to be approximately \$0 to provide for any out-of-pocket costs associated with any then outstanding litigation of BioSante; and
- one-half of certain settlement payments.

#### **Treatment of ANI Stock Options and Warrants**

All options and warrants to purchase shares of ANI capital stock outstanding immediately prior to the effective time of the merger will terminate and will no longer be outstanding immediately after the merger, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger.

#### **Conditions to Completion of the Merger**

The obligations of each of BioSante and ANI to complete the merger are subject to the satisfaction or waiver (if permissible) at or before the effective time of the merger of the following conditions:

- the adoption by the requisite vote of BioSante stockholders of the merger agreement, including the merger and the issuance of BioSante common stock pursuant to the merger agreement, and approval by the requisite vote of BioSante stockholders of the amendments to BioSante's certificate of incorporation to change the company's corporate name and effect the reverse stock split;
- the adoption of the merger agreement, including the merger, by the requisite vote of ANI stockholders;
- the absence of any legal prohibition to completing the merger;
- the effectiveness of, and the absence of any stop order with respect to, the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part;

- the continued listing of BioSante common stock on The NASDAQ Global Market and the approval for listing on The NASDAQ Global Market or The NASDAQ Capital Market of the shares of BioSante common stock issuable in the merger; and
- the receipt of legal opinions from BioSante's and ANI's outside counsel that the merger will qualify as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended.

In addition, each party's obligation to complete the merger is further subject to the satisfaction or waiver (if permissible) by that party of the following additional conditions:

- the representations and warranties of the other party in the merger agreement being true and correct in all material respects, in each case as of the date of the merger agreement and as of the effective time of the merger, or, if such representations and warranties address matters as of a particular date, then as of that particular date;
- the other party to the merger agreement having performed or complied with in all material respects all agreements and covenants required to be performed or complied with by it at or before the closing of the merger;
- the other party having delivered a certificate signed by a duly authorized officer certifying to the satisfaction of such party of the above conditions in the merger agreement; and
- no material adverse effect on the other party shall have occurred and be continuing since the date of the merger agreement.

In addition, the obligation of ANI to complete the merger is further subject to the satisfaction or waiver at or before the effective time of the merger of the following additional conditions:

- BioSante's net cash as of the closing being no less than \$17.0 million, as calculated and as adjusted as provided in the merger agreement; and
- no new legal proceeding having been instituted against BioSante by any stockholder or holder of BioSante's convertible senior notes that has not been settled prior to the closing.

#### **No Solicitation**

Prior to the consummation of the merger or the termination of the merger agreement in accordance with its terms, BioSante and ANI each agreed that, except as described below, they and any of their subsidiaries will not, and will cause any of their respective officers, directors, employees and advisors retained by them or any of their subsidiaries not to, directly or indirectly:

- solicit, initiate, encourage, facilitate or induce the making of any "acquisition proposal" of the type described below;
- enter into, continue or otherwise participate in any discussions or negotiations regarding or otherwise facilitate or induce any effort or attempt to make or implement any acquisition proposal;
- approve, endorse or recommend any acquisition proposal; or
- agree, resolve or commit to do any of the foregoing.

An "acquisition proposal" is any proposal or offer in a single transaction or series of related transactions, other than pursuant to the merger agreement, with respect to either ANI or BioSante, respectively, involving: (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction pursuant to which a person or group of persons would own 15 percent or

more of the voting power of any class of equity securities of such party; (ii) any issuance of securities representing 15 percent or more of the outstanding shares of any class of voting securities of such party; (iii) any sale, lease, exchange, transfer or other disposition of assets that constitute or represent 15 percent or more of the consolidated net revenue or fair market value of the assets of such party; or (iv) any liquidation or dissolution of such party.

However, prior to BioSante stockholder adoption of the merger agreement, BioSante is permitted to engage in discussions or negotiations with, and provide information to, any person in response to an unsolicited written acquisition proposal that is a "superior proposal" of the type described below or could reasonably be expected to lead to a superior proposal if:

- the BioSante board of directors determines, after receiving the advice of its advisors, that such acquisition proposal is a superior proposal or could reasonably be expected to lead to a superior proposal and that failing to take such action would be inconsistent with its fiduciary duties to the BioSante stockholders;
- the person or group of persons making the acquisition proposal enter into a confidentiality agreement with terms no less restrictive to such person as the terms of the confidentiality agreement between ANI and BioSante; and
- within one day of receipt of an acquisition proposal, BioSante advises ANI in writing of such receipt or any inquiry to request to enter into discussions with respect to an acquisition proposal, provides a summary of the material terms and conditions of such acquisition proposal, the identity of the person making such proposal, and copies of any acquisition proposal and other written materials provided in connection with such acquisition proposal.

In connection with a superior proposal, BioSante may make a change in its board recommendation of the merger and the amendments to BioSante's certificate of incorporation or terminate the merger agreement to enter into such superior proposal concurrent with or immediately following such termination, if:

- the BioSante board of directors determines, after receiving the advice of its advisors, that such acquisition proposal is a superior proposal and that failing to take such action would be inconsistent with its fiduciary duties to the BioSante stockholders; and
- prior to changing its board recommendation or terminating the merger agreement, BioSante gives ANI (i) at least three business days' notice of its intention to change its board recommendation or terminate the merger agreement and the material terms and conditions of such superior proposal, and (ii) the opportunity to negotiate with BioSante during such notice period in good faith to revise the terms and conditions of the merger agreement so that the superior proposal ceases to be a superior proposal.

A "superior proposal" is an bona fide written acquisition proposal, changing the references to 15 percent in the definition of "acquisition proposal" above to be references to 50 percent, which the BioSante board of directors determines, after receiving the advice of its advisors, to be reasonably likely to be consummated if accepted and to be more favorable to the BioSante stockholders from a financial point of view than the merger with ANI, after taking into account, among other factors the BioSante board of directors may deem relevant, the various legal, financial and regulatory aspects of the proposal, all the terms and conditions of the proposal and any changes to the terms of the merger agreement offered by ANI in response to such proposal.

The merger agreement also provides that the parties will keep each other reasonably informed of the status of any negotiations with respect to an acquisition proposal and will provide each other the identity of the person making the proposal and any non-public information provided to any other person in connection with an acquisition proposal.

## **Meetings of Stockholders; Change in Board Recommendation**

BioSante is obligated under the merger agreement to call and hold the BioSante special meeting for purposes of considering the adoption of the merger agreement, the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation. The BioSante board of directors has recommended the adoption of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation by the BioSante stockholders and has agreed that it will not change or publicly propose to change, in any manner adverse to ANI, the approval or recommendation by the BioSante board of directors of the merger agreement, the merger or the issuance of BioSante common stock pursuant to the merger or the amendments to BioSante's certificate of incorporation, or take any action inconsistent with its recommendation. However, the BioSante board of directors may make a change in its recommendation prior to the BioSante stockholder approval of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation under the circumstances described above under the heading "The Merger Agreement—No Solicitation."

Unless the merger agreement is otherwise terminated in accordance with its terms, even if the BioSante board of directors has made an adverse recommendation change regarding the merger and the issuance of the BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation, those proposals must be submitted to the BioSante stockholders at a meeting of the BioSante stockholders called for such purpose.

ANI is obligated under the merger agreement to call and hold the ANI special meeting for purposes of considering the adoption of the merger agreement. The ANI board of directors has recommended the adoption of the merger agreement by the ANI stockholders and has agreed that it will not change or publicly propose to change, in any manner adverse to BioSante, the approval or recommendation by the ANI board of directors of the merger agreement or merger, or take any action inconsistent with its recommendation. However, the ANI board of directors may make a change in its recommendation prior to the ANI stockholder approval of the merger and the merger agreement, if:

- the BioSante board of directors has changed its recommendation of the approval of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the amendments to BioSante's certificate of incorporation by the BioSante stockholders;
- BioSante has engaged in discussions or negotiations with, or provided information to, any person in response to a superior proposal; or
- ANI has terminated the merger agreement.

Unless the merger agreement is otherwise terminated in accordance with its terms or the BioSante board of directors changes its recommendation as described above, even if the ANI board of directors has made an adverse recommendation change regarding the merger, the proposal to adopt the merger agreement must be submitted to the ANI stockholders at a meeting of the ANI stockholders called for such purpose.

## **Covenants; Conduct of Business Pending the Merger**

BioSante and ANI each agreed to certain restrictions on their respective businesses until the later of either the effective time of the merger or the date the merger agreement is terminated. In general, BioSante and ANI must conduct their operations in the ordinary course of business and use their reasonable best efforts to preserve intact their business and keep available the services of their officers and employees. Each of BioSante and ANI also agreed that, subject to certain limited exceptions



described in the merger agreement, without the consent of the other party, it would not, during the period prior to the closing of the merger:

- enter into certain material contracts or terminate or amend any material contracts;
- adopt any new severance plan or grant any severance or termination payments to any officer or director, except in accordance with existing agreements or policies;
- declare dividends or split, combine or reclassify its shares of capital stock;
- amend its certificate of incorporation or bylaws;
- sell or pledge any assets other than immaterial assets;
- incur any indebtedness for borrowed money;
- adopt or amend any employee benefit plan, enter into any employment contract, pay any special bonus to or increase the salaries or wages of any director or employee;
- pay or discharge any material claim or obligation;
- acquire or dispose of any material amount of assets or securities;
- fail to maintain any material intellectual property;
- change its accounting policies and procedures;
- make or change any material tax election, settle or compromise any material tax liability or engage in certain other activities with respect to taxes;
- issue or sell equity securities, options or other securities convertible into or exercisable for equity securities;
- enter into any agreement that would limit it from engaging or competing in any line of business;
- allow any material permit to lapse;
- make material capital expenditures;
- tax any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Internal Revenue Code; or
- agree or commit to do any of the foregoing.

In addition, BioSante agreed that it will, during the period prior to the closing of the merger, make all required filings with the SEC in a timely manner and take all such actions as may be necessary or advisable to effect a conclusion of its LibiGel product clinical trials and safety study in accordance with a budget agreed upon with ANI.

#### **Other Agreements**

Each of BioSante and ANI has agreed:

- to use its reasonable best efforts to cause the registration statement of which this joint proxy statement/prospectus is a part to become effective as promptly as practicable;
- to coordinate with the other in preparing and exchanging information and promptly provide the other with copies of all filings or submissions made in connection with the merger;
- to use its reasonable best efforts to take all actions necessary, proper or advisable to complete the merger and to obtain all consents, approvals and authorizations necessary to complete the merger;

- to use its reasonably best efforts to structure the merger to qualify as a reorganization under Section 368 of the Internal Revenue Code; and
- to consult with each other about any public statement either will make concerning the merger, subject to certain exceptions.

BioSante and ANI also agreed that:

- BioSante will promptly prepare and submit to The NASDAQ Stock Market a listing application covering the shares of BioSante common stock that ANI stockholders will be entitled to receive pursuant to the merger, and to use its reasonable best efforts to obtain approval for the listing of such shares prior to the effective time of the merger.
- The combined company will continue to indemnify each of the directors and officers of BioSante and ANI to the fullest extent permitted under the Delaware General Corporation Law and, for a period of six years after the merger, and will maintain directors' and officers' liability insurance for BioSante's and ANI's directors and officers.
- Immediately prior to the merger, BioSante will terminate all of its employees, including its officers, except for any employees as to whom ANI has delivered written notice that they should not be terminated, if any.
- The directors and officers of the combined company will be as described under the heading "Management of the Combined Company Following the Merger."

## **Termination**

The merger agreement may be terminated at any time before the completion of the merger, whether before or after the required stockholder approvals to complete the merger have been obtained as set forth below:

- by mutual written consent of BioSante and ANI;
- by BioSante or ANI, if the merger has not been completed by May 31, 2013, subject to extension to no later than July 31, 2013, based on the date of filing of the registration statement on Form S-4 of which this joint proxy statement/prospectus forms a part, except that a party whose material breach of the merger agreement resulted in the failure of the merger to occur by such date cannot seek termination for this reason;
- by BioSante or ANI, if any applicable law irrevocably prohibits or makes the merger illegal or a governmental entity has issued a final and non-appealable order, decree or ruling or taken any other action that permanently restrains, enjoins or otherwise prohibits the merger, except that the right to terminate the merger agreement for this reason is not available to any party who has not used reasonable best efforts to cause such law or order to be lifted;
- by BioSante or ANI, if ANI stockholders fail to adopt the merger agreement at the ANI special meeting or if BioSante stockholders fail to adopt the merger agreement, including the merger and the issuance of shares of BioSante common stock pursuant to the merger, and approve the amendments to BioSante's certificate of incorporation at the BioSante special meeting;

- by ANI, if either of the following occur, each a "BioSante triggering event":
  - BioSante fails to include in this joint proxy statement/prospectus the recommendation of the BioSante board of directors to the BioSante stockholders in favor of adoption of the merger agreement, including the merger and the issuance of shares of BioSante common stock in the merger, and approval of the amendments to BioSante's certificate of incorporation; or
  - prior to the BioSante special meeting the BioSante board of directors has withdrawn or made a change, or publicly proposed to withdraw or make a change, in its recommendation to the BioSante stockholders to adopt the merger agreement, including the issuance of shares of BioSante common stock in the merger, and to approve the amendments to BioSante's certificate of incorporation in a manner adverse to ANI;
  - by BioSante, if BioSante enters into a superior proposal in accordance with the terms of the merger agreement. For a more detailed description of BioSante's ability to terminate the merger agreement in connection with a superior proposal, see under the heading above "The Merger Agreement—No Solicitation"; or
  - by BioSante or ANI, if the other party has breached any of its representations, warranties, covenants or other agreements contained in the merger agreement or if any representation or warranty has become inaccurate, in either case such that the conditions to the closing of the merger would not be satisfied, provided that if such breach or inaccuracy is curable, then the merger agreement will not terminate pursuant to this provision as a result of a particular breach or inaccuracy until the expiration of a 30-day period after delivery of notice of such breach or inaccuracy if such breach has not been cured; or
  - by ANI, if after BioSante receives an acquisition proposal, BioSante has materially breached its obligations under the merger agreement with respect to the acquisition proposal.

### Termination Fees and Expenses

BioSante must pay ANI up to \$500,000 of ANI's fees and expenses incurred in connection with the merger if:

- ANI terminates the merger agreement in accordance with the merger agreement because of a BioSante triggering event or an uncured BioSante breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied; or
- BioSante terminates the merger agreement because (i) ANI's stockholders fail to adopt the merger agreement, including the merger, at the ANI stockholder meeting or (ii) the BioSante board of directors changed its recommendation and terminates the merger agreement for the purpose of entering into a superior proposal.

In addition, BioSante must pay ANI a termination fee equal to \$1.0 million, less the amount of any expenses already paid, if any one of the following occurs:

- ANI terminates the merger agreement due to a BioSante triggering event or an uncured BioSante breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied and within 12 months after the date of any such termination BioSante enters into a definitive agreement with respect to (and subsequently consummates) an acquisition proposal (changing the 15 percent amount referred to in the definition of "acquisition proposal" described above under the heading "The Merger Agreement—No Solicitation," to 30 percent for purposes of this provision);
- BioSante terminates the merger agreement because the ANI stockholders did not adopt the merger agreement and within two months after the date of such termination BioSante enters

into a definitive agreement with respect to (and subsequently consummates) an acquisition proposal (using the 30 percent amount described above); or

- BioSante terminates the merger agreement because of a superior proposal in accordance with the merger agreement, as described under the heading above "The Merger Agreement—No Solicitation."

ANI must pay BioSante a termination fee of \$750,000 if BioSante terminates the merger agreement because an uncured ANI breach of the merger agreement that causes the conditions to closing of the merger to not be satisfied.

These termination fees would be the exclusive remedy of the parties for any damages suffered as a result of the failure of the merger to be consummated.

## **Representations and Warranties**

The merger agreement contains customary representations and warranties of ANI and BioSante related to, among other things:

- due organization, good standing and qualification;
- capitalization;
- corporate authority to enter into the merger agreement and complete the merger;
- required stockholder vote to approve the merger and related transactions;
- absence of any breach of organizational documents, laws and agreements as a result of the merger;
- required consents and filings with government entities;
- compliance with applicable laws;
- conformity of the financial statements with applicable accounting principles and that the financial statements fairly present, in all material respects, the consolidated financial positions of BioSante and ANI;
- absence of undisclosed liabilities;
- sufficiency of internal controls over financial reporting;
- absence of material pending or threatened legal proceedings;
- tax matters;
- material contracts;
- employee benefit plans;
- ownership of subsidiaries;
- absence of material changes or events since December 31, 2011;
- approval and adoption of the merger agreement and related matters by the board of directors;
- real property ownership and leases;
- intellectual property;
- regulatory compliance;
- environmental matters;

- labor and employment matters;
- insurance coverage;
- information contained in this joint proxy statement/prospectus;
- affiliate transactions; and
- no finder's fees.

The merger agreement contains additional representations and warranties made of BioSante to ANI related to:

- BioSante's compliance with applicable SEC requirements with respect to, and sufficiency of, documents filed with the SEC by BioSante;
- the registration of BioSante's common stock under the Securities Exchange Act of 1934, as amended, and its listing on The NASDAQ Global Market; and
- certain statements made by BioSante in news releases issued by it in respect of its LibiGel product.

The representations and warranties are, in many respects, qualified by materiality and knowledge, and will not survive the merger, but their accuracy forms the basis of one of the conditions to the obligations of BioSante and ANI to complete the merger.

### **Amendments**

The merger agreement may be amended by the parties at any time, except that after the merger agreement has been adopted (and, in the case of BioSante, the issuance of BioSante common stock and amendments to its certificate of incorporation have been approved) by either the ANI stockholders or the BioSante stockholders, no amendment that by law requires further approval of the ANI stockholders or BioSante stockholders, as applicable, may be made without such further approval.

## VOTING AND OTHER ANCILLARY AGREEMENTS

### **ANI Voting Agreements**

Concurrently and in connection with the execution of the merger agreement, Meridian Venture Partners II, L.P., Argentum Capital Partners II, L.P. and four funds affiliated with First Analysis Corp., who in the aggregate held approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 entered into a voting agreement with BioSante, pursuant to which they agreed to vote their shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. The form of ANI voting agreement is attached as Annex B to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of ANI voting agreement carefully and in its entirety.

In addition, one of ANI's stockholders, Meridian Venture Partners II, L.P., has agreed in its voting agreement with BioSante to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of stockholders of the combined company following completion of the merger. As of October 3, 2012, Meridian Venture Partners II, L.P. held approximately 57 percent of the outstanding shares of ANI capital stock, approximately 60 percent of the outstanding shares of ANI common stock on an as-converted basis and 58 percent of the outstanding shares of ANI series D preferred stock, and is expected to hold approximately 27 percent of the outstanding shares of capital stock of the combined company immediately after completion of the merger. The voting agreement between BioSante and Meridian Venture Partners II, L.P. is attached as Annex C to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the voting agreement between BioSante and Meridian Venture Partners II, L.P. carefully and in its entirety.

The ANI voting agreements will terminate upon the earlier of the consummation of the merger or the termination of the merger agreement, except that, if the merger is completed, the obligation of Meridian Venture Partners II, L.P. to vote in favor of the two directors designated by BioSante under its voting agreement with BioSante will terminate upon the completion of the first annual meeting of stockholders of the combined company following completion of the merger. In addition, the ANI voting agreements will terminate if (1) the BioSante board of directors changes its recommendation that the BioSante stockholders vote in favor of the adoption of the merger agreement and the issuance of BioSante common stock pursuant to the merger and the approval of the amendments to BioSante's certificate of incorporation or (2) if BioSante has engaged in discussions or negotiations with, or provided information to, any person in response to a superior acquisition proposal.

### **BioSante Voting Agreements**

All of BioSante's directors and officers entered into voting agreements with ANI, pursuant to which each stockholder agreed to vote its shares of BioSante capital stock in favor of adoption of the merger agreement and the merger and the other transactions contemplated by the merger agreement, including the approval of the merger and the issuance of shares of BioSante common stock in the merger, and in favor of the two proposed amendments to BioSante's certificate of incorporation as described in this joint proxy statement/prospectus, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transactions contemplated by the merger agreement. As of October 3, 2012, such BioSante stockholders collectively held approximately two percent of the outstanding shares of BioSante capital stock. The form of the BioSante voting agreement is attached as Annex D to this joint proxy statement/prospectus and is incorporated by

reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of BioSante voting agreement carefully and in its entirety.

The BioSante voting agreements will terminate upon the earlier of the consummation of the merger or the termination of the merger agreement.

### **Lock-Up Agreements**

Concurrently and in connection with the execution of the merger agreement, ANI's chief executive officer and chief financial officer, both of whom are entitled to receive shares of ANI series D preferred stock prior to completion of the merger as described under the heading "Interests of ANI's Directors and Officers in the Merger," and each of the ANI stockholders that entered into voting agreements with BioSante in connection with the execution of the merger agreement, entered into lock-up agreements with BioSante pursuant to which the shares of BioSante common stock received by those ANI stockholders in the merger may not be sold, transferred or encumbered for a 180-day period following completion of the merger, except in limited circumstances. The form of the lock-up agreement is attached as Annex E to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus.

## CONTINGENT VALUE RIGHTS

### General

Under the terms of the merger agreement, BioSante has the right in its sole discretion to distribute and issue contingent value rights (CVRs), to holders of BioSante common stock as of immediately prior to completion of the merger. As of the date of this joint proxy statement/prospectus, BioSante plans to distribute and issue CVRs to holders of record of BioSante common stock as of March 15, 2013. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of the record date for the distribution of the CVRs. Since shares of BioSante class C special stock are not entitled to receive any distributions or dividends, holders of BioSante class C special stock will not be entitled to receive any CVRs, if CVRs are issued.

### Contingent Value Rights Agreement

BioSante plans to enter into a contingent value rights agreement with Computershare Inc., as rights agent, for the purpose of establishing the terms and conditions of the CVRs and the procedures by which payments, if any, will be made to the CVR holders. The form of the contingent value rights agreement is attached as Annex F to this joint proxy statement/prospectus and is incorporated by reference into this joint proxy statement/prospectus. BioSante and ANI urge you to read the form of the contingent value rights agreement carefully and in its entirety.

### Material Terms of the CVRs

The CVRs will not be certificated and will not be attached to the shares of BioSante common stock. The CVRs will be nontransferable, subject to certain limited exceptions as set forth in the contingent value rights agreement. The CVRs will not represent an equity or ownership interest in the combined company or otherwise, and CVR holders will have no voting or dividend rights. The rights of CVR holders will be limited to those rights expressly set forth in the contingent value rights agreement.

Pursuant to the contingent value rights agreement, CVR holders, under certain circumstances, may have rights to receive a portion of the net cash proceeds actually received by the combined company in connection with a LibiGel transaction. A "LibiGel transaction" for purposes of the contingent value rights agreement means a full or partial sale, license, transfer or other disposition entered into by the combined company with respect to the LibiGel assets. The "LibiGel assets" for purposes of the contingent value rights agreement mean the intellectual property rights and know-how and related assets, that currently are or have been used in the research, development and manufacture of BioSante's LibiGel product, a proprietary transdermal testosterone formulation subject to a license agreement with Antares Pharma Inc., including all BioSante generated regulatory filings, clinical and non-clinical safety, efficacy and pharmacokinetic data, compiled by or on behalf of BioSante in connection with the development of the LibiGel product.

Subject to the terms and conditions of the contingent value rights agreement, if the combined company consummates a LibiGel transaction within the 10-year period following completion of the merger, CVR holders will be entitled to receive cash payments equal to such holder's pro rata portion of 66 percent of the net cash proceeds actually received by the combined company in connection with such LibiGel transaction during the 10-year period following completion of the merger, up to an aggregate of \$40.0 million. If the combined company does not consummate a LibiGel transaction during the 10-year period following completion of the merger, no cash payment will be payable to CVR holders.

Under the contingent value rights agreement, the combined company's only obligation will be to act in good faith in connection with: (1) any continued operation of, development of or investment in



the LibiGel assets; (2) pursuing, negotiating or entering into one or more LibiGel transactions; and (3) the terms and conditions of any LibiGel transaction.

**Discretion of BioSante to Issue CVRs**

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to holders of BioSante common stock, there is no assurance that BioSante will distribute and issue the CVRs at all or based on the terms currently set forth in the form of contingent value rights agreement attached as Annex F to this joint proxy statement/prospectus. As of the date of this joint proxy statement/prospectus, BioSante has not entered into the contingent value rights agreement and it is possible that the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the tax impact to the holders of BioSante common stock of the distribution and issuance of the CVRs. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as currently contemplated may be changed prior to BioSante entering into the contingent value rights agreement.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE MERGER

The following discussion summarizes the material U.S. federal income tax consequences of the merger. This summary is based upon current provisions of the Code, existing Treasury Regulations promulgated thereunder and current administrative rulings and court decisions, all of which are subject to change and to differing interpretations, possibly with retroactive effect. Any change could alter the tax consequences to BioSante, ANI or ANI stockholders, as described in this summary. This summary is not binding on the IRS, and there can be no assurance that the IRS (or a court, in the event of an IRS challenge) will agree with the conclusions stated herein.

This discussion does not address all of the U.S. federal income tax consequences of the merger that may be relevant to ANI stockholders and BioSante stockholders in light of their particular circumstances and does not apply to stockholders that are subject to special treatment under U.S. federal income tax laws, including, without limitation:

- dealers, brokers and traders in securities;
- individuals who are not citizens or residents of the U.S., including U.S. expatriates;
- corporations (or other entities taxable as a corporation for U.S. federal income tax purposes) created or organized outside of the U.S.;
- tax-exempt entities;
- financial institutions, regulated investment companies, real estate investment trusts or insurance companies;
- partnerships, limited liability companies that are not treated as corporations for U.S. federal income tax purposes, subchapter S corporations and other pass-through entities and investors in such entities;
- an estate or trust;
- holders who are subject to the alternative minimum tax provisions of the Code;
- holders who acquired their shares in connection with stock option or stock purchase plans or in other compensatory transactions;
- holders who hold their shares through a pension plan or other qualified retirement plan;
- holders who hold their shares as part of an integrated investment such as a hedge or as part of a hedging, straddle or other risk reduction strategy;
- holders who do not hold their shares as capital assets within the meaning of Section 1221 of the Code (generally, property held for investment will be a capital asset); or
- holders who have a functional currency other than the U.S. dollar.

In addition, the following discussion does not address:

- the tax consequences of the merger under any U.S. federal non-income tax laws or under state, local or foreign tax laws;
- the tax consequences of transactions effectuated before, after or at the same time as the merger, whether or not they are in connection with the merger;
- the tax consequences of the exchange of any ANI capital stock that constitutes "Section 306 stock" within the meaning of Section 306 of the Code;
- the tax consequences of the receipt of shares of BioSante common stock other than in exchange for shares of ANI capital stock;

- the tax consequences of the ownership or disposition of shares of BioSante common stock acquired in the merger; or
- all of the tax implications of a failure of the merger to qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

**Accordingly, ANI stockholders are advised and expected to consult their own tax advisors regarding the U.S. federal income tax consequences of the merger in light of their personal circumstances and the consequences of the merger under U.S. federal non-income tax laws and state, local and foreign tax laws.**

#### ***U.S. Federal Income Tax Consequences of the Merger***

The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Code. BioSante and ANI have agreed to use reasonable best efforts to structure the merger to qualify as a "reorganization" and not to take any action that would prevent the merger from qualifying as a reorganization under Section 368(a) of the Code. Further, as a condition to the completion of the merger, Oppenheimer Wolff & Donnelly LLP must render a tax opinion to BioSante that the merger will constitute a "reorganization" within the meaning of Section 368(a) of the Code and SNR Denton US LLP must render a tax opinion to ANI that the merger will constitute a "reorganization" within the meaning of Section 368(a) of the Code. Neither BioSante nor ANI presently intends to waive these conditions. The tax opinions discussed in this section will be conditioned upon certain assumptions and qualifications stated in the tax opinions and will be based on the truth, accuracy, and completeness, as of the completion of the merger, of certain representations and other statements made by each of BioSante and ANI, as applicable, in letters delivered to counsel rendering such opinions.

Neither BioSante nor ANI will request a ruling from the IRS regarding the tax consequences of the merger. The opinions of counsel do not bind the IRS or courts of law and thus do not prevent the IRS from asserting a contrary position, or a court from upholding any such assertion. In addition, if any of the representations or assumptions upon which the opinions are based are inconsistent with the actual facts, the tax consequences of the merger and the vitality of the opinions could be adversely affected.

It is expected that Oppenheimer Wolff & Donnelly LLP and SNR Denton US LLP, subject to the qualifications described above, will each deliver an opinion that the merger will be treated for U.S. federal income tax purposes as a "reorganization" within the meaning of Section 368(a) of the Code. Assuming that the merger will qualify as a "reorganization" within the meaning of Section 368(a) of the Code, the following material U.S. federal income tax consequences should result:

- BioSante, ANI and the BioSante stockholders generally will recognize no gain or loss solely as a result of the merger;
- ANI stockholders, other than ANI stockholders who exercise appraisal rights (as discussed below), generally will recognize no gain or loss upon the receipt of BioSante common stock for their ANI capital stock, other than with respect to cash received in lieu of fractional shares of BioSante common stock (as discussed below);
- the aggregate tax basis of the shares of BioSante common stock that are received by an ANI stockholder in the merger will be equal to the aggregate tax basis of the shares of ANI capital stock surrendered in exchange therefor, reduced by any amount allocable to a fractional share of BioSante common stock for which cash is received;
- the holding period of the shares of BioSante common stock received by an ANI stockholder in connection with the merger will include the holding period of the shares of ANI capital stock surrendered in exchange therefor; and

- an ANI stockholder who receives cash instead of a fractional share of BioSante common stock generally will recognize a capital gain or loss in an amount equal to the difference, if any, between such stockholder's basis in the fractional share and the amount of cash received.

There will be no material U.S. federal income tax consequences of the merger for BioSante stockholders whether or not the merger qualifies as a "reorganization" within the meaning of Section 368(a) of the Code.

#### ***Treatment of ANI Stockholders Who Exercise Appraisal Rights***

The discussion above does not apply to ANI stockholders who properly perfect appraisal rights with respect to such stockholder's shares of ANI capital stock. Generally, an ANI stockholder who perfects appraisal rights and receives cash in exchange for such stockholder's ANI capital stock will recognize capital gain or loss measured by the difference between the amount of cash received and such stockholder's adjusted tax basis in those shares. Such gain or loss will generally be long-term capital gain or loss, provided the shares of ANI capital stock were held for more than one year before the disposition of the shares. The deductibility of capital losses is subject to limitations.

#### ***Information Reporting and Backup Withholding***

Generally, non-corporate ANI stockholders may be subject to information reporting and backup withholding (currently at a rate of 28 percent) with respect to cash received in lieu of a fractional share interest in BioSante common stock or cash received for perfecting appraisal rights. However, backup withholding will not apply to an ANI stockholder who furnishes a valid taxpayer identification number and complies with certain certification procedures or otherwise establishes an exemption from backup withholding. Backup withholding is not an additional U.S. federal income tax. Any amounts so withheld will be allowed as a refund or credit against the ANI stockholder's U.S. federal income tax liability (if any), provided that the ANI stockholder timely furnishes the required information to the IRS.

**The foregoing summary of material U.S. federal income tax consequences is not intended to be a complete analysis or description of all potential U.S. federal income tax consequences of the merger. In addition, the summary does not address tax consequences that may vary with, or are contingent on, individual circumstances. Moreover, the summary does not address any U.S. federal non-income tax or any foreign, state or local tax consequences of the merger, nor any tax consequences of any transaction other than the merger. Accordingly, each ANI stockholder is strongly urged to consult his, her or its own tax advisor to determine the particular federal, state, local, or foreign income or other tax consequences of the merger to such ANI stockholder.**

## BIOSANTE'S BUSINESS

### Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

BioSante's products, either approved or in clinical development, include:

- LibiGel—once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).
- Male testosterone gel—once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).
- GVAX cancer vaccines—a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.
- The Pill-Plus (triple component contraceptive)—once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.
- Elestrin—once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda Pharmaceuticals), BioSante's licensee.

BioSante's corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of BioSante's corporate strategy, BioSante seeks to implement strategic alternatives with respect to its products and its company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, from time to time, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies, with the goal of maximizing stockholder value.

BioSante's lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and a LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

BioSante is in the process of developing a protocol for the two new efficacy trials and applying for an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials. BioSante expects that any potential new LibiGel Phase III efficacy trials would include the same FDA-required efficacy endpoints as its prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials would be similar to the cost of the previous trials, approximately \$15 to \$18 million each, or a combined \$30 to \$36 million spread

over approximately 18 months. No assurance can be provided that these cost estimates will be correct or that BioSante, if it decides to pursue the trials, will be able to obtain the necessary working capital to fund the trials. In addition, no assurance can be provided that BioSante will be able to design the two new efficacy trials to the FDA's satisfaction or to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials.

With respect to BioSante's LibiGel Phase III safety study, in September 2012, BioSante announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised BioSante that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained.

Elestrin is BioSante's first FDA approved product and now is one of BioSante's two FDA approved products. Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business and which in turn acquired Azur Pharma International II Limited (Azur), BioSante's prior licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to \$140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante's male testosterone gel is its second FDA approved product. This product initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

BioSante's GVAX cancer vaccines, which are designed to stimulate a patient's immune system to fight effectively the patient's own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines—to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma—have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and BioSante's licensees. BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of BioSante's GVAX cancer vaccine portfolio to its stockholders. This objective includes monetizing the entire

portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transaction with an unidentified third party pursuant to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

**BioSante's Primary Product Portfolio**

Product	Indication	Early Human Clinical	Late Human Clinical	FDA Approval	Collaborations
LibiGel® (testosterone gel)	Female sexual dysfunction (FSD)	→			Non-partnered
Male Testosterone Gel	Male hypogonadism	→			Teva
GVAX Cancer Vaccines	Various cancers	→			Aduro BioTech, The John P. Hussman Foundation, Johns Hopkins
The Pill Plus™ (birth control with androgen)	Contraception	→			Pantarhei for oral use
Elestrin™ (estradiol gel)	Menopausal symptoms	→			Meda Pharmaceuticals

**Description of BioSante's Female Sexual Health, Menopause, Contraception and Male Hypogonadism Products**

**Overview.** BioSante's products for female sexual health, menopause, contraception and male hypogonadism include its gel formulations of estradiol or testosterone and combinations of estrogen, progesterone and androgen.

BioSante's gel products are designed to be quickly absorbed through the skin after application on the upper arm for the women's products, delivering the active component to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue and to dry in under one to two minutes. BioSante believes its gel products have a number of benefits over competitive products, including the following:

- BioSante's transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus transdermal patches;
- BioSante's transdermal gels have been shown to be well absorbed, thus allowing effective therapeutic levels to reach the systemic circulation;
- transdermal gels may allow for better dose adjustment than either transdermal patches or oral tablets or capsules; and
- transdermal gels may be more appealing to patients since they are less conspicuous than transdermal patches, which may be aesthetically unattractive.

BioSante licenses the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). BioSante's male testosterone gel was developed by BioSante and

licensed to Teva. BioSante licenses the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center.

**LibiGel.** BioSante's lead product in development is LibiGel, a once daily transdermal testosterone gel designed to treat FSD, specifically HSDD in postmenopausal women.

Although generally thought of as being limited to men, testosterone also is important to women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone therapy in women can boost sexual desire, sexual activity and pleasure, increase bone density, raise energy levels and improve mood. According to a study published in the *Journal of the American Medical Association*, 43 percent of American women between the ages of 18 to 59, or about 40 million women, experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex (low sexual desire). Furthermore, according to a study published in the *New England Journal of Medicine*, 43 percent of American women between the ages of 57 to 85 experience low sexual desire. Importantly, according to IMS data, approximately two million testosterone prescriptions were written off-label for women in the U.S. in 2010. In addition, according to independent primary market research, approximately two million additional prescriptions of compounded testosterone were written for women in the U.S. in 2010. Female sexual dysfunction is defined as a consistent lack of sexual desire, arousal or pleasure. The majority of women with FSD are postmenopausal, experiencing symptoms due to hormonal changes that occur with aging or following surgical menopause.

Although treatment with LibiGel in BioSante's Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD, the Phase III efficacy trials did not meet the co-primary endpoints of increase in satisfying sexual events or increase in sexual desire or the secondary endpoint of decrease in sexual distress. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline; this increase also was significant versus placebo. In this trial, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, in surgically menopausal women distressed by their low sexual desire and activity.

The Phase III safety and efficacy trials were randomized, double-blind, placebo-controlled, multi-center trials of a total of 1,172 menopausal women, exposed to LibiGel or placebo for six months. Subjects in the first trial, called BLOOM-1, who were treated with LibiGel showed an increase of 1.47 days with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.26 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.463. (The smaller the p value, the stronger the statistical significance. A p-value of .05 or less is typically used to represent statistical significance of trial results.) In BLOOM 1, there was an increase in the total number of satisfying sexual events of 3.87 from baseline (an increase of 83 percent) in the LibiGel group and in the placebo group there was an increase of 3.52 satisfying sexual events from baseline (an increase of 65 percent) for a p value of 0.698. Subjects in BLOOM-2 who were treated with LibiGel showed an increase of 1.0 day with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.28 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.214. Subjects in BLOOM-1 showed an increase in mean sexual desire of 0.03 over placebo, a p value of 0.672, while subjects in BLOOM-2 demonstrated an increase in mean sexual desire of 0.03 compared to placebo, a p value of 0.48. Subjects in both trials demonstrated a decrease in sexual distress when treated with LibiGel (p=0.569 and p=0.26) compared to baseline.



As seen in previous pharmacokinetic data, the LibiGel groups in both Phase III efficacy trials showed an increase in free testosterone levels compared to baseline and placebo. In BLOOM-1, mean free testosterone at baseline was approximately 1.19 picograms per milliliter (pg/ml) and 1.10 pg/ml in the placebo and LibiGel groups, respectively. In month six of the trial, free testosterone levels were approximately 1.35 pg/ml and 4.01 pg/ml in the placebo and LibiGel groups, respectively. In BLOOM-2, mean free testosterone at baseline was approximately 1.06 pg/ml and 1.19 pg/ml in the placebo and LibiGel group, respectively. In month six of the trial, free testosterone levels were approximately 1.09 pg/ml and 3.70 pg/ml in the placebo and LibiGel groups, respectively.

Results of the two Phase III efficacy trials were announced on December 14, 2011. Subsequently, BioSante continued to analyze the data from the Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

In September 2012, BioSante announced that the independent DMC completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised BioSante that subjects in the safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained. BioSante remains blinded as to whether the CV events and breast cancers are experienced by subjects in the LibiGel arm or the placebo arm of the study.

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials.

**Male Testosterone Gel.** BioSante's once daily transdermal testosterone gel indicated for the treatment of hypogonadism, or testosterone deficiency, in men is BioSante's second FDA approved product.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone also may experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Testosterone therapy has been shown to restore levels of testosterone with minimal side effects.

There are currently several products on the market for the treatment of low testosterone levels in men. As opposed to estrogen therapy products, oral administration of testosterone is currently not possible as the hormone is, for the most part, rendered inactive in the liver making it difficult to achieve adequate levels of the compound in the bloodstream. Current methods of administration include testosterone injections, patches and gels. Testosterone injections require large needles, are often painful and not effective for maintaining adequate testosterone blood levels throughout the day.

Delivery of testosterone through transdermal patches was developed primarily to promote the therapeutic effects of testosterone therapy without the often painful side effects associated with testosterone injections. Transdermal patches, however, similar to estrogen patches, have a physical presence, can fall off and can result in skin irritation. Testosterone gel formulated products for men are designed to deliver testosterone without the pain of injections and the physical presence, skin irritation and discomfort associated with transdermal patches. BioSante is aware of four gel testosterone products for men currently on the market in the United States.

Unlike LibiGel and Elestrin, BioSante's male testosterone gel was developed by BioSante and therefore BioSante has no royalty or milestone obligations to any other party. BioSante's male testosterone gel is subject to a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Under the development and license agreement, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a \$1.5 million upfront payment by Teva, which was paid to BioSante in December 2002, and an obligation by Teva to pay BioSante certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more detail below. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. BioSante may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

In October 2012, BioSante and Teva entered into an amendment to the development and license pursuant to which Teva made a \$1.0 million payment to BioSante upon the signing of the amendment and agreed to make the following milestone based payments to BioSante: (1) \$500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an "AB-rated" equivalent to AndroGel®; (2) \$750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva's submission to the FDA of a final report regarding a "washing" clinical study required by the FDA; and (3) \$500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva's commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay BioSante \$4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to BioSante under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

**The Pill-Plus.** The Pill-Plus is based on three issued U.S. patents claiming triple component therapy via any route of administration (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone). The Pill-Plus adds a third component, an androgen, to the normal two component (estrogen and progestogen) oral contraceptive to prevent testosterone deficiency which can result from the estrogen and progestogen components and which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousability and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to avoid or to improve the symptoms of female sexual dysfunction in oral contraceptive users.

BioSante has an exclusive license from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center for the three issued U.S. patents for triple component contraception. The financial terms of the license include an upfront payment, regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed.

The Pill-Plus is subject to a sublicense agreement with Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market the product. BioSante may receive certain development and regulatory milestones for the first product developed under the license. In addition, BioSante will receive royalty payments on any sales of the product in the U.S., if and when approved and marketed. If the product is sublicensed by Pantarhei to another company, BioSante will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. BioSante has retained all rights under its licensed patents to the transdermal delivery of triple component contraceptives.

**Elestrin.** Elestrin is BioSante's first FDA approved product. Elestrin is a once daily transdermal gel that delivers estrogen without the skin irritation associated with, and the physical presence of, transdermal patches, and to avoid the effects of oral estrogen. Elestrin contains estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen.

Elestrin is indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. Elestrin is administered using a metered dose applicator. Two doses of Elestrin were approved by the FDA.

Meda Pharmaceuticals Inc. is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur (which was acquired by Jazz Pharmaceuticals, Inc. which subsequently sold its women's health business to Meda Pharmaceuticals) pursuant to which BioSante received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to \$140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

Elestrin also is subject to an exclusive agreement with Valeant Pharmaceuticals International, Inc. (which acquired PharmaSwiss SA) for the marketing of Elestrin in Israel. Valeant Pharmaceuticals will be responsible for regulatory and marketing activities in Israel. Israeli authorities have approved Elestrin, but the product has not been launched.

**Other Products.** Marketing rights to BioSante's gel products in Canada are subject to an agreement with Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in BioSante's company, make future milestone payments and pay royalties on sales of the

products in Canada. The milestone payments are required to be in the form of a series of equity investments by Paladin in BioSante's common stock at a 10 percent premium to the market price of its stock at the time the equity investment is made. No recent investments have been made and none are expected in the foreseeable future.

### **Description of BioSante's GVAX Cancer Vaccines and Other Technologies**

**GVAX Cancer Vaccine Technology.** BioSante's GVAX cancer vaccines are designed to stimulate the patient's immune system to effectively fight cancer. BioSante's cancer vaccines are comprised of tumor cells that are genetically modified to secrete an immune-stimulating cytokine known as granulocyte-macrophage colony-stimulating factor (GM-CSF), and are then irradiated for safety. Since BioSante's cancer vaccines consist of whole tumor cells, the cancer patient's immune system can be activated against multiple tumor cell components, or antigens, potentially resulting in greater clinical benefit than if the vaccine consisted of only a single tumor cell component. Additionally, the secretion of GM-CSF by the modified tumor cells can enhance greatly the immune response by recruiting and activating dendritic cells at the injection site, a critical step in the optimal response by the immune system to any immunotherapy product. The antitumor immune response which occurs throughout the body following administration of BioSante's cancer vaccine potentially can result in the destruction of tumor cells that persist or recur following surgery, radiation therapy or chemotherapy treatment.

BioSante's cancer vaccines can be administered conveniently in an outpatient setting as an injection into the skin, a site where immune cells, including in particular dendritic cells, can be optimally accessed and activated. These cancer vaccines are being tested primarily as non patient-specific, or allogeneic, vaccines. BioSante's GVAX cancer vaccines are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines—to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma—have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving BioSante's GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and BioSante's licensees.

In March 2011, BioSante licensed aspects of its GVAX pancreas cancer vaccine and GVAX prostate cancer vaccine to Aduro BioTech, Inc., a clinical-stage immunotherapy company, solely for use in combination with Aduro's proprietary vaccine platform based on *Listeria monocytogenes* (Lm). Under the agreement, BioSante is entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using its GVAX cancer vaccine technology in combination with Aduro's vaccines.

In July 2011, BioSante announced an exclusive worldwide license of its melanoma vaccine to The John P. Hussman Foundation (Hussman Foundation), in exchange for its receipt of an upfront license fee, milestone payments, royalties on any sales and a percentage of any sublicense fees. Additionally, the Hussman Foundation has committed up to approximately \$11 million in GVAX melanoma vaccine Phase I and Phase II clinical development funding.

BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of BioSante's GVAX cancer vaccine portfolio to the BioSante stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transaction with an unidentified third party pursuant to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

**Oncolytic Virus Technology.** In November 2010, BioSante entered into an assignment and technology transfer agreement with Cold Genesys, Inc. pursuant to which BioSante sold to Cold

Genesys exclusive, worldwide rights to develop and commercialize its oncolytic virus technology. The oncolytic virus technology uses replication-competent adenoviruses derived from Adenovirus type 5, a common "cold" virus that replicate in and selectively kill tumor cells. The replication of the virus is controlled by replacing the promoter of a gene required for replication with a promoter that is preferentially expressed only in tumor cells. Furthermore, the virus may optionally include a gene encoding a cytokine, which enhances immune stimulation to the tumor, thereby providing a dual mechanism of action for killing targeted cancer cells by direct cell lysis as well as via cellular and humoral immune responses to the tumor. The oncolytic virus technology includes CG0070, a replication-competent adenovirus that has completed a Phase I clinical trial for treatment of superficial bladder cancer. In exchange for the technology, BioSante received an initial 19.9 percent ownership position in Cold Genesys and a \$95,000 upfront cash payment and is eligible to receive future milestone and royalty payments.

## **Sales and Marketing**

BioSante currently has no sales and marketing personnel to sell any of its products on a commercial basis. Under BioSante's license agreements, its licensees have agreed to market the products covered by the agreements in certain countries. For example, under BioSante's license agreement with Meda Pharmaceuticals, Meda Pharmaceuticals has agreed to use commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States, and under BioSante's agreement with Teva, Teva has agreed to use commercially reasonable efforts to market its male testosterone gel in the United States. If and when BioSante is ready to launch commercially a product not covered by its license agreements, BioSante will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist BioSante with this function.

## **Research and Product Development**

BioSante historically has spent a significant amount of its financial resources on product development activities, with the largest portion being spent on clinical studies for LibiGel. BioSante spent approximately \$44.2 million in 2011, \$39.7 million in 2010 and \$13.7 million in 2009 on research and product development activities. BioSante spent an average of approximately \$3.7 million per month on its research and product development activities during 2011, the substantial majority of which was spent on its LibiGel Phase III clinical studies. BioSante incurred expenses of \$14.5 million on research and development activities during the nine months ended September 30, 2012, the substantial majority of which was spent on its LibiGel Phase III cardiovascular events and breast cancer study, and which is a 61 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of BioSante's prior two LibiGel Phase III efficacy trials at the end of 2011. BioSante anticipates that its research and development expenses for 2013 will consist primarily of expenses associated with the conclusion of the safety study and the planning for the two new LibiGel Phase III efficacy trials.

## **Manufacturing**

BioSante does not have any facilities suitable for manufacturing on a commercial scale basis any of its products nor does it have any experience in volume manufacturing. BioSante currently uses third-party current Good Manufacturing Practices (cGMP), manufacturers to manufacture its products in development in accordance with FDA and other appropriate regulations.

## **Patents, Licenses and Proprietary Rights**

BioSante's success depends and will continue to depend in part upon its ability to maintain its exclusive licenses, to obtain and maintain patent protection for its products and processes, to preserve its proprietary information, trademarks and trade secrets and to operate without infringing the

proprietary rights of third parties. BioSante's policy is to attempt to protect its technology by, among other things, filing patent applications or obtaining license rights for technology that BioSante considers important to the development of its business.

**Gel Products.** BioSante licensed the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. Under the agreement, Antares granted BioSante an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories, including the U.S., Canada, New Zealand, South Africa, Israel, Mexico, China (including Hong Kong) and Indonesia. BioSante is the exclusive licensee in certain territories for issued U.S. patents for these products and additional patent applications have been filed for this licensed technology in the U.S. and several foreign jurisdictions. Under the agreement, BioSante is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its sub-licensees sell incorporating the in-licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee.

BioSante and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if BioSante does not continue development, seeking regulatory approval or marketing of such products in the covered territories. BioSante may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

The patents covering the formulations used in these gel products are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. In addition, BioSante has other patents pending, which, if issued, may expire later than 2028. BioSante's male testosterone gel was developed by BioSante and not covered under the Antares license.

**GVAX Cancer Vaccine Technology.** BioSante owns development and commercialization rights to its GVAX cancer vaccine technology as a result of its merger with Cell Genesys in October 2009. The patent estate covering BioSante's cancer vaccine technology is licensed exclusively to BioSante from Johns Hopkins University and The Whitehead Institute for Biomedical Research. In addition, BioSante owns several patents and patent applications that build upon its in-licensed technology, and provides for significant additional patent term.

BioSante's cancer vaccine patent estate broadly covers its cancer vaccine products and pipeline. The cancer vaccine patent estate includes 17 patent families, comprising over 50 issued US and foreign patents, directed to various aspects of BioSante's cancer vaccine technology. The patents expire between 2012 and 2026.

Under the various agreements, BioSante is required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its sub-licensees sell incorporating the in-licensed technology. BioSante currently is negotiating the terms of a potential transaction with an unidentified third party pursuant to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

**The Pill Plus.** BioSante licensed the technology underlying its triple component contraceptives, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed. The patents covering the technology underlying The Pill Plus expire in 2016.

**Trademarks and Trademark Applications/Registrations.** BioSante owns trademark registrations in the U.S. and/or in certain foreign jurisdictions for several marks, including BIOSANTE® and LIBIGEL®. In addition, BioSante has filed trademark applications for several other marks including ELESTRIN™ (pursuant to a license agreement regarding Elestrin, the Elestrin trademark in the U.S. is now owned by Meda Pharmaceuticals). In addition, BioSante owns common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, GVAX™, THE PILL-PLUS™ and ELESTRIN™. For those trademarks for which registration has been sought, registrations have issued for some of those trademarks in certain jurisdictions and others currently are in the application/prosecution phase.

**Confidentiality and Assignment of Inventions Agreements.** BioSante requires its employees, consultants and advisors having access to its confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with BioSante. These agreements generally provide that all confidential information BioSante develops or makes known to the individual during the course of the individual's employment or consulting relationship with BioSante must be kept confidential by the individual and not disclosed to any third parties. BioSante also requires all of its employees and consultants who perform research and development for BioSante to execute agreements that generally provide that all inventions and works-for-hire conceived by these individuals during their employment by BioSante will be BioSante's property.

## Competition

There is intense competition in the biopharmaceutical industry. Potential competitors in the United States are numerous and include major pharmaceutical and specialized biotechnology companies, universities and other institutions. In general, competition in the pharmaceutical industry can be divided into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions. Many of BioSante's competitors have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than BioSante does, as well as substantially greater experience than BioSante in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. A significant amount of research is carried out at academic and government institutions. These institutions are aware of the commercial value of their findings and are aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

There are several firms currently marketing or developing products that may be competitive with BioSante's gel products. They include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc. (a subsidiary of Hisamitsu Pharmaceutical Co., Inc.), Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc. and Abbott Laboratories. Competitor products include oral tablets, transdermal patches, a spray and gels. BioSante expects its FDA-approved products, Elestrin and its male testosterone gel, and its other products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position and potentially on cost. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market and may result in certain marketing exclusivity as per federal legislation. Acceptance by physicians and other health care providers, including managed care groups, also is critical to the success of a product versus competitor products.

With regard to BioSante's GVAX cancer vaccine technology and other related technologies, BioSante faces substantial competition in the development of products for cancer and other diseases. This competition from other manufacturers is expected to continue in both U.S. and international markets. Cancer vaccines are evolving areas in the biotechnology industry and are expected to undergo many changes in the coming years as a result of technological advances. BioSante currently is aware of a number of groups that are developing cancer vaccines including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. Examples in the cancer vaccine area include Dendreon Corporation, which has an FDA approved vaccine for prostate cancer.

## **Governmental Regulation**

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies in countries in which they do business. Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA regulations in the United States and by comparable regulations in foreign countries. Any products developed by BioSante will require FDA approvals in the United States and comparable approvals in foreign markets before they can be marketed.

The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) and other federal and state statutes and regulations govern or influence, among other things, the development, testing, manufacture, safety, labeling, storage, recordkeeping, approval, advertising, promotion, sale, import, export and distribution of pharmaceutical products in the United States. Pharmaceutical manufacturers also are subject to certain record-keeping and reporting requirements, establishment registration and product listing, and FDA inspections.

Manufacturers of controlled substances also must comply with the federal Controlled Substances Act of 1970 (CSA) and regulations promulgated by the U.S. Drug Enforcement Administration (DEA), as well as similar state and local regulatory requirements for manufacturing, distributing, testing, importing, exporting and handling controlled substances.

Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, and criminal prosecution.

Product development and approval within the FDA regulatory framework take a number of years, involve the expenditure of substantial resources, and are uncertain. Many products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA's other regulatory requirements. After a product is approved, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies or evidence of safety concerns. Further, the current regulatory framework may change and additional regulatory or approval requirements may arise at any stage of BioSante's product development that may affect approval, delay the submission or review of an application or require additional expenditures by BioSante. BioSante may not be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of its products under development. Delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on BioSante's business.



**New Product Development and Approval.** All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, product testing, manufacturing processes, manufacturing facilities, packaging, labeling, quality control, and evidence of safety and effectiveness for intended uses. For a generic drug product, instead of safety and effectiveness data, an application must demonstrate that the proposed product is the same as the branded drug in several key characteristics. There are two types of applications used for obtaining FDA approval of new non-biological drug products, other than a generic product:

- An NDA, sometimes referred to as a "full NDA," generally is submitted when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. Full NDAs typically are submitted for newly developed branded products and, in certain instances, an applicant submits an NDA or NDA supplement for a change to one of its previously approved products, such as a new dosage form, a new delivery system or a new indication.
- Another form of an NDA is the "505(b)(2) NDA," which typically is used to seek FDA approval of products that share characteristics (often, the active ingredient(s)) with a previously approved product of another company, but contain modifications to, or differences from, the approved product that preclude submission of an abbreviated new drug application. A 505(b)(2) NDA is required where at least some of the information required for approval does not come from studies conducted by or for the applicant or for which the applicant has obtained a right of reference. Usually, this means the application relies on the FDA's previous approval of a similar product or reference listed drug, or published data in scientific literature that are not the applicant's.

The process by which a product, other than a generic product, is approved for marketing in the United States can take from three to more than 10 years, and generally involves the following:

- laboratory and preclinical tests;
- submission of an Investigational New Drug (IND) application, which must become effective before clinical studies may begin;
- adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;
- submission of a full NDA or 505(b)(2) NDA containing, to the extent required, the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;
- scale-up to commercial manufacturing;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and
- FDA approval of the application.

To the extent that a 505(b)(2) NDA applicant can rely on a previously approved application or published literature, it may not be required to conduct some or all laboratory and preclinical tests or human clinical studies.

**Pre-Clinical Studies and Clinical Trials.** Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a product's uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical

investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information. BioSante's submission of an IND, or those of its collaboration partners, may not result in FDA authorization to commence a clinical trial.

A separate submission to an existing IND also must be made for each successive clinical trial conducted during product development. Depending on its significance, the FDA also must approve changes to an existing IND. Further, an independent institutional review board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. Alternatively, a central IRB may be used instead of individual IRBs. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

The sponsor of a drug product typically conducts human clinical trials in three sequential phases, but the phases may overlap or not all phases may be necessary. The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

Phase II trials are designed to evaluate the effectiveness of the product in the treatment of a given disease and involve people with the disease under study. These trials often are well controlled, closely monitored studies involving a relatively small number of subjects, usually no more than several hundred. The optimal routes, dosages and schedules of administration are determined in these studies. If Phase II trials are completed successfully, Phase III trials are often commenced, although Phase III trials are not always required.

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials are usually conducted with several hundred to several thousand subjects.

A clinical trial may combine the elements of more than one phase and typically two or more Phase III studies are required. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the trial will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to complete Phase I, II and III studies with respect to a given product.

Success in early-stage clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative

interpretations that could delay, limit or even prevent regulatory approval. Regulations require the posting of certain details about active clinical trials on government (i.e., [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) or independent websites, and subsequently a limited posting of the results of those trials. This helps prospective patients find out about trials they may wish to enroll in, but also provides some competitive intelligence to other companies working in the field. Failure to post the trial or its results in a timely manner can result in civil penalties and the rejection of the drug application.

**New Drug Applications.** The results of the product development, including preclinical studies, clinical studies, and product formulation and manufacturing information, are then submitted to the FDA as part of the NDA.

The FDA reviews each submitted application before accepting it for filing, and may refuse to file the application if it does not appear to meet the minimal standards for filing. If the FDA refuses to file an application and requests additional information, the application must be resubmitted with the requested information. Once the submission is accepted for filing, the FDA begins an in-depth review of the application to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate FDA-advisory committee of outside experts, typically a panel of clinicians, for review, evaluation and a recommendation. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy, and there is no assurance that the FDA will ultimately approve an NDA.

Acceptance for filing of an application does not assure FDA approval for marketing. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the submitted data, which could delay, limit, or prevent regulatory approval. If it concludes that the application does not satisfy the regulatory criteria for approval, the FDA typically issues a "complete response" letter communicating the agency's decision not to approve the application and outlining the deficiencies in the submission. The complete response letter may request additional information, including additional preclinical testing or clinical trials. Even if such information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If the FDA approves the application, the agency may require post-marketing studies, also known as Phase IV studies, as a condition to approval. These studies may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side effects associated with long-term use. After approval, the FDA also may require post-marketing studies or clinical trials if new safety information develops.

The FDA also may conclude that as part of the NDA or the 505(b)(2) NDA, the sponsor must develop a risk evaluation and mitigation strategy (REMS) to ensure that the benefits of the drug outweigh the risks. A REMS may have different components, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug's distribution, or a medication guide to provide better information to consumers about the drug's risks and benefits.

**Special Protocol Assessments.** The special protocol assessment process generally involves FDA evaluation of a proposed Phase III clinical trial protocol and a commitment from the FDA that the design and analysis of the trial are adequate to support approval of an NDA, if the trial is performed according to the SPA and meets its endpoints. The FDA's guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA

for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA's evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases.

If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has the latitude to change its assessment if certain exceptions apply. Exceptions include identification of a substantial scientific issue essential to safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

**The Hatch-Waxman Act.** The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act (Hatch-Waxman), established an abbreviated process for obtaining FDA approval for generic versions of approved branded drug products. In addition to establishing a shorter, less expensive pathway for approval of generic drugs, Hatch-Waxman provides incentives for the development of new branded products and innovations to approved products by means of marketing exclusivities and extension of patent rights. Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five years of marketing exclusivity if the product's active ingredient is a new chemical entity not previously approved. The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs for, among other things, new indications, dosages or strengths of a drug containing a previously approved active ingredient, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. This three-year marketing exclusivity period protects against the approval of abbreviated new drug applications and 505(b)(2) NDAs for the innovation that required clinical data; it does not prohibit the FDA from accepting or approving abbreviated new drug application or 505(b)(2) applications for other products containing the same active ingredient. The five- and three-year marketing exclusivity periods apply equally to patented and non-patented drug products. It is under this provision that BioSante received three years marketing exclusivity for Elestrin.

**Orphan Drug Exclusivity.** The Orphan Drug Act was enacted by Congress to provide financial incentives for the development of drugs for rare conditions (affecting less than 200,000 individuals per year) in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs may be exempt from application fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50 percent of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment.

**Other Regulatory Requirements.** Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with "current good manufacturing practice"

regulations, commonly referred to as "cGMP" regulations, which govern the production of pharmaceutical products. BioSante currently does not have any manufacturing capability.

The FDA regulates and monitors all promotion advertising and of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

**U.S. Drug Enforcement Administration.** The DEA regulates certain drug products containing controlled substances, such as testosterone, pursuant to the U.S. Controlled Substances Act. The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

**Foreign Regulation.** Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European and other countries (i.e., Canada, Australia and Japan), the sales price of a product also must be approved. The pricing review period often begins after market approval is granted. BioSante intends to seek and utilize foreign partners to apply for foreign approvals of its products.

## **Employees**

As of September 30, 2012, BioSante had 45 employees, including 33 in product development and 12 in management or administrative positions. None of BioSante's employees is covered by a collective bargaining agreement. BioSante also engages independent contractors from time to time on an as needed, project by project, basis.

## **Properties**

BioSante's principal executive office is located in a leased facility in Lincolnshire, Illinois, where BioSante leases approximately 20,000 square feet of office space for approximately \$20,000 per month. BioSante's lease for this space expires in February 2014. Management of BioSante's company considers its leased properties suitable and adequate for its current and foreseeable needs.

## **Legal Proceedings**

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that

certain of BioSante's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante's securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint on December 28, 2012.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming BioSante's directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante's corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante's operations, including its financial condition, results of operations, or cash flows.

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

#### **Available Information**

BioSante is a Delaware corporation that was initially formed as a corporation organized under the laws of the Province of Ontario in 1996. BioSante's principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. BioSante's telephone number is (847) 478-0500, and its Internet web site address is [www.biosantepharma.com](http://www.biosantepharma.com). The information contained on BioSante's web site or connected to its web site is not incorporated by reference into and should not be considered part of this joint proxy statement/prospectus.

BioSante makes available, free of charge and through its Internet web site, its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after BioSante electronically files such material with, or furnishes it to, the SEC. BioSante also makes available, free of charge and through its Internet web site, to any stockholder who requests, its corporate governance guidelines, the charters of its board committees and its Code of Conduct and Ethics. Requests for copies can be directed to Investor Relations at (847) 478-0500, extension 120, or by e-mail at [info@biosantepharma.com](mailto:info@biosantepharma.com).

## BIOSANTE'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of financial condition and results of operations together with the "Selected Historical Financial Data of BioSante" section of this joint proxy statement/prospectus and BioSante's financial statements and the related notes included in this joint proxy statement/prospectus. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. BioSante's actual results could differ materially from those anticipated by the forward-looking statements due to important factors including, but not limited to, those set forth in the "Risk Factors—Risks Related to BioSante" section of this joint proxy statement/prospectus.*

### Business Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

BioSante's products, either approved or in clinical development, include:

- LibiGel—once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).
- Male testosterone gel—once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).
- GVAX cancer vaccines—a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.
- The Pill-Plus (triple component contraceptive)—once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.
- Elestrin—once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda Pharmaceuticals), BioSante's licensee.

BioSante's corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of its corporate strategy, BioSante seeks to implement strategic alternatives with respect to its products and company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, from time to time, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies or a merger or sale of our company, with the goal of maximizing stockholder value.

### Proposed Merger with ANI

#### *Agreement and Plan of Merger*

On October 3, 2012, BioSante entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation. All options, warrants or

other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following completion of the transactions contemplated by the merger agreement, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante's net cash as of the determination date is \$18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of BioSante's "net cash," as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The merger agreement provides that, immediately following the effective time of the merger, the board of directors of the combined company will consist of five former directors of ANI and two former directors of BioSante, and ANI's current executive officers are expected to serve as executive officers of the combined company. In connection with the merger, BioSante will seek to amend its certificate of incorporation to: (i) effect a reverse split of BioSante common stock at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five, as determined by BioSante and ANI, which is intended to ensure that the listing requirements of The NASDAQ Global Market or The NASDAQ Capital Market are satisfied; and (ii) change the name of the company to "ANI Pharmaceuticals, Inc." or another name as designated by ANI (together, the charter amendments).

Completion of the merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the merger agreement and the transactions contemplated thereby by both the BioSante and ANI stockholders and the approval of the charter amendments by the BioSante stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by BioSante with the Securities and Exchange Commission to register the shares of BioSante common stock to be issued in connection with the merger, which will contain a joint proxy statement/prospectus; (iii) approval for the listing of shares of BioSante common stock to be issued in the merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iv) written opinions of counsel that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (v) other customary closing conditions. In addition, the obligation of ANI to effect the merger is subject to a condition that BioSante's net cash, after deducting all remaining liabilities, as calculated and as adjusted pursuant to the terms of the merger agreement, be no less than \$17.0 million immediately prior to the effective time of the merger. No fractional shares of BioSante common stock will be issued in connection with the reverse split and holders of BioSante common stock will be entitled to receive cash in lieu thereof.

Each of BioSante and ANI have made customary representations, warranties and covenants in the merger agreement, including among others, covenants that (i) each party will conduct its business in the ordinary course consistent with past practice during the interim period between the execution of the merger agreement and the consummation of the merger; (ii) each party will not engage in certain kinds of transactions or take certain actions during such period; (iii) ANI will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the merger agreement and the transactions contemplated thereby and the board of directors of ANI will recommend that the ANI stockholders adopt and approve the merger agreement, subject to certain exceptions; and (iv) BioSante will convene and hold a meeting of the BioSante stockholders for the purpose of considering the



adoption and approval of the merger agreement and the transactions contemplated thereby and the approval of the charter amendments and the BioSante board of directors will recommend that the BioSante stockholders adopt and approve the merger agreement and approve the charter amendments, subject to certain exceptions. Each of BioSante and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for BioSante in the event of its receipt of a "superior proposal."

The merger agreement contains certain termination rights in favor of each of ANI and BioSante in certain circumstances. If the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante will be required to pay ANI a termination fee of up to \$1.0 million or ANI will be required to pay BioSante a termination fee of up to \$750,000. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to \$500,000 for ANI's expenses in connection with the transaction. Any expenses paid by BioSante will be credited against the \$1.0 million termination fee if the termination fee subsequently becomes payable by BioSante.

#### ***Voting Agreements***

Concurrently and in connection with the execution of the merger agreement, certain ANI stockholders, who collectively held approximately 90 percent of the outstanding shares of ANI common stock on an as-converted basis and approximately 86 percent of the outstanding shares of ANI series D preferred stock as of October 3, 2012, entered into voting agreements with BioSante, pursuant to which each ANI stockholder agreed to vote its shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. In addition, one of the ANI stockholders, who held approximately 57 percent of the outstanding shares of ANI capital stock as of October 3, 2012, has agreed to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of BioSante stockholders following completion of the merger.

In addition, all of BioSante's directors and officers, who collectively held approximately two percent of the outstanding shares of BioSante capital stock as of October 3, 2012, entered into voting agreements with ANI, pursuant to which each BioSante stockholder agreed to vote its shares of BioSante capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and the charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

#### ***Lock-Up Agreements***

Concurrently and in connection with the execution of the merger agreement, ANI's chief executive officer and chief financial officer and certain ANI stockholders, who collectively held approximately 85 percent of the outstanding shares of ANI common stock, on an as-converted basis, as of October 3, 2012, entered into lock-up agreements with BioSante, pursuant to which each ANI stockholder will be subject to a six-month lock-up on the sale of shares of BioSante common stock received in the merger.

#### ***Contingent Value Rights Agreement***

BioSante has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to holders of BioSante common stock as of immediately prior to completion of the merger. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of the record date to be set at a date prior to completion of the merger. However, the

CVRs will not be certificated and will not be attached to the shares of BioSante common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event BioSante receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante and its transfer agent, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to BioSante's LibiGel program, as determined pursuant to the CVR agreement, and will not exceed \$40 million in the aggregate.

## Financial Overview

BioSante's lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and its LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

In September 2012, BioSante announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante also announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA advised BioSante that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.5 months; more than 3,200 subjects had been in the study for more than one year and over 1,700 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained.

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA SPA agreement covering aspects of the two new efficacy trials.

Elestrin was BioSante's first FDA approved product and now is one of BioSante's two FDA approved products. Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc.'s women's health business and which in turn had acquired Azur Pharma International II Limited (Azur),

BioSante's prior licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to \$140 million in sales-based milestone payments from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante's male testosterone gel is its second FDA approved product. This product initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

Under BioSante's development and license agreement with Teva, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a \$1.5 million upfront payment by Teva, which was paid to BioSante in December 2002, and an obligation by Teva to pay BioSante certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more detail below. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. BioSante may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

In October 2012, BioSante entered into an amendment to its agreement with Teva pursuant to which Teva made a \$1.0 million payment to BioSante upon the signing of the amendment and agreed to make the following milestone based payments to BioSante: (1) \$500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an "AB-rated" equivalent to AndroGel®; (2) \$750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva's submission to the FDA of a final report regarding a "washing" clinical study required by the FDA; and (3) \$500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva's commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay BioSante \$4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to BioSante under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

BioSante licenses the technology underlying certain of its gel products, including LibiGel and Elestrin, but not the male testosterone gel, from Antares Pharma, Inc. The patents covering the formulations used in the gel products covered under the license agreement are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. BioSante's license agreement with Antares requires BioSante to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its licensees sell incorporating the licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee. Since entering into the agreement and through September 30, 2012, BioSante has paid Antares an upfront payment of \$1.0 million, an aggregate of \$5.1 million in milestone payments and an aggregate of \$100,000 in royalties. Aggregate potential milestone payments to be paid by BioSante to Antares under the agreement include 25 percent of the potential \$140 million in sales-based milestone payments, or \$35 million from Meda Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

The term of BioSante's license agreement with Antares will expire on a country-by-country and product-by-product basis when the royalties expire (at patent expiration), at which time BioSante will have a fully paid-up exclusive license regarding the applicable product in such country. BioSante and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if BioSante does not continue development, seeking regulatory approval or marketing of such products in the covered territories. BioSante may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

BioSante licenses the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by BioSante if a product incorporating the licensed technology gets approved and subsequently is marketed.

BioSante's GVAX cancer vaccines, which are designed to stimulate a patient's immune system to fight effectively the patient's own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines—to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma—have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving our GVAX cancer vaccines ongoing. The studies are being funded by various sources, including certain foundations and our licensees. BioSante's objective with respect to its GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of the GVAX cancer vaccine portfolio to the BioSante stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines. BioSante currently is negotiating the terms of a potential transaction with an unidentified third party pursuant to which, if completed, BioSante would sell all of its assets related to its GVAX cancer vaccine portfolio in exchange for a \$1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

## Financial Overview

Substantially all of BioSante's revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. BioSante's business operations to date have consisted primarily of licensing and research and development activities and if BioSante does not complete its proposed merger with ANI, BioSante would expect this to continue for the immediate future. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, Inc., to fund its ongoing business operations and short-term liquidity needs.

As of September 30, 2012, BioSante had \$38.0 million of cash and cash equivalents and had outstanding \$8.3 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed, BioSante expects its cash and cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the requirement under the merger agreement to have at least \$17 million of "net cash," as defined in the merger agreement, available upon the closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone business, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante incurred expenses of \$14.5 million on research and development activities during the nine months ended September 30, 2012, which is a 61 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of the two LibiGel Phase III efficacy trials at the end of 2011. BioSante anticipates that its research and development expenses for the remainder of 2012 and 2013 will consist primarily of expenses associated with the conclusion of the safety study and continuing to develop a protocol for the two new LibiGel Phase III efficacy trials. BioSante currently expects to spend approximately \$1.1 million per month on research and development activities during the remainder of 2012, which is based on the assumption that BioSante does not in-license additional products and technologies requiring additional development.

General and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the same period in 2011 due primarily to an increase in professional fees and other administrative expenses. BioSante's general and administrative expenses generally fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

BioSante recognized an income tax benefit based on the receipt of an income tax credit for the nine months ended September 30, 2012 of \$121,791 compared to the recognition of no income tax benefit for the nine months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended.

BioSante recognized a net loss for the nine months ended September 30, 2012 of \$23.7 million compared to a net loss of \$45.0 million for the nine months ended September 30, 2011. This decrease

was primarily a result of the conclusion of the prior two LibiGel Phase III efficacy trials at the end of 2011 and in September 2012 the conclusion of the LibiGel Phase III safety study, and was offset in part by an increase in the non-cash fair value adjustment relating to the cancellation of \$12.5 million in aggregate principal amount of its convertible senior notes. BioSante recognized a net loss per share for the nine months ended September 30, 2012 of \$1.14 compared to a net loss per share of \$2.86 for the nine months ended September 30, 2011. This decrease in net loss per share was the result of the significantly higher weighted average number of shares outstanding, partially offset by the lower net loss described above.

## Results of Operations

### Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

The following table sets forth BioSante's results of operations for the nine months ended September 30, 2012 and 2011.

	Nine Months Ended September 30,		\$ Change	% Change
	2012	2011		
Revenue	\$ 333,163	\$ 320,787	\$ 12,376	3.9%
Expenses				
Research and development	14,454,258	37,480,873	(23,026,615)	(61.4)%
General and administrative	5,327,711	5,257,853	69,858	1.3%
Other expense—Convertible note fair value adjustment	(4,037,797)	(1,929,000)	2,108,797	109.3%
Other expense—Interest expense	(283,348)	(516,000)	(232,652)	(45.1)%
Other income—Interest income	5,300	6,472	(1,172)	(18.1)%
Income tax benefit	121,791	—	121,791	100.0%
Net loss	\$ (23,730,408)	\$ (44,959,682)	\$ (21,229,274)	(47.2)%
Net loss per common share (basic and diluted)	\$ (1.14)	\$ (2.86)	\$ 1.72	(60.1)%
Weighted average number of common shares and common equivalent shares outstanding	20,841,417	15,744,738	5,096,679	32.4%

The only revenue recognized during the nine months ended September 30, 2012 consisted of royalty revenue from Jazz Pharmaceuticals for Elestrin sales, which royalty revenue is offset by BioSante's corresponding obligation to pay Antares royalties representing the same amount. BioSante's corresponding obligation to pay Antares a portion of the royalties received, which equaled \$333,163 during the nine months ended September 30, 2012 and \$220,787 during the nine months ended September 30, 2011, is recorded within general and administrative expenses in BioSante's condensed statements of operations. In addition, during the nine months ended September 30, 2011, BioSante recognized an additional \$100,000 in revenue from its receipt of an upfront non-refundable licensing fee from The John P. Hussman Foundation.

Research and development expenses for the nine months ended September 30, 2012 decreased 61 percent compared to the nine months ended September 30, 2011 primarily as a result of the completion of BioSante's two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012.

General and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the nine months ended September 30, 2011 primarily as a result of an increase in professional fees and other administrative expenses.

The fair value adjustment on BioSante's convertible senior notes for the nine months ended September 30, 2012 was \$4.0 million compared to \$1.9 million for the nine months ended

September 30, 2011. The increase in the expense for the nine months ended September 30, 2012 was primarily as a result of \$3,157,151 non-cash fair value adjustment (expense) recorded upon cancellation of \$12.5 million in aggregate principal amount of BioSante's convertible senior notes in February and July 2012. The convertible fair value adjustment for the nine months ended September 30, 2011 increased the recorded liability and corresponding expense by \$1,929,000 and included the 2011 and 2013 Notes.

Interest expense was \$283,348 and \$516,000 for the nine months ended September 30, 2012 and 2011, respectively, as a result of BioSante's convertible senior notes. Interest expense decreased during the most recent current year period as a result of the repayment of BioSante's 3.125% convertible senior notes due November 1, 2011 during the fourth quarter of 2011 and the cancellation of \$12.5 million in aggregate principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first and third quarter of 2012 in exchange for the issuance of 3,652,125 shares of BioSante common stock.

Interest income decreased \$1,172 for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 as a result of lower cash balances and lower average interest rates during the nine months ended September 30, 2012.

BioSante recognized an income tax benefit based on the receipt of an income tax credit for the nine months ended September 30, 2012 of \$121,791 compared to the recognition of no income tax benefit for the nine months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended.

#### **Years Ended December 31, 2011, 2010 and 2009**

The following table sets forth, for the periods indicated, BioSante's results of operations.

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Revenue	\$ 435,160	\$ 2,474,237	\$ 1,258,054
Expenses			
Research and development	44,182,260	39,705,502	13,680,573
General and administrative	6,981,490	5,940,360	5,373,945
Acquired in-process research and development	—	—	9,000,000
Excess consideration paid over fair value	—	—	20,192,194
Licensing expense	50,000	268,750	299,616
Total expenses	51,361,990	46,082,598	48,683,608
Other (expense) income—Convertible note fair value adjustment	(23,427)	(1,870,916)	33,163
Other expense—Investment impairment charge	—	(286,000)	—
Other expense—Interest expense	(681,573)	(688,083)	147,025
Other income	15,000	244,479	—
Other income—Interest income	8,326	12,665	11,648
Net loss	\$ (51,608,504)	\$ (46,196,216)	\$ (47,527,768)
Net loss per common share (basic and diluted)	\$ (3.15)	\$ (4.21)	\$ (8.40)
Weighted average number of common shares and common equivalent shares outstanding	16,397,618	10,985,291	5,658,609

***Year Ended December 31, 2011 Compared to Year Ended December 31, 2010***

Revenue decreased \$2.0 million, or 82.4 percent in 2011 compared to 2010, primarily as a result of the recognition of royalty revenue during 2010 resulting primarily from the receipt of \$2.3 million in non-refundable upfront payments from Azur, partially offset by BioSante's receipt during 2011 of \$100,000 in a non-refundable upfront licensing fee from the Hussman Foundation relating to an exclusive worldwide license of BioSante's melanoma vaccine. The \$2.3 million payment from Azur in 2010 was in exchange for the elimination of all remaining future royalty payments that BioSante is not required to pay Antares under a separate agreement and certain future milestone payments due BioSante under the terms of the original license, as permitted by the amendment to BioSante's license agreement signed in December 2009. The only other revenue recognized during 2011 consisted of royalty revenue from Jazz Pharmaceuticals for Elestrin sales, which royalty revenue is offset by a corresponding obligation of BioSante to pay Antares royalties representing the same amount.

Research and development expenses for 2011 increased 11.3 percent compared to 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies, particularly the safety study.

General and administrative expenses for 2011 increased 17.5 percent compared to 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during 2011.

The fair value adjustment on BioSante's convertible senior notes for 2011 was \$23,427 compared to \$1.9 million for 2010 as the fair value of the debt did not change significantly between December 31, 2010 and 2011.

Interest expense for 2011 was \$681,573 compared to \$688,083 for 2010. BioSante expects interest expense to decrease in 2012 compared to 2011 as a result of the repayment of \$1.2 million in aggregate principal amount of BioSante's 3.125% convertible senior notes due November 1, 2011 and the cancellation of \$9.0 million in aggregate principal amount of BioSante's 3.125% convertible senior notes previously due May 1, 2013, which were exchanged for shares of common stock as previously discussed.

During 2010, BioSante recorded an investment impairment loss of \$286,000 based on BioSante's determination that an other-than-temporary loss had occurred with respect to BioSante's investment in Ceregene, Inc. based on a third-party investment in Ceregene in 2010.

***Year Ended December 31, 2010 Compared to Year Ended December 31, 2009***

Revenue increased \$1.2 million in 2010 compared to 2009 primarily as a result of an increase in royalty and licensing revenue during 2010 compared to 2009. Of the \$2.3 million in royalty revenue during 2010, \$2.2 million resulted from BioSante's receipt of non-refundable upfront payments from Jazz Pharmaceuticals as a result of the December 2009 amendment to BioSante's license agreement. Pursuant to a separate agreement with Antares and related to the December 2009 amendment, BioSante paid Antares an aggregate of \$268,750 in February 2010. In addition, during 2010, BioSante recorded royalty revenue of \$152,228 and a corresponding amount of royalty expense, which is recorded within general and administrative expenses in BioSante's statements of operations, to reflect the Antares portion of the Elestrin royalty revenues, which revenues were not eliminated as a result of the December 2009 Jazz Pharmaceuticals license amendment. In October 2010, BioSante received \$244,479, the maximum per project, after LibiGel qualified for a grant under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

Research and development expenses increased 190 percent in 2010 compared to 2009 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.



General and administrative expenses increased 11 percent in 2010 compared to 2009 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses in 2010.

BioSante recognized total additional non-cash expenses of \$29.2 million in 2009 related to its merger with Cell Genesys, consisting of \$9.0 million related to the write-off of acquired in-process research and development, and \$20.2 million related to transaction related expenses and additional charges related to the excess of merger consideration over fair values of the net assets acquired. No similar expense was recognized in 2010.

BioSante recognized licensing expense of \$268,750 related to its payment to Antares as a result of the December 2009 Jazz Pharmaceuticals license amendment compared to licensing expense of \$299,616 in 2009 as a result of expenses associated with the Jazz Pharmaceuticals licensing agreement and the termination of BioSante's prior licensing agreement for Elestrin.

The fair value adjustment on BioSante's convertible senior notes to increase the recorded liability and corresponding expense was \$1.9 million in 2010 compared to a fair value adjustment to decrease the recorded liability and corresponding expense of \$33,163 in 2009.

BioSante recorded an investment impairment charge of \$286,000 in 2010 based on its determination that an other-than-temporary impairment had occurred with respect to its investment in Ceregene, Inc. based on a third-party investment in Ceregene in 2010. No similar investment impairment charge was recognized in 2009.

Interest expense increased \$541,058, or 368 percent, in 2010 compared to 2009 as a result of BioSante's convertible senior notes, which BioSante assumed during the fourth quarter of 2009.

Interest income increased \$1,017, or 9 percent, in 2010 compared to 2009 primarily as a result of higher cash balances and cash being in a U.S. Treasury portfolio for a portion of 2010 compared to cash being in a non-interest bearing checking account for the majority of 2009.

## **Liquidity and Capital Resources**

### ***Working Capital***

Since its inception, BioSante has incurred significant operating losses resulting in an accumulated deficit of \$241.0 million as of September 30, 2012. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs.

As of September 30, 2012, BioSante had \$38.0 million of cash and cash equivalents and \$8.3 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 outstanding. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed during the first quarter of 2013, BioSante expects its cash and cash equivalents as of September 30, 2012 to meet its liquidity requirements through at least the anticipated closing of the merger, including the requirement under the merger agreement to have at least \$17 million of "net cash" as defined in the merger agreement available upon closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone company, a sale of the company, liquidation of the company or other strategic transaction. BioSante's liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet its liquidity requirements for at

least the next three to five years. Substantial additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante's future capital requirements will depend upon numerous factors, including:

- the timing, cost and successful completion of the proposed merger between BioSante and ANI;
- the progress, timing, cost and results of BioSante's clinical development programs, including in particular the conclusion of the LibiGel Phase III safety study, and if BioSante has not completed the proposed merger between BioSante and ANI, beginning in mid-2013, the two new LibiGel Phase III efficacy trials if BioSante decides to commence such trials, and if BioSante in-license additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to BioSante's products;
- the success, progress, timing and costs of BioSante's business development efforts to implement business collaborations, licenses and other business combinations or transactions, and BioSante's efforts to evaluate various strategic alternatives available with respect to its products and company.
- BioSante's ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;
- BioSante's ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of BioSante's products;
- the outstanding principal amount of BioSante's 3.125% convertible senior notes due May 1, 2013 that are scheduled to mature and become due and payable on May 1, 2013 and BioSante's ability to avoid a "fundamental change" or an "event of default" under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- BioSante's operating expenses; and
- the resolution of BioSante's pending purported class action and shareholder derivative litigation and any amount BioSante may be required to pay in excess of its directors' and officers' liability insurance.

BioSante does not have any existing credit facilities under which it could borrow funds. In the event that BioSante would require additional working capital to fund future operations, it could seek to acquire such funds through additional equity or debt financing arrangements. If BioSante raises additional funds by issuing equity securities, its stockholders may experience dilution. Debt financing, if available, may involve covenants restricting BioSante's operations or its ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to BioSante, or at all. As an alternative to raising additional financing, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued

development and, if approved, commercialization of that licensed product, or sell certain assets or rights under its existing license agreements. In addition, from time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. In February 2012, BioSante issued an aggregate of 1,868,055 shares of its common stock to one of the holders of its convertible senior notes in exchange for the cancellation of \$9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest of \$79,024, and in July 2012, BioSante issued an aggregate of 1,784,070 shares of its common stock to two of the holders of BioSante's convertible senior notes in exchange for the cancellation of \$3.5 million in aggregate principal amount of such notes and accrued and unpaid interest of \$20,686. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante's available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante's cash balance. A significant decrease in BioSante's cash balance, together with an inability to raise additional financing when needed, may impair BioSante's ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante is subject to pending purported class action and shareholder derivative litigation, which litigation is described elsewhere in this joint proxy statement/prospectus. Such litigation could divert management's attention, harm BioSante's business and/or reputation and result in significant liabilities, as well as harm BioSante's ability to raise additional financing and execute certain strategic alternatives.

BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in the success of the proposed merger between BioSante and ANI, BioSante's LibiGel development program, the future value of BioSante and/or economic and market conditions deteriorate. If BioSante does not complete the proposed merger between BioSante and ANI and if adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to reduce its operating costs further or it may be forced to explore other strategic alternatives, such as other business combination transactions or winding down its operations and liquidating the company. In such case, BioSante stockholders could lose some or all of their investment.

### **Uses of Cash and Cash Flow**

#### *Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011*

Net cash used in operating activities was \$22.1 million for the nine months ended September 30, 2012 compared to net cash used in operating activities of \$36.9 million for the nine months ended September 30, 2011. Net cash used in operating activities for the nine months ended September 30, 2012 was primarily the result of the net loss for that period which was lower compared to the prior year period due to lower clinical trial related expenses primarily as a result of the completion of BioSante's two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012. Net cash used in operating activities for the nine months ended September 30, 2011 was primarily the result of the net loss for that period.

Net cash used in investing activities was \$536,697 for the nine months ended September 30, 2012 compared to net cash used in investing activities of \$645,603 for the nine months ended September 30, 2011. Net cash used in investing activities for each of the nine months ended September 30, 2012 and 2011 was due primarily to the purchase of fixed assets.

Net cash provided by financing activities was \$3.5 million for the nine months ended September 30, 2012 compared to net cash provided by financing activities of \$69 million for the nine months ended September 30, 2011. Net cash provided by financing activities for the nine months ended September 30, 2012 was the result of BioSante's August 2012 registered direct offering, which resulted in net proceeds of \$3.3 million, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2011 was the result of BioSante's August 2011 underwritten public offering and March 2011 registered direct offering, which resulted in net proceeds of \$45.1 million and \$23.9 million, respectively, after deduction of underwriting discounts and commissions or placement agent fees and offering expenses.

*Years Ended December 31, 2011, 2010 and 2009*

Net cash used in operating activities was \$47.9 million for the year ended December 31, 2011 compared to net cash used in operating activities of \$40.1 million for the year ended December 31, 2010 and net cash used in operating activities of \$18.4 million for the year ended December 31, 2009. Net cash used in operating activities for 2011 was primarily the result of the net loss for that period which was higher compared to 2010 due to higher LibiGel Phase III clinical study related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities and the non-cash mark-to-market expense for BioSante's convertible senior notes. Net cash used in operating activities for 2010 was primarily the result of the net loss for that period, which was slightly higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets. Net cash used in operating activities for 2009 was primarily the result of the net loss for that period. Technology and transaction related expenses and charges of \$29.2 million were incurred as a result of BioSante's merger with Cell Genesys in 2009 but did not result in an operating cash payment by BioSante as it issued shares of its common stock as consideration for the transaction and cash payments for transaction costs were classified as a financing activity based on the nature of the transaction.

Net cash used in investing activities was \$719,925 for the year ended December 31, 2011 compared to net cash provided by investing activities of \$60,366 for the year ended December 31, 2010 and net cash provided by investing activities of \$2.9 million for the year ended December 31, 2009. The increase in net cash used in investing activities for 2011 compared to 2010 was due to a significant increase in the purchase of fixed assets, including in particular machinery, computers and furniture. The machinery purchased during 2011 relates to new BioSante-owned machinery for LibiGel product manufacturing at its contract manufacturer and the increased amounts spent on computers and furniture during 2011 was due primarily to its increased number of personnel compared to 2010. Net cash used in investing activities for 2011 and 2010 was primarily for the purchase of capital assets.

Net cash provided by financing activities was \$67.7 million for the year ended December 31, 2011 compared to \$48.5 million for the year ended December 31, 2010 and \$33.7 million for the year ended December 31, 2009. Net cash provided by financing activities in 2011 resulted from the net proceeds to BioSante, after deducting placement agent fees, underwriters' discounts, commissions and other offering expenses, from the completion of BioSante's March 2011 registered direct offering and August 2011 underwritten public offering, partially offset by the repayment of the 3.125% convertible senior notes due November 1, 2011 of \$1.2 million. Net cash provided by financing activities in 2010 resulted from the net proceeds to BioSante, after deducting placement agent fees and offering expenses, from the completion of BioSante's March, June and December 2010 registered direct offerings. Net cash provided by financing activities for 2009 resulted from a combination of recognizing \$24.7 million in cash acquired as a result of BioSante's merger with Cell Genesys and \$11.4 million in net proceeds to BioSante, after deducting placement agent fees and offering expenses, from the completion of

BioSante's August 2009 registered direct offering, partially offset by \$2.4 million in cash paid for Cell Genesys acquisition-related costs.

### **3.125% Convertible Senior Notes Due May 1, 2013**

As a result of BioSante's merger with Cell Genesys in 2009, BioSante assumed \$1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 and \$20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 issued by Cell Genesys. Prior to the November 1, 2011 maturity date, BioSante repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued and unpaid interest thereon through such date. During the nine months ended September 30, 2012, BioSante issued an aggregate of approximately 3.7 million shares of BioSante common stock to holders of the 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of \$12.5 million in aggregate principal amount of such notes, including accrued and unpaid interest.

Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the remaining convertible senior notes is approximately \$259,000.

The remaining outstanding convertible senior notes are convertible into an aggregate of approximately 370,871 shares of BioSante common stock at a conversion price of \$22.32 per share, subject to adjustments for stock dividends, stock splits and other similar events. The convertible senior notes are general, unsecured obligations of BioSante, ranking equally with all of BioSante's existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of BioSante's existing and future secured indebtedness to the extent of the value of the related collateral, and structurally subordinated to all existing and future liabilities and other indebtedness of any subsidiaries of BioSante. The convertible senior notes are subject to repurchase by BioSante at each holder's option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the convertible senior notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by BioSante, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of BioSante common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of September 30, 2012, the convertible senior notes were not eligible for redemption. The indenture governing the convertible senior notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict us from paying dividends, incurring additional debt or issuing or repurchasing other securities of BioSante. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the convertible senior notes in the event of a highly leveraged transaction or a fundamental change of BioSante except in certain circumstances specified in the indenture.

In addition, from time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. The amounts involved may be material. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, BioSante's available cash and cash equivalents, its liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the existing BioSante stockholders and/or decrease BioSante's cash balance. A

significant decrease in BioSante's cash balance may impair its ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante has elected to record the convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, BioSante has adjusted the carrying value of the convertible senior notes to their fair value as of September 30, 2012, with changes in the fair value of the convertible senior notes occurring since December 31, 2011 reflected in convertible note fair value adjustment in BioSante's statement of operations for the nine months ended September 30, 2012. The fair value of the convertible senior notes are based on Level 2 inputs according to the fair value hierarchy required under GAAP, which means fair value of the convertible senior notes is based on observable prices that are based on inputs not quoted on active markets, but corroborated by market data. The aggregate recorded fair value of the convertible senior notes of \$7.6 million as of September 30, 2011 differs from their total stated principal amount of \$8.3 million as of September 30, 2012 by \$0.7 million. The aggregate recorded fair value of the convertible senior notes of \$17.3 million as of December 31, 2011 differs from their total stated principal amount of \$20.8 million as of such date by \$3.5 million.

### **Commitments and Contractual Obligations**

BioSante did not have any material commitments for capital expenditures as of September 30, 2012. BioSante has a purchase obligation relating to a gel packaging machine of \$40,608. This obligation is due upon the shipment, assembly and calibration of the machine at a location designated by BioSante. In light of the proposed merger between BioSante and ANI, BioSante is evaluating the future plans for this gel packaging machine. BioSante also have several financial commitments, including its convertible senior notes, product development milestone payments to the licensors of certain of its products, payments under its license agreements with Johns Hopkins University and Wake Forest University Health Sciences, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of September 30, 2012:

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1 - 3 Years</b>	<b>3 - 5 Years</b>	<b>More than 5 Years</b>
Convertible senior notes	\$ 8,277,850	\$ 8,277,850	\$ 0	\$ 0	\$ 0
Interest payment obligations related to convertible senior notes	150,898	150,898	0	0	0
Operating lease	350,413	246,119	104,295	0	0
Commitments under license agreements with Johns Hopkins University	320,000	45,000	135,000	90,000	50,000
Commitments under license agreement with Massachusetts Institute of Technology	100,000	50,000	50,000	0	0
Commitments under license agreement with University of California	300,000	20,000	60,000	40,000	180,000
Commitments under license agreement with Wake Forest	360,000	80,000	200,000	80,000	40,000
Total contractual cash obligations	<u>\$ 9,859,162</u>	<u>\$ 8,869,867</u>	<u>\$ 549,295</u>	<u>\$ 210,000</u>	<u>\$ 230,000</u>

### **Off-Balance Sheet Arrangements**

BioSante does not have any off-balance sheet arrangements that have or reasonably are likely to have a material effect on BioSante's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, BioSante is not exposed materially to any financing, liquidity, market or credit risk that could arise if BioSante had engaged in these arrangements.

### **Critical Accounting Policies**

BioSante's significant accounting policies are described in Note 2 to its financial statements for the year ended December 31, 2011, included in this joint proxy statement/prospectus. The discussion and analysis of BioSante's financial statements and results of operations are based upon BioSante's financial statements, which have been prepared in accordance with GAAP. The preparation of BioSante's financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The SEC has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires BioSante to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, BioSante has identified the critical accounting policy described below. Although BioSante believes that its estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

### **Accounting for Convertible Senior Notes Assumed in Connection with the Cell Genesys Acquisition**

On October 14, 2009, BioSante completed a legal merger with Cell Genesys, as a result of which BioSante acquired all of the assets and liabilities of Cell Genesys. Concurrently with the merger, the common stock of Cell Genesys was converted into common stock of BioSante, and Cell Genesys ceased to exist. The primary reason BioSante merged with Cell Genesys was BioSante's need at that time for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for BioSante to access capital prior to and at the time the merger agreement was entered into by BioSante and Cell Genesys in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been BioSante's primary method for raising additional financing. BioSante has accounted for this transaction with Cell Genesys under GAAP as an acquisition of the net assets of Cell Genesys, whereby BioSante has recorded the individual assets and liabilities of Cell Genesys as of the completion of the merger based on their estimated fair values. As Cell Genesys had ceased operations, the acquisition was not considered to be a business combination, and the allocation of the purchase price did not result in recognition of goodwill. As a result of this treatment, during the fourth quarter of 2009, BioSante recognized a non-cash expense of approximately \$20.2 million representing the excess of the consideration and costs of the transaction over the fair value of assets and liabilities received.

BioSante assumed \$22.0 million in aggregate principal amount of convertible senior notes in connection with the Cell Genesys acquisition, including \$1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011, which were repaid prior to the November 1, 2011 maturity date, and \$20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013, which were outstanding as of December 31, 2011. As of September 30, 2012, \$8.3 million in aggregate principal amount of convertible senior notes remained outstanding following the exchange transactions previously discussed.

BioSante elected to apply the fair value option to the debt at the time of the acquisition, with recognition of subsequent changes in the fair value of the convertible senior notes recognized in

BioSante's statements of operations immediately. As a result of this election, BioSante periodically must estimate the fair value of its convertible senior notes, which requires BioSante to make certain judgments and estimates about appropriate discount rates, BioSante's creditworthiness, and assumptions regarding potential conversion of the notes. BioSante believes that its estimates and assumptions are reasonable; however, changes in these estimates and assumptions could result in significant differences in the carrying value of the convertible senior notes. The most sensitive of these assumptions is the discount rate used in the fair value estimate, which was 18.5 percent at December 31, 2011, and is based on the median yield to maturity of Ca and Caa3 rated debt instruments as of December 31, 2011. A one percentage point increase or decrease in the discount rate would cause the recorded value of the convertible senior notes to decrease or increase by approximately \$191,000 and \$194,000, respectively.

### Recently Issued Accounting Pronouncements

BioSante does not expect the adoption of any recent accounting pronouncements to have a material effect on its financial position, results of operations or cash flows.

### Quantitative and Qualitative Disclosures About Market Risk

BioSante is exposed to interest rate sensitivity on its cash equivalents in money market funds and its outstanding fixed rate debt. The objective of BioSante's investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, BioSante invests in highly liquid U.S. Treasury money market funds. BioSante's investments in U.S. Treasury money market funds are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, BioSante invests in short-term securities and its goal is to maintain an average maturity of less than one year. As of the date of this proxy statement/prospectus, all of BioSante's cash equivalents are only invested in a U.S. Treasury money market fund and a certificate of deposit.

The following table provides information about BioSante's financial instruments that are sensitive to changes in interest rates.

#### Interest Rate Sensitivity Principal Amount by Expected Maturity and Average Interest Rate

<u>As of September 30, 2012</u>	<u>2012</u>	<u>2013</u>	<u>Total</u>	<u>Fair Value September 30, 2012</u>
Total cash equivalents	\$ 36,957,469	—	—	\$ 36,957,469
Average interest rate	0.04%	—	—	—
Fixed interest rate convertible senior notes	—	\$ 8,277,850	\$ 8,277,850	\$ 7,593,216
Average interest rate	3.125%	3.125%	3.125%	

<u>As of December 31, 2011</u>	<u>2012</u>	<u>2013</u>	<u>Total</u>	<u>Fair Value December 31, 2011</u>
Total cash equivalents	\$ 55,465,507	—	—	\$ 55,465,507
Average interest rate	0.02%	—	—	—
Fixed interest rate convertible senior notes	—	\$ 20,782,000	\$ 20,782,000	\$ 17,336,760
Average interest rate	3.125%	3.125%	3.125%	



## ANI'S BUSINESS

### Overview

ANI is a fully integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies. ANI's targeted areas of product development include narcotics, anti-cancers and hormones (potent compounds) and extended release niche generic prescription product opportunities.

ANI was organized as a Delaware corporation in March 2004 and is headquartered in Baudette, Minnesota. The address of ANI's main office is 210 Main Street West, Baudette, Minnesota, 56623, and the telephone number is (218) 634-3500.

ANI acquired its two facilities in May 2007 from Solvay Pharmaceuticals, Inc. (Solvay). Solvay in turn had acquired the facilities in 1986 through its purchase of Atlanta-based Reid-Rowell, Inc., after which the facilities served as Solvay's sole U.S.-based manufacturing facilities for hormone, steroid and other prescription products.

In March 2009, ANI's leadership transitioned from founding management to a new team focused initially on stabilizing the business and then developing and executing a strategy based on ANI's prescription pharmaceutical manufacturing assets and capabilities. To that end, since the first quarter of 2009, ANI's new management team has:

- Consolidated and relocated ANI's corporate offices to its facilities in Minnesota.
- Successfully divested an over-the-counter pharmaceutical manufacturing operation in Gulfport, Mississippi in 2010 for \$2.3 million. The net assets of the Gulfport operation had a carrying value of \$5.8 million on the date of the sale, resulting in a loss of \$3.7 million on disposal of the discontinued operation. The decision to sell the Gulfport operation was based on the historical underperformance and recurring losses at such operation and ANI's change in strategic direction to focus on the prescription pharmaceutical market.
- Implemented cost reductions and early lease terminations yielding \$3.0 million in annual savings.
- Retired all third-party long-term debt and capital leases totaling \$4.7 million.
- Raised over \$13.5 million in capital from existing investors.
- Increased prescription product sales 40-fold through market share gains on established products, a product acquisition and new product launches.
- Generated positive cash flow from operations.
- Developed three new contract manufacturing customer relationships.
- Established an external product development partnership to bolster the internal pipeline.
- Filed three Abbreviated New Drug Applications (ANDAs) and developed a pipeline of eight additional ANDAs.

### Operations

ANI's two facilities have highly specialized manufacturing capabilities as a result of capital investments by Solvay during its ownership. ANI's Baudette-based manufacturing and product development teams have successfully developed and manufactured liquid, powder and oral solid dose

products, including those requiring containment. The plants have sufficient capacity, including analytical and stability laboratories, to expand production and substantially grow revenues. ANI can offer no assurances that it will in fact be successful in growing revenues, as multiple other factors, including those discussed in "Risk Factors—Risks Related to ANI" may impair its ability to do so.

In addition to laboratories that support all of the requirements of raw material, finished product and stability testing, ANI has a 1,000 square foot pilot laboratory offering liquid, suspension and solid dose development capabilities. This pilot laboratory offers a full range of analytical capabilities including method development, validation and de-formulation, and is licensed by the Drug Enforcement Administration (DEA). In addition, a separate development suite located within ANI's high-potency manufacturing facility offers additional capabilities for product development.

ANI has filed three ANDAs for products and has eight ANDAs in progress—three internal and five with development partner RiconPharma LLC (RiconPharma). RiconPharma, an experienced pharmaceutical development firm, shares in the development costs, which enables ANI to expand and diversify beyond its own suite of products. See "—Research and Development."

Over the previous ten years, ANI has had six general inspections by the Food and Drug Administration, resulting in two 483 observations, which are observations in which, in the investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product may be in violation of FDA's requirements. In addition, ANI is regularly audited by its contract manufacturing customers, including but not limited to Abbott Laboratories, JDS/Noven, MEDA Pharmaceuticals and County Line Pharmaceuticals, LLC.

## Mission and Strategy

ANI's mission is to use its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on opportunities in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations including extended release and combination products.

ANI considers a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

- **Formulation Difficulty.** Potent, extended release, combination and low dosage products.
- **Patent Status.** Existing patent protection, if any, time remaining to patent expiration, and existing patent challenges.
- **Market Size.** Current and expected market size at launch based on forecasted price erosion upon conversion from branded to generic pricing.
- **Profit Potential.** Availability and cost of active pharmaceutical ingredients combined with forecasted market share.
- **Manufacturing.** Ability of ANI to manufacture in company-owned facilities.
- **Competition.** Existing and expected competitors.

## Government Regulation

### Generic Pharmaceutical Products

Prescription pharmaceutical products in the United States are generally marketed as either branded or generic drugs. Branded products are marketed under brand names through marketing programs that are designed to generate physician and consumer loyalty. Branded products are generally patent protected, which provides a period of market exclusivity during which time they are sold with

little or no competition for the compound, although typically there are other products in the same therapeutic area. Additionally, branded products may benefit from additional periods of non-patent market exclusivity. Exclusivity ordinarily provides branded products with the ability to maintain their profitability for relatively long periods of time, and branded products typically continue to play a significant role in the market after the end of patent protection or other market exclusivities due to physician and consumer loyalties.

Generic pharmaceutical products are the chemical and therapeutic equivalents of reference branded drugs. A reference branded drug is an approved drug product listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, popularly known as the "Orange Book." The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) provides that generic drugs may enter the market after the approval of an ANDA, which requires that bioequivalence to a reference branded product be demonstrated, and the expiration, invalidation or circumvention of any patents on the corresponding reference branded drug, or the end of any other relevant market exclusivity periods related to the reference branded drug. Generic drugs are bioequivalent to their reference branded name counterparts. Bioequivalence compares the bioavailability of one drug product with that of the referenced drug product containing the same active ingredient. Bioavailability indicates the rate and extent to which the active ingredients or active moiety is absorbed from a drug product and becomes available at the site of action. When established, bioequivalence confirms the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Accordingly, generic products provide a safe, effective and cost-efficient alternative to users of these reference branded products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of branded drugs for which patent terms and/or other market exclusivities have expired.

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

*New Drug Application*—An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug.

*Abbreviated New Drug Application*—An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the FDA's Orange Book or (following FDA approval of a petition) for a new dosage form, strength or route of administration for a drug previously approved under an NDA.

The ANDA development process is generally less time-consuming and less complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the reference branded drug previously approved through the NDA process. The ANDA process, however, typically requires one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved referenced branded drug.

Generic products are generally introduced to the marketplace after the expiration of patent protection for the branded product and after the end of a period of non-patent market exclusivity. However, if an ANDA applicant files an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the Orange Book with respect to the

reference branded drug product, that generic equivalent may be able to be marketed prior to the expiration of patent protection for the branded product. Such patent certification is commonly referred to as a Paragraph IV certification. If the holder of the NDA sues, claiming patent infringement, within 45 days of notification by the applicant, the FDA may not approve the ANDA until the earlier of the rendering of a court decision favorable to the ANDA applicant or the expiration of 30 months. An ANDA applicant that is first to file a Paragraph IV certification is eligible for a period of generic marketing exclusivity. This exclusivity, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, lasts for 180 days, during which the FDA cannot grant final approval to other ANDA sponsors holding applications for a generic equivalent to the same reference branded drug.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic version product. If the reference drug is a new chemical entity, the FDA may not accept an ANDA for a generic product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for reference NDA product before the expiration of three years. Certain other periods of exclusivity may be available if the referenced drug is indicated for treatment of a rare disease or is studied for pediatric indications.

Prior Approval Supplements are required for approval of various types of changes to an approved ANDA, and these supplements may be under review for six months or more. In addition, certain types of changes may only be approved once new bioequivalence studies are conducted or other requirements are satisfied.

One requirement for FDA approval of NDAs and ANDAs is that ANI's manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as cGMP. The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the DEA and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether ANI's systems and processes are in compliance with cGMP and other FDA regulations. ANI's suppliers are subject to similar regulations and periodic inspections.

ANI has filed three ANDAs for products for which FDA approvals are expected beginning in 2014; however, ANI can offer no assurances that it in fact will be able to obtain such approvals. In addition, ANI has eight ANDAs in progress—three internal and five with a development partner. ANI expects to file an ANDA for one of these products in 2012, and the remaining seven ANDAs in 2013, with approvals expected beginning in 2015; however, there can be no assurances that the filing of these ANDAs will not be delayed or abandoned and no assurances that approval will be obtained. Further, ANI's pipeline of future development candidates includes products in each area of strategic focus, i.e., pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations including extended release and combination products.

#### ***Generic Drug User Fee Amendment***

The Generic Drug User Fee Amendment of 2012 (GDUFA) to the FDA Safety and Innovation Act gives the FDA the authority to collect user fees from the generic pharmaceutical industry to fund reviews of generic drugs. GDUFA is designed to speed access to safe and effective generic drugs to the public. The law requires generic industry participants to pay user fees to supplement the costs of reviewing generic drug applications and inspecting facilities. The FDA believes these additional resources will enable it to reduce a current backlog of pending ANDA applications and cut the average

time required to review generic drug applications for safety. For FDA's fiscal year 2013, the user fee rates are \$51,520 for new ANDAs, \$25,760 for Prior Approval Supplements, and \$17,434 for each ANDA already on file at FDA. ANI also will have to pay a facility user fee, the amount of which has not yet been established by the FDA.

During 2012, ANI paid \$68,954 for its two ANDAs on file at the FDA and \$51,520 for a new ANDA filing.

### ***Unapproved Pharmaceutical Products***

Certain of ANI's generic products are marketed without approved NDAs or ANDAs, specifically, Esterified Estrogen with Methyltestosterone and Opium Tincture. During the nine months ended September 30, 2012 and 2011, combined net revenues for these products were \$3.6 million and \$2.2 million, respectively and during the years ended December 31, 2011 and 2010, combined net revenues for these products were \$3.5 million and \$95,000, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 Compliance Policy Guide, titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. ANI believes that so long as it complies with applicable manufacturing and labeling standards, it will not be targeted for enforcement under the FDA's current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

In addition, one group of products that ANI manufactures on behalf of a contract customer, and based on the sale of which ANI receives royalties, is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market, which could materially adversely affect ANI's contract manufacturing and royalty revenue. ANI's contract manufacturing revenue for this group of products for the nine months ended September 30, 2012 and 2011 was \$775,000 and \$1.1 million, respectively. ANI's royalties on the net sales of these products for the nine months ended September 30, 2012 and 2011 were \$220,000 and \$249,000, respectively. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was \$1.3 million and \$623,000, respectively. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were \$320,000 and \$118,000, respectively.

See also "Risk Factors—Risks Related to ANI—Certain of ANI's generic products are marketed without approved NDAs or ANDAs and ANI can offer no assurances that the FDA will not require ANI to seek approval for these products or withdraw them from the market. In either case, ANI's business, financial position, results of operations and cash flows could be materially adversely affected."

### **Controlled Substances**

**U.S. Drug Enforcement Administration.** The DEA regulates certain drug products containing controlled substances, such as opium, pursuant to the U.S. Controlled Substances Act (CSA). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, ANI must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient (opium) needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture.

### **Medicaid/Medicare**

Medicaid, a U.S. federal health care program, requires all pharmaceutical manufacturers to pay rebates to state Medicaid agencies. The rebates are based on the volume of drugs that are reimbursed by the states for Medicaid beneficiaries. The Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA, raised the rebate percentages for both generic and branded pharmaceuticals effective January 1, 2010. The required rebate is currently 13 percent of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs, up from 11 percent for periods prior to 2010. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of approximately 23 percent (up from 15 percent) of the average manufacturer's price or the difference between the average manufacturer's price and the best price during a specific period. ANI believes that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public.

Under Part D of the Medicare Modernization Act, Medicare beneficiaries are eligible to obtain discounted prescription drug coverage from private sector providers. As a result, usage of pharmaceuticals has increased, which is a trend that ANI believes will continue to benefit the generic pharmaceutical industry. However, such potential sales increases may be offset by increased pricing pressures, due to the enhanced purchasing power of the private sector providers that are negotiating on behalf of Medicare beneficiaries.

Under the Patient Protection and Affordable Care Act, pharmaceutical companies are required to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. Under the Medicare Coverage Gap Discount Program authorized by PPACA, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the rebate. ANI's generic hydrocortisone enema and fluvoxamine maleate tablets, while marketed as "generics", are actually the subject of approved NDAs and, therefore, are subject to the rebate.

## Research and Development

ANI obtains new generic products through a combination of internal development and in partnership with other firms. Additionally, ANI licenses and co-develops products through arrangements with other companies.

To accelerate its product development pipeline, ANI entered into a relationship with RiconPharma. Under the parties' master product development and collaboration agreement from July 2011, ANI and RiconPharma have agreed to collaborate in a cost, asset and profit sharing arrangement for the development, manufacturing, regulatory approval and marketing of pharmaceutical products in the United States. The specific terms and conditions of each new product collaboration, including a description of the product, estimated cost of development and percentage allocation of costs and profits, are included in amending exhibits to the agreement. Unless otherwise set forth in the amending exhibit, RiconPharma is responsible for developing the products and ANI is responsible for manufacturing, sales, marketing and distribution of the products. The parties are jointly responsible for directing any bioequivalence studies. ANI is responsible for obtaining and maintaining all necessary regulatory approval, including the preparation of all ANDAs. Under the agreement and unless otherwise specified in the amending exhibit, the parties will own equally all the rights, title and interest in the products. To the extent permitted by applicable law, ANI will be identified on the product packaging as the manufacturer and labeler/distributor of the product. During the term of the agreement, both parties are prohibited from developing, manufacturing, selling or distributing any products that are identical or bioequivalent to products covered under the agreement. The master product development and collaboration agreement and any amending exhibit may be terminated as a result of uncured material breach upon 30 days' prior written notice, subject to a 30-day extension. The terminating party may not develop, manufacture, market, distribute or sale any covered product or a bioequivalent product for five years after termination. In addition, either party may terminate an amending exhibit upon 30 to 60 days' prior written notice.

During the years ended December 31, 2011 and 2010, ANI's research and development expenses were \$799,302 and \$84,762, respectively.

## Patents, Trademarks and Licenses

ANI owns the trademark names for each of its branded products, Cortenema® and Reglan®. Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. ANI does not own or license any patents associated with these products. Further, patent protection and market exclusivity for these products have long-since expired. Therefore, ANI considers the trademark names to be of material value and acts to protect these rights from infringement. However, ANI's business is not dependent upon any single trademark. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely.

In the branded pharmaceutical industry, the majority of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there can often be very substantial and rapid declines in the branded product's sales. The rate of this decline varies by country and by therapeutic category; however, following patent expiration, branded products often continue to have market viability based upon the goodwill of the product name, which typically benefits from trademark protection. ANI believes that sales of its branded products have and will continue to benefit from the goodwill of the product name.

ANI has licensed the right to manufacture and market an authorized generic version, fluvoxamine maleate, of Luvox® IR from Jazz Pharmaceuticals, which in turn acquired the rights to Luvox® IR from Solvay Pharmaceuticals, Inc. This license is in addition to a manufacturing and supply agreement with

Jazz Pharmaceuticals, under which ANI manufactures and supplies Jazz Pharmaceuticals' requirements for Luvox® IR. Under the license agreement, Jazz Pharmaceuticals transferred responsibility for the related NDA to ANI. The license agreement may be terminated by Jazz Pharmaceuticals if the Solvay license agreement is terminated, if ANI breaches or defaults in the performance or observance of any material provisions of the agreement or the related supply agreement and such breach or default is not cured within 60 days after written notice is received, in the case of voluntary or involuntary bankruptcy filings by/against ANI, if ANI does not make royalty payments when due, or in the event ANI receives an adverse finding letter from the FDA relating to the NDA and is either not able to cure or provide evidence of a reasonable plan to cure within 30 days of receipt by ANI of such adverse finding letter, among other events. ANI may terminate the agreement with the consent of Jazz Pharmaceuticals, such consent not to be unreasonably withheld.

## Customers

ANI's products are sold by four major retail pharmacy chains, Walgreens, CVS, RiteAid and Wal-Mart, and are included in the source programs of four major national wholesalers, Cardinal, McKesson, AmerisourceBergen and Morris Dickson. In addition, ANI's customers include national mail order houses and group purchasing organizations.

Abbott Laboratories, formerly Solvay Pharmaceuticals, is one of ANI's largest ongoing contract manufacturing customers, the loss of whom would have a material adverse effect on ANI's business. For 2011 and 2010, sales to Abbott represented 15.6 percent and 41.6 percent of net revenues, respectively. The written agreement under which ANI performed contract manufacturing services for Abbott Laboratories expired in April 2012 and has not been renewed. ANI currently conducts its contract manufacturing services for Abbott Laboratories based on periodic individual purchase orders submitted by Abbott Laboratories to ANI, and there can be no assurances that Abbott Laboratories will continue submitting such orders and not choose another contract manufacturer for its products.

Consistent with industry practice, ANI maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. See "ANI's Management's Discussion and Analysis of Results of Operations and Financial Condition—Critical Accounting Policies and Estimates" for a discussion of several of ANI's revenue recognition provisions.

## Markets

ANI's target markets have limited competition due to complexities in formulation, active pharmaceutical ingredient sourcing, material handling and manufacturing, and regulatory hurdles.

### *Hormone and Steroidal Drugs*

The market for hormone and steroidal drugs includes hormone therapy to alleviate menopausal symptoms in women, contraceptives, testosterone replacement therapies for men, and therapies for treating hormone-sensitive and other cancers.

Hormone Therapy (HT) has been an accepted medical treatment for alleviating the symptoms of menopause since the 1930s, with formal FDA approval for that use granted in 1942. In the beginning, HT consisted of estrogen only, but has evolved to include combination therapies of estrogen, progesterone and androgens. In 2000, the FDA approved the use of estrogen for prevention of osteoporosis. ANI targets niche products in the HT and steroidal products market for several reasons:

- Hormone and steroid products are a core competency based on ANI's manufacturing and product development teams' long history of manufacturing these types of products; and



- The aging baby boom population, of which women represent a majority, is expected to support continued growth in the HT market.

### **Oncolytics**

ANI is positioned to develop and manufacture niche oncolytic (anti-cancer) drugs due to the capabilities of the ANI's containment facility and its expertise in manufacturing segregation. In particular, ANI is targeting products subject to priority review by the FDA, those with no blocking patents, and those with no generic competition. In addition to one such product already under development, ANI has identified six additional priority review opportunities in oncolytics.

### **Narcotics**

ANI's main manufacturing facility in Baudette, Minnesota is licensed by the DEA for the manufacture and distribution of Schedule II narcotics, i.e., drugs considered to have a high abuse risk but that also have safe and accepted medical uses in the United States. In addition to its existing pipeline of three ANDAs (and five additional ANDAs with a development partner), ANI has identified additional product development opportunities in this segment.

### **Contract Manufacturing**

Contract manufacturers are experiencing significant growth as both branded and generic companies are outsourcing some or all of their production to contract manufacturing organizations (CMOs) for the following reasons:

- Free-up internal resources to focus on core competencies in sales and marketing as well as research and development;
- Utilize internal manufacturing operations for higher volume or more critical products;
- Provide an alternative cGMP production site in the event of regulatory compliance issues at primary manufacturing site; and
- Specialized equipment or unique intellectual property possessed by the CMO.

ANI considers contract manufacturing to be an important component of its ongoing business strategy. Given its highly specialized manufacturing capabilities, ANI is focused on attracting niche contract manufacturing opportunities that fill idle capacity and offer higher margins.

### **Marketing and Distribution**

ANI's products are distributed through the following channels:

- **Wholesalers.** ANI has contracts with four major wholesalers in the United States: Cardinal, McKesson, AmerisourceBergen and Morris Dickson, as well as access to their respective retail source programs.
- **Retail Market Chains.** ANI conducts business with the four major retail chains in the United States, including Walgreens, CVS, RiteAid and Wal-Mart.
- **Distributors and Mail Order Pharmacies.** ANI has contracts with several major distributors and mail order pharmacies in the United States including Anda, ExpressScripts and Omnicare.
- **Hospital Market.** ANI has contracts with group purchasing organizations in the United States, such as Premiere, MedAssets, Minnesota Multi-State and the Federal Supply Schedule (FSS).

## Competition

The U.S. pharmaceutical industry is highly competitive. ANI's primary competitors include other generic companies (both major multinational and regional companies) and branded drug companies that continue to sell or license branded pharmaceutical products after patent and other statutory expirations.

The primary means of competition among generic companies are pricing and contract terms, service levels, and supplier reliability. To compete effectively, ANI establishes active working relationships with each of its customers, continually gathers important market information in order to respond successfully to requests for proposals, maintains sufficient inventories to assure high service levels, and works to reduce product costs by sourcing and qualifying alternative suppliers whenever possible and rebidding product components on a routine basis.

ANI's sales can be impacted by new studies that indicate that a competitor's product has greater efficacy for treating a disease or particular form of a disease than one of ANI's products. If competitors introduce new products and processes with therapeutic or cost advantages, ANI's products can be subject to progressive price reductions and/or decreased volume of sales.

Principal competitors for the types of drugs in which ANI transacts business are as follows:

**Hormones and Steroids.** Competition for hormone and steroidal drugs is limited because of the small number of plants in the United States capable of safely manufacturing these high-potency compounds. Key generic participants in hormone and steroidal drugs include Amneal Pharmaceuticals, Creekwood Pharmaceuticals, Endo Pharmaceuticals, Glenmark Pharmaceuticals, Watson Pharmaceuticals and Teva Pharmaceuticals USA.

**Oncolytics.** Competitors for oncolytic products include both top-tier generic pharmaceutical companies as well as niche players. Key market participants include Mylan, Par Pharmaceutical Companies, Sandoz, the generic pharmaceuticals division of Novartis AG, Watson Pharmaceuticals and Teva Pharmaceuticals USA.

**Narcotics.** Although market share in narcotic products is concentrated among two principal companies, i.e., Purdue Pharma and Mallinckrodt, several other companies with material market share in specific product categories within narcotics include Endo Pharmaceuticals, Roxane Laboratories and Watson Pharmaceuticals.

## Product Liability

Product liability litigation represents an inherent risk to firms in the pharmaceutical industry. ANI utilizes traditional third-party insurance policies with regard to its product liability claims. Such insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time the policy is written, and the decision to obtain commercial insurance coverage or to self-insure varies accordingly.

In February 2009, the FDA mandated a "black box" warning for the drug metoclopramide, specifically highlighting the risks of patients developing tardive dyskinesia, a movement disorder, when taking metoclopramide for longer than 12 weeks. As a result, numerous state-level lawsuits were brought against pharmaceutical manufacturers, both branded and generic, who had ever manufactured and/or sold metoclopramide. Among the defendants is ANI, which manufactures the generic version and since 2011 has been manufacturing the branded version under the name Reglan®. The plaintiffs in these lawsuits claim to have incurred bodily injuries as a result of ingestion of metoclopramide or Reglan® prior to the FDA's black box warning requirement. The allegations involve a failure, based on various state-level consumer protection laws, to adequately warn patients and doctors about the risks of using metoclopramide for longer than 12 weeks as evidenced by the FDA's mandate to strengthen the

labeled warning. ANI has been named and served in 79 separate complaints between December 2009 and November 2012, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, ANI was dismissed with prejudice as a defendant in all of the cases brought in New Jersey.

As the state-level litigation progressed, the generic pharmaceutical defendants appealed to the US Supreme Court arguing that generic companies could not comply with state laws that required them to strengthen their labels because generic companies are prohibited by federal law from making any changes except those adopted by the brand or mandated by FDA for all manufacturers, e.g. federal pre-emption. The US Supreme Court decided in favor of the generic companies in June 2011 in what is known now as the *Mensing* decision. While many cases have since been dismissed by state courts, several judges, including in Pennsylvania and California, have allowed the plaintiffs to resubmit their complaints.

At the present time, ANI's management is unable to assess the likely outcome of the remaining cases. ANI's insurance company has assumed the defense of this matter. In addition, ANI's insurance company renewed ANI's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. ANI cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, ANI in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

## **Suppliers and Raw Materials**

ANI sources the raw materials for its products, including active pharmaceutical ingredients (API) from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability. ANI's principal API suppliers include Mallinckrodt, Symbiotech Pharmed, Johnson Matthey and Pfizer Centertech.

In addition, each year, ANI must submit a request to the Drug Enforcement Agency (DEA) for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase this ingredient from its supplier. As a result, ANI is dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture.

## **Employees**

ANI's workforce includes 69 full-time employees, including 36 salaried employees, and a flexible direct labor pool of 18 experienced pharmaceutical manufacturing and packaging staff. Of the full-time employees, 44 are in selling, general and administrative, 20 in production and five in research and development.

## ANI'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with ANI's financial statements and condensed financial statements and accompanying notes appearing elsewhere in this joint proxy statement/prospectus. This discussion contains forward-looking statements, based on current expectations and related to future events and ANI's future financial performance, that involve risks and uncertainties. ANI's actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors—Risks Related to ANI" and "Risk Factors—Risks Related to the Combined Company" and elsewhere in this joint proxy statement/prospectus.

### Overview

ANI is a fully integrated specialty branded and generic pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, ANI manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. ANI also performs contract manufacturing for other pharmaceutical companies.

ANI's established product portfolio consists of both branded and generic pharmaceuticals, including:

<u>Generic Products</u>	<u>Branded Products</u>
Opium Tincture	Cortenema®
Fluvoxamine Maleate Tablets	Reglan® Tablets
Esterified Estrogen with Methyltestosterone Tablets	
Hydrocortisone Enema	
Metoclopramide Syrup	

ANI's business strategy is to utilize its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on products in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations, including extended release and combination products. These areas of focus reflect ANI's specialized manufacturing experience and capabilities and offer a large number of attractive niche generic product opportunities.

ANI considers a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

- **Formulation Difficulty.** Potent, extended release, combination and low dosage products.
- **Patent Status.** Existing patent protection, if any, time remaining to patent expiration, and existing patent challenges.
- **Market Size.** Current and expected market size at launch based on forecasted price erosion upon conversion from branded to generic pricing.
- **Profit Potential.** Availability and cost of active pharmaceutical ingredients combined with forecasted market share.
- **Manufacturing.** Ability of ANI to manufacture in company-owned facilities.
- **Competition.** Existing and expected competitors.

## **Recent Developments**

In October 2012, ANI entered into a definitive merger agreement with BioSante pursuant to which the companies are to merge in an all-stock transaction. Under the terms of the agreement, upon completion of the merger, BioSante will issue to ANI stockholders shares of BioSante common stock such that the ANI stockholders will own approximately 53 percent of the combined company's shares outstanding, and the BioSante stockholders will own approximately 47 percent, subject to adjustment as provided in the merger agreement. In addition, immediately prior to the merger, BioSante plans to distribute to its then current stockholders contingent value rights (CVR) providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel® (female testosterone gel). Upon completion of the merger, the combined company will be renamed ANI Pharmaceuticals, Inc. and will operate under the leadership of ANI's management team. The board of directors of the combined company is expected to have two directors from BioSante and five directors from ANI. The merger, which is subject to normal closing conditions including approval of the stockholders of both BioSante and ANI, is expect to close during the first quarter of 2013. Completion of the merger is subject to the number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible not waived, the merger will not be consummated. For further details, please refer to the sections entitled "The Merger" and "The Merger Agreement" in this joint proxy statement/prospectus.

## **Critical Accounting Policies and the Use of Estimates**

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on ANI's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires ANI to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, ANI evaluates these estimates and assumptions, including those described below. ANI bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

Some of the estimates and assumptions ANI has to make under GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding ANI's business operations, financial condition and results of operations.

### ***Revenue Recognition***

Revenue is recognized for product sales upon shipment and when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured and ANI has no further performance obligations. These estimates reduce gross revenues to net revenues in the statements of operations, or are presented as current liabilities or reductions in accounts receivable in the balance sheets.

### ***Accruals for Chargebacks, Returns and Other Allowances***

ANI's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. ANI accrues for these items at the time of sale based on the estimates and methodologies

described below. In the aggregate, these gross-to-net accruals exceed 65 percent of generic and branded gross product sales and reduce gross revenues to net revenues in the statements of operations, or are presented as current liabilities or reductions in accounts receivable in the balance sheets. ANI continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. ANI makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances.

### *Chargebacks*

Chargebacks, primarily from wholesalers, are the most significant of ANI's accruals. Chargebacks result from arrangements ANI has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, ANI may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, ANI provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost (WAC).

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price (ASP) for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- a change in customer mix;
- a change in negotiated terms with customers;
- a change in product sales mix;
- a change in the volume of off-contract purchases; and
- changes in WAC.

As necessary, ANI adjusts ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded at the same time ANI recognizes revenue from the product sale as a reduction in both gross revenues and accounts receivable.

To evaluate the adequacy of its chargeback accruals, ANI obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. ANI continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

### *Returns*

Consistent with industry practice, ANI maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date until up to one year after its expiration date. ANI's product returns are settled through the issuance of a credit to the customer. ANI's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. ANI continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

### Administrative Fees and Other Rebates

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers, consistent with pharmaceutical industry practice. ANI accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, ANI obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. ANI continually monitors administrative fee activity and adjusts its accruals when it believes that actual administrative fees will differ from the accruals.

### Prompt Payment Discounts

Sales discounts are granted for prompt payment. The reserve for sales discounts is based on invoices outstanding. ANI assumes based on past experience that 100 percent of available discounts will be taken.

The following table summarizes activity in the balance sheet for accruals and allowances for the nine months ended September 30, 2012 and fiscal years ended December 31, 2011 and 2010:

	Accruals for Chargebacks, Returns and Other Allowances			
	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2009	\$ 439,176	\$ —	\$ —	\$ —
Accruals/Adjustments	1,975,853	80,067	114,727	25,000
Credits Taken Against Reserve	(1,664,571)	—	(55,125)	—
Balance at December 31, 2010	\$ 750,458	\$ 80,067	\$ 59,602	\$ 25,000
Accruals/Adjustments	13,005,579	356,364	672,882	446,187
Credits Taken Against Reserve	(10,075,199)	(184,386)	(494,289)	(304,748)
Balance at December 31, 2011	\$ 3,680,838	\$ 252,045	\$ 238,195	\$ 166,439
Accruals/Adjustments	15,996,550	486,844	925,488	522,812
Credits Taken Against Reserve	(15,348,165)	(351,274)	(892,370)	(481,435)
Balance at September 30, 2012	\$ 4,329,223	\$ 387,615	\$ 271,313	\$ 207,816

### Accounts Receivable

ANI extends credit to customers on an unsecured basis. ANI utilizes the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable. ANI provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. ANI's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. ANI determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. ANI determined that no allowance for doubtful accounts was necessary as of September 30, 2012 or December 31, 2011 and 2010.

### Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05, Presentation of Comprehensive Income. ASU 2011-05 revises the manner in which entities present comprehensive income in their financial statements. The new guidance removes the presentation options in Accounting Standards Codification 220 and requires entities to report

components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. ASU 2011-05 did not change the items that must be reported in other comprehensive income. ANI adopted the provisions of ASU 2011-05 in the first quarter of 2012. As ANI's net loss is the same as comprehensive loss, ANI did not present a statement of comprehensive loss.

## General

The following table sets forth, for all periods indicated, the percentage relationship that items in ANI's Statements of Operations bear to net revenues.

	Nine Months Ended September 30,		Years Ended December 31,	
	2012	2011	2011	2010
Net revenues	100.0%	100.0%	100.0%	100.0%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	41.8%	40.8%	41.5%	38.5%
Salaries and benefits	23.4%	27.1%	26.5%	49.4%
Freight	1.6%	1.5%	1.5%	1.5%
Research and development	4.2%	6.1%	4.8%	0.9%
Selling, general and administrative	19.7%	23.0%	22.5%	35.8%
Depreciation and amortization	2.8%	3.3%	3.2%	5.4%
Operating income (loss) from continuing operations	6.5%	(1.8)%	0.0%	(31.5)%
Interest expense	8.2%	13.4%	13.6%	13.1%
Other expense	1.3%	2.1%	2.3%	1.5%
Net loss from continuing operations	(3.0)%	(17.3)%	(15.9)%	(46.1)%
Gain (loss) on discontinued operation	0.7%	2.4%	1.2%	(57.1)%
Net loss	(2.3)%	(14.9)%	(14.7)%	(103.2)%

The following table summarizes ANI's results of operations for the nine months ended September 30, 2012 and 2011 and the years ended December 31, 2011 and 2010.

	Nine Months Ended September 30,		Years Ended December 31,	
	2012	2011	2011	2010
Net revenues	\$ 15,049,619	\$ 11,954,985	\$ 16,514,579	\$ 8,974,818
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	6,292,377	4,875,692	6,860,551	3,456,999
Salaries and benefits	3,516,427	3,245,637	4,352,250	4,425,012
Freight	242,814	178,499	253,394	137,837
Research and development	636,726	726,960	799,302	84,762
Selling, general and administrative	2,961,649	2,744,334	3,711,669	3,214,706
Depreciation and amortization	425,238	391,917	532,768	486,315
Operating income (loss) from continuing operations	\$ 974,388	\$ (208,054)	\$ 4,645	\$ (2,830,813)
Interest expense	1,239,137	1,597,156	2,253,794	1,179,431
Other expense	190,605	254,006	384,555	138,061
Net loss from continuing operations	\$ (455,354)	\$ (2,059,216)	\$ (2,633,704)	\$ (4,148,305)
Gain (loss) on discontinued operation	104,120	291,096	205,545	(5,124,805)
Net loss	\$ (351,234)	\$ (1,768,120)	\$ (2,428,159)	\$ (9,273,110)



**Results of Operations for the Nine Months Ended September 30, 2012 and 2011****Net Revenues**

	Nine Months Ended September 30,		Change	% Change
	2012	2011		
ANI generic pharmaceutical products	\$ 7,401,002	\$ 4,974,433	\$ 2,426,569	48.8%
ANI branded pharmaceutical products	1,320,480	599,582	720,898	120.2%
Contract manufacturing	5,701,893	5,884,512	(182,619)	(3.1)%
Contract services and other income	626,244	496,458	129,786	26.1%
<b>Total net revenues</b>	<b>\$ 15,049,619</b>	<b>\$ 11,954,985</b>	<b>\$ 3,094,634</b>	<b>25.9%</b>

ANI has historically derived substantially all of its revenues from sales of generic and branded pharmaceutical products, contract manufacturing and contract services, which includes product development services for potential contract customers, laboratory services for existing contract customers where those services are billed separately from contract manufacturing and royalties on net sales of certain contract manufactured products. Revenue for the nine months ended September 30, 2012 was \$15.0 million compared to \$12.0 million for the nine months ended September 30, 2011.

Revenue for the nine months ended September 30, 2012 increased \$3.1 million, or 25.9 percent, compared to revenue for the nine months ended September 30, 2011, primarily as a result of the following factors:

- Net revenues for ANI generic pharmaceutical products were \$7.4 million in the nine months ended September 30, 2012, an increase of 48.8 percent compared to \$5.0 million for the same period in 2011. The primary reasons for the increase were significant market share gains on Opium Tincture, Fluvoxamine Maleate tablets, and Esterified Estrogen with Methyltestosterone tablets. For Fluvoxamine Maleate and Esterified Estrogen with Methyltestosterone, the market share gains resulted from winning primary positions on wholesaler source programs through competitive bidding processes. For Opium Tincture, ANI secured additional market share due to a decrease in competition. Additional competition ordinarily has a negative impact on the pricing and volume of the affected products and, conversely, reduced competition ordinarily has a positive impact. In addition to the decrease in competition, the cost of the active pharmaceutical ingredient for Opium Tincture increased on January 1, 2012. This increased cost was passed along to ANI's end customers through finished product price increases. Increased sales of Hydrocortisone enema, and Metoclopramide oral solution also contributed to the positive results. Partially offsetting these increases was a decrease in average pricing for Esterified Estrogen with Methyltestosterone tablets as a result of ANI matching lower pricing offered by a competitor to an established ANI customer. As described in further detail under "Business—Government Regulation—Unapproved Pharmaceutical Products," ANI markets Opium Tincture and Esterified Estrogen with Methyltestosterone without FDA-approved New Drug Applications (NDAs). The FDA has stated that it will follow a risk-based approach, on a case-by-case basis, in deciding whether to take enforcement action against unapproved products, and ANI believes that so long as it complies with applicable manufacturing and labeling standards, the FDA will not take enforcement action against it with respect to the marketing of Opium Tincture and Esterified Estrogen with Methyltestosterone. However, there can be no assurance that the FDA will continue its policy or not take a contrary position with respect to such products. If the FDA were to take a contrary position, ANI may be required to seek FDA approval for Opium Tincture, Esterified Estrogen with Methyltestosterone, or both, or withdraw those products from the market. ANI's combined net revenues for Opium Tincture and Esterified Estrogen with Methyltestosterone for the nine months ended September 30, 2012 and

2011 were \$3.6 million and \$2.2 million, respectively. In addition, if ANI decided to seek FDA approval, it would face increased expenses. In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product.

- Net revenues for ANI branded pharmaceutical products were \$1.3 million in the nine months ended September 30, 2012, an increase of 120.2 percent compared to approximately \$600,000 for the same period in 2011. In mid-2011, ANI acquired and launched Reglan® tablets, which contributed to revenue for all nine months ended September, 2012 but only for three of the nine months in the prior year period. Increased sales for Cortenema® also contributed to the increase.
- Contract manufacturing revenues were \$5.7 million in the first nine months of 2012, a decrease of 3.1 percent from \$5.9 million for the corresponding period in 2011, due to decreased orders from contract manufacturing customers during the 2012 period. Abbott Laboratories, formerly Solvay Pharmaceuticals, is one of ANI's largest ongoing contract manufacturing customers, the loss of whom would have a material adverse effect on ANI's business. For 2011 and 2010, sales to Abbott Laboratories represented 15.6 percent and 41.6 percent of net revenues, respectively. The written agreement under which ANI performed contract manufacturing services for Abbott Laboratories expired in April 2012 and has not been renewed. ANI currently conducts its contract manufacturing services for Abbott Laboratories based on periodic individual purchase orders submitted by Abbot Laboratories to ANI, and there can be no assurance that Abbott Laboratories will continue submitting such orders and not choose another contract manufacturer for its products. In addition, one group of products that ANI manufactures on behalf of a contract customer is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. ANI's contract manufacturing revenue for the group of unapproved products for the nine months ended September 30, 2012 and 2011 was \$775,000 and \$1.1 million, respectively.
- Contract services and other income were approximately \$626,000 in the first nine months of 2012, an increase of 26.1 percent from approximately \$496,000 for the corresponding period in 2011, due to increased fees charged to contract manufacturing customers during the period. ANI receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. ANI's royalties on the net sales of these unapproved products for the nine months ended September 30, 2012 and 2011 were \$220,000 and \$249,000, respectively.

#### ***Cost of Sales (Exclusive of Depreciation and Amortization)***

	Nine Months Ended September 30,		Change	% Change
	2012	2011		
Cost of sales (exclusive of depreciation and amortization)	\$ 6,292,377	\$ 4,875,692	\$ 1,416,685	29.1%

Cost of sales consists of direct labor, including manufacturing and packaging, active pharmaceutical ingredients, excipients and packaging components. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on ANI's statements of operations.

For the nine months ended September 30, 2012, cost of sales increased to \$6.3 million from \$4.9 million for the corresponding 2011 period, an increase of \$1.4 million or 29.1 percent, primarily as a result of an increase in sales of ANI generic and branded pharmaceutical products. Cost of sales as a percentage of net revenues increased to 41.8 percent during the nine months ended September 30, 2012 from 40.8 percent for the corresponding 2011 period, primarily as a result of the following factors:

- The cost of the active pharmaceutical ingredient for Opium Tincture increased on January 1, 2012. This increased cost was partially passed along to ANI's end customers.
- The average selling price for Esterified Estrogen with Methyltestosterone tablets decreased as a result of ANI matching lower pricing offered by a competitor.

ANI sources the raw materials for its products, including active pharmaceutical ingredients (API), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which approval can take 18 months or longer. As a result, ANI is dependent upon its current vendors to supply reliably the API required for ongoing product manufacturing. During the nine months ended September 30, 2012, ANI purchased approximately 43 percent of total costs of sales from two suppliers. As of September 30, 2012, amounts payable to these suppliers totaled \$159,705.

Each year, ANI must submit a request to the Drug Enforcement Agency (DEA) for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from DEA, ANI would not be able to purchase API from its supplier. As a result, ANI is dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

#### **Other Operating Expenses**

	Nine Months Ended September 30,		Change	% Change
	2012	2011		
Salaries and benefits	\$ 3,516,427	\$ 3,245,637	\$ 270,790	8.3%
Freight	242,814	178,499	64,315	36.0%
Research and development	636,726	726,960	(90,234)	(12.4)%
Selling, general and administrative	2,961,649	2,744,334	217,315	(7.9)%
Depreciation and amortization	425,238	391,917	33,321	8.5%
Total other operating expenses	<u>\$ 7,782,854</u>	<u>\$ 7,287,347</u>	<u>\$ 495,507</u>	<u>6.8%</u>

Other operating expenses consist of salaries and benefits, outbound freight, research and development costs, selling, general and administrative expenses, and depreciation and amortization. ANI expects other operating expenses to continue to increase in the future due to anticipated hiring of additional employees to support the activities associated with being a public company, assuming ANI's pending merger with BioSante is completed and to support anticipated additional revenue growth, as well as from anticipated additional research and product development costs.

For the nine months ended September 30, 2012, other operating expenses increased to \$7.8 million from \$7.3 million for the corresponding 2011 period, an increase of approximately \$496,000 or 6.8 percent, primarily as a result of the following factors:

- Salaries and benefits increased from \$3.2 million to \$3.5 million, as a result of hiring new employees combined with increases in benefit costs, particularly health insurance.
- Freight expense increased from approximately \$178,000 to \$243,000 due to higher sales.

- Research and development expenses decreased from approximately \$727,000 to \$637,000, due to timing differences in product development schedules between the periods.
- Selling, general and administrative expenses increased from \$2.7 million to \$3.0 million as a result of expenses incurred relating to ANI's pending merger with BioSante, which were partially offset by decreases in promotional allowances. Promotional allowances during the 2011 prior period were higher as a result of the launches of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture.
- Depreciation and amortization expense increased from approximately \$392,000 to \$425,000 as a result of an increase in manufacturing equipment.

Other operating expenses as a percentage of net revenues decreased to 51.7 percent during the nine months ended September 30, 2012 from 61.0 percent for the corresponding 2011 period, primarily as a result of ANI controlling these costs while increasing net revenues by \$3.1 million during the same period.

#### **Other Expenses**

	Nine Months Ended September 30,		Change	% Change
	2012	2011		
Interest expense	\$ 1,239,137	\$ 1,597,156	\$ (358,019)	(22.4)%
Other expense	190,605	254,006	(63,401)	(25.0)%
<b>Total other expenses</b>	<b>\$ 1,429,742</b>	<b>\$ 1,851,162</b>	<b>\$ (421,420)</b>	<b>(22.8)%</b>

Other expenses consist of interest expense associated with ANI's revolving line of credit and secured subordinated convertible notes, and other non-operating expenses including monitoring and advisory fees totaling \$200,000 annually to certain of ANI's investors. See "Management of the Combined Company Following the Merger-Certain Relationships and Related Transactions" for further details.

- Interest expense decreased from \$1.6 million to \$1.2 million as a result of the conversion on June 6, 2012 of all of the outstanding subordinated debt to Series D convertible preferred stock.
- Other expense decreased from approximately \$254,000 to \$191,000 as a result of higher costs, including forbearance fees, in the 2011 prior period related to ANI's then-existing line of credit. ANI expects other expense to decrease assuming the completion of its pending merger with BioSante, which will terminate the monitoring and advisory fee agreements. At the closing of the merger, however, approximately \$540,000 will be payable under the monitoring and advisory fee agreements, which amounts cover the accrued portion of monitoring and advisory fees as well as approximately \$390,000 for overall management, deal structuring, financial advisory and due diligence services in connection with the merger. See "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions" for further details.

#### **Gain on Discontinued Operation**

	Nine Months Ended September 30,		Change	% Change
	2012	2011		
Gain on discontinued operation	\$ 104,120	\$ 291,096	\$ (186,976)	(64.2)%

Gain on discontinued operation consists of revenue and expenses associated with ANI's over-the-counter pharmaceutical products operation in Gulfport, Mississippi. This operation was sold in September 2010.

For the nine months ended September 30, 2012, gain on discontinued operation decreased to approximately \$104,000 from \$291,000 for the corresponding 2011 period, primarily as a result of a recovery of bad debt and increased settlement activity with suppliers in 2011.

## Results of Operations for the Years Ended December 31, 2011 and 2010

### Net Revenues

	Years Ended December 31,		Change	% Change
	2011	2010		
ANI generic pharmaceutical products	\$ 6,852,338	\$ 1,394,006	\$ 5,458,332	391.6%
ANI branded pharmaceutical products	952,439	233,567	718,872	307.8%
Contract manufacturing	7,945,704	6,443,272	1,502,432	23.3%
Contract services and other income	764,098	903,973	(139,875)	(15.5)%
Total net revenues	\$ 16,514,579	\$ 8,974,818	\$ 7,539,761	84.0%

Revenue for the year ended December 31, 2011 increased to \$16.5 million from \$9.0 million in 2010, an increase of \$7.5 million or 84.0 percent, primarily as a result of the following factors:

- Net revenues for ANI generic pharmaceutical products were \$6.9 million in the year ended December 31, 2011, an increase of 391.6 percent compared to \$1.4 million for the same period in 2010. The primary reasons for the increase were the launches of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture during 2011 as well as market share gains on Fluvoxamine Maleate tablets and Hydrocortisone enema, partially offset by lower sales for Metoclopramide oral solution. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011—Net Revenues" for material uncertainties relating to ANI's marketing of Opium Tincture and Esterified Estrogen with Methyltestosterone. ANI's combined net revenues for Opium Tincture and Esterified Estrogen with Methyltestosterone for the years ended December 31, 2011 and 2010 were \$3.5 million and \$95,000, respectively.
- Net revenues for ANI branded pharmaceutical products were approximately \$952,000 in the year ended December 31, 2011, an increase of 307.8 percent compared to approximately \$234,000 for the same period in 2010. In mid-2011, ANI acquired and launched Reglan® tablets, which contributed to net revenues for the six months ended December 31, 2011, as further explained above under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011—Net Revenues." Increased sales for Cortenema® also contributed to the increase.
- Contract manufacturing revenues were \$7.9 million in the year ended December 31, 2011, an increase of 23.3 percent from \$6.4 million for the corresponding period in 2010, due to increased orders totaling \$2.3 million from contract manufacturing customers, partially offset by a decrease in orders from a single contract manufacturing customer during the period. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011—Net Revenues" for material uncertainties relating to contract manufacturing services provided for Abbott Laboratories as well as material uncertainties relating to revenue from one of ANI's customer's marketing of a group of unapproved products. ANI's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was \$1.3 million and \$623,000, respectively.

- Contract services and other income were approximately \$764,000 in the year ended December 31, 2011, a decrease of 15.5 percent from approximately \$904,000 for the corresponding period in 2010, due to decreased laboratory service fees charged to contract manufacturing customers during the period, partially offset by increased fees charged for contract product development. Please refer to the description under "Results of Operations for the Nine Months Ended September 30, 2012 and 2011—Net Revenues" for material uncertainties relating to one of ANI's customer's marketing of its group of unapproved products. ANI's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were \$320,000 and \$118,000, respectively.

#### **Cost of Sales (Exclusive of Depreciation and Amortization)**

	<u>Years Ended December 31,</u>		<u>Change</u>	<u>% Change</u>
	<u>2011</u>	<u>2010</u>		
Cost of sales (exclusive of depreciation and amortization)	\$ 6,860,551	\$ 3,456,999	\$ 3,403,552	98.5%

For the year ended December 31, 2011, cost of sales increased to \$6.9 million from \$3.5 million in 2010, an increase of \$3.4 million or 98.5 percent, primarily as a result of an increase in sales of ANI generic and branded pharmaceutical products. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on ANI's statements of operations.

Cost of sales as a percentage of net revenues increased to 41.5 percent during year ended December 31, 2011 from 38.5 percent for the corresponding 2010 period, primarily as a result of a higher percentage of net revenues comprised of ANI's generic pharmaceutical products, which generally produce lower margins than contract manufacturing. Please refer to "—Results of Operations for the Nine Months Ended September 30, 2012 and 2011—Cost of Sales" for a description of material uncertainties faced by pharmaceutical manufacturers, including ANI, with respect to their suppliers.

#### **Other Operating Expenses**

	<u>Years Ended December 31,</u>		<u>Change</u>	<u>% Change</u>
	<u>2011</u>	<u>2010</u>		
Salaries and benefits	\$ 4,352,250	\$ 4,425,012	\$ (72,762)	(1.6)%
Freight	253,394	137,837	115,557	83.8%
Research and development	799,302	84,762	714,540	843.0%
Selling, general and administrative	3,711,669	3,214,706	496,963	15.5%
Depreciation and amortization	532,768	486,315	46,453	9.6%
Total other operating expenses	<u>\$ 9,649,383</u>	<u>\$ 8,348,632</u>	<u>\$ 1,300,751</u>	<u>15.6%</u>

For the year ended December 31, 2011, other operating expenses increased to \$9.6 million from \$8.3 million in 2010, an increase of \$1.3 million or 15.6 percent, primarily as a result of the following factors:

- Salaries and benefits decreased by approximately \$73,000, primarily as a result of concluding in 2010 severance payments to a former employee.
- Freight expense increased from approximately \$138,000 to \$253,000 due to higher sales.
- Research and development expenses increased from approximately \$85,000 to \$799,000, due to the initiation of ANI's internal product development program during 2011.

- Selling, general and administrative expenses increased from \$3.2 million to \$3.7 million as a result of increases in maintenance expenses, promotional allowances and utility costs. Maintenance expenses increased due to ANI's greater production volumes during 2011 compared to 2010. Promotional allowances during 2011 were higher as a result of the launch of Esterified Estrogen with Methyltestosterone tablets and Opium Tincture during the period. Utility costs increased due to higher production volumes as well as significant rate hikes in March 2011 from ANI's electricity providers.
- Depreciation and amortization expense increased from approximately \$486,000 to \$533,000 as a result of an increase in manufacturing equipment.

#### **Other Expenses**

	Years Ended December 31,		Change	% Change
	2011	2010		
Interest expense	\$ 2,253,794	\$ 1,179,431	\$ 1,074,363	91.1%
Other expense	384,555	138,061	246,494	178.5%
Total other expenses	<u>\$ 2,638,349</u>	<u>\$ 1,317,492</u>	<u>\$ 1,320,857</u>	<u>100.3%</u>

For the year ended December 31, 2011, other expenses increased to \$2.6 million from \$1.3 million in 2010, an increase of \$1.3 million or 100.3 percent, primarily as a result of the following factors:

- Interest expense increased from \$1.2 million to \$2.3 million as a result of increases in the amount of secured subordinated convertible notes on ANI's balance sheet.
- Other expense increased from approximately \$138,000 to \$384,000. In 2011, ANI entered into an agreement to pay monitoring and advisory fees totaling \$200,000 annually to certain of ANI's investors. See "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions" for further details.

#### **Gain (Loss) on Discontinued Operation**

	Years Ended December 31,		Change	% Change
	2011	2010		
Gain (loss) on discontinued operation	\$ 205,545	\$ (5,124,805)	\$ 5,330,350	104.0%

For the year ended December 31, 2011, gain (loss) on discontinued operation was a gain of approximately \$206,000 versus a loss of \$5.1 million in 2010. Upon the sale in October 2010 of the Gulfport, Mississippi operation, ANI recognized a loss for the difference between the consideration received from the sale and the carrying value of the operation's net assets on the date of sale. The gain in 2011 resulted from a recovery of bad debt and increased settlement activity with suppliers.

**Liquidity and Capital Resources**

The following table highlights selected liquidity and working capital information from ANI's balance sheets.

	September 30,	December 31,	
	2012	2011	2010
Cash and cash equivalents	\$ 148,331	\$ —	\$ —
Accounts receivable, net	5,622,997	5,104,568	1,689,203
Inventories	2,494,635	2,107,463	2,361,990
Prepaid expenses	402,335	224,618	978,408
<b>Total current assets</b>	<b>\$ 8,668,298</b>	<b>\$ 7,436,649</b>	<b>\$ 5,029,601</b>
Accounts payable	\$ 1,296,220	\$ 1,208,323	\$ 1,638,226
Accrued expenses	876,712	824,011	338,422
Returned goods reserve	387,615	252,045	80,067
Borrowing under line of credit	3,428,776	3,064,414	1,722,678
Current maturities of long-term debt	—	—	400,000
Notes payable	—	300,000	275,000
Current liabilities of discontinued operation	378,565	512,275	1,500,693
<b>Total current liabilities</b>	<b>\$ 6,367,888</b>	<b>\$ 6,161,068</b>	<b>\$ 5,955,086</b>

At September 30, 2012, ANI had approximately \$148,000 in cash, cash equivalents and short-term investments and unused availability under its line of credit of approximately \$1.6 million. At December 31, 2011, ANI had zero cash, cash equivalents and short-term investments and approximately \$36,000 of unused availability under its then-existing line of credit.

ANI's primary cash requirements are to fund operations, including research and development programs, and support general and administrative activities. ANI's future capital requirements will depend on many factors, including, but not limited to:

- proportions of net revenues comprised of contract manufacturing and sales of ANI generic and branded products;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

Consolidation among wholesale distributors, chain drug stores and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. ANI's net revenues are concentrated among three customers representing 24 percent, 21 percent and 12 percent of net revenues, respectively, during the nine months ended September 30, 2012. As of September 30, 2012, accounts receivable from these three customers totaled \$3.6 million, or approximately 64 percent of ANI's net accounts receivable. ANI's net revenues for those same three customers were 21 percent, 16 percent and 16 percent for the year ended December 31, 2011 and six percent, four percent and 42 percent for the year ended December 31, 2010. As of December 31, 2011 and 2010, accounts receivable from these three customers totaled \$3.2 million or approximately 63 percent of net accounts receivable, and \$840,000 or approximately 50 percent of net accounts receivable, respectively. As a result, negotiated payment terms with these customers have a material impact on ANI's liquidity and working capital.



Two of ANI's generic pharmaceutical products, Opium Tincture and Fluvoxamine Maleate tablets, account for approximately 30 percent of ANI's net revenues. As a result, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on ANI's liquidity and working capital.

Other than during the nine months ended September 30, 2012, ANI has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, ANI has relied on a variety of financing sources, including the issuance of equity securities and convertible notes and revolving lines of credit. Based on projected revenue and expenses for the next twelve months, ANI anticipates that current cash on hand and borrowing availability under its revolving line of credit will be sufficient to meet ongoing expenses and capital requirements at least through December 31, 2013, assuming the pending merger with BioSante is not completed. Assuming the merger is completed, ANI anticipates that its current resources, combined with the additional cash, expected future licensing revenues, and other assets of BioSante, will be sufficient to meet ongoing expenses and capital requirements at least through December 31, 2015. If ANI's assumptions underlying estimated revenue and expenses prove to be wrong or if its cash requirements change materially as a result of shifts in its business and strategy, ANI or the combined company, as the case may be, may require additional financing to fund operating and capital requirements, and may require such financing prior to the dates specified above.

The continuing global economic uncertainty, exacerbated by the European debt crisis and the "fiscal cliff" in the United States, has resulted in extreme volatility in the capital markets and is threatening to once again tighten the credit markets. As a result, there can be no assurance that future funding will be available to ANI on reasonably acceptable terms, or at all.

ANI has incurred cumulative net losses and expects to incur additional losses in conducting further research and development activities. ANI has relatively limited capital resources. ANI's plans with regard to these matters include raising additional capital through the issuance of equity securities, debt securities, or both, increasing net revenues through product acquisitions, new product launches, reducing manufacturing costs and completion of the planned merger with BioSante. Although ANI continues to pursue these plans, there is no assurance that sufficient future financing will be available on commercially reasonable terms or at all, that ANI will be able to generate sufficient revenue or that ANI will be able to lower its manufacturing costs. ANI's consolidated financial statements have been prepared on a basis that assumes that it will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. These statements do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

### **Sources and Uses of Cash**

#### *Debt Financing*

ANI utilizes a revolving line of credit to finance its operations. Under the line of credit in place at December 31, 2011, ANI's borrowings were based on a percentage of eligible accounts receivable and inventory, up to a maximum of \$3.5 million. Without considering the \$3.5 million limit, but applying the applicable percentage to eligible accounts receivable and inventory, ANI could have borrowed up to \$4.9 million at December 31, 2011. As a result of the loan limit restriction and other factors, on June 6, 2012, ANI refinanced its line of credit with a new lender, Alostark Bank of Commerce.

Under the new arrangement, ANI may borrow on a revolving basis, based on a percentage of eligible accounts receivable and inventory, up to a maximum of \$5.0 million. The loan agreement bears interest daily at the greater of (i) LIBOR plus 5 percent or (ii) 6 percent. The line of credit is secured by substantially all of ANI's assets. The principal is repayable at the termination date, unless accelerated as a result of certain events of default. If ANI generates any proceeds from the collateral

securing the line of credit, such proceeds must be paid to the lender up to the amount of any outstanding balance. Interest is due and payable on the first of every month and at the termination date, unless accelerated as a result of an event of default. In addition, a usage fee equal to 0.375 percent per annum of the unused amounts under the facility and a management fee equal to \$18,000 per annum are assessed monthly. The revolving loan agreement expires in June 2015, but can be terminated early in the following circumstances: (a) automatically upon the commencement of insolvency proceedings by or against ANI, (b) at the option of the lender without notice upon any other event of default, and (c) at the option of ANI upon ten business days' prior written notice.

In the event of early termination, whether effected by ANI, the lender or automatically, ANI is obligated to pay an amount corresponding to a percentage of \$5.0 million, with such percentage being: 3 percent if termination occurs in the first year, 2 percent if termination occurs in the second year and 1 percent if termination occurs after the second year but prior to the last day of the term.

The loan agreement contains customary representations, warranties and covenants.

ANI must maintain a minimum fixed charge coverage ratio of 1.1 to 1.0, calculated by dividing (a) (i) Earnings before Interest, Taxes, Depreciation and Amortization (EBITDA) less (ii) unfinanced capital expenditures, by (b) the sum of cash paid for (i) interest and (ii) monitoring and advisory fees (See "Management of the Combined Company Following the Merger—Certain Relationships and Related Transactions.") Also, ANI must generate at least \$800,000 in EBITDA, measured on a trailing four-quarter basis. Restrictive covenants apply to, among other things, research and development expenditures, incurrence of additional indebtedness, prepayment of other indebtedness, additional liens, acquisitions, mergers or consolidations and sales of assets.

The representations, warranties and covenants contained in the loan agreement were made only for purposes of such agreement and as of a specific date or specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the loan agreement.

Events of default under the agreement include, but are not limited to: (i) liquidation, bankruptcy or similar events; (ii) failure to pay any debts due on a timely basis; (iii) failure to observe any covenant or condition under the loan agreement, which failure, in most cases, is not cured within 30 days of written notice by lender; (iv) material misrepresentations; (v) ANI is restrained by court order from continuing to conduct all or any material part of ANI's business; (vi) certain money judgments are entered against ANI; and (vii) ANI challenges the validity or enforceability of the loan agreement in any proceeding. Remedies for events of default include acceleration of amounts owing under the loan agreement and taking immediate possession of, and selling, any collateral securing the loan.

As of September 30, 2012, approximately \$3.4 million was outstanding under the loan agreement, at an effective interest rate of 6.0 percent. ANI was in compliance with all of the covenants under the loan agreement as of September 30, 2012 and expects to remain in compliance with such covenants during the remainder of 2012.

At September 30, 2012, ANI had approximately \$148,000 in cash, cash equivalents and short-term investments and unused availability under its line of credit of approximately \$1.6 million. At December 31, 2011, ANI had zero cash, cash equivalents and short-term investments and approximately \$36,000 of unused availability under its then-existing line of credit.

#### *Equity Financing*

In 2009, ANI issued \$2,502,814 of secured subordinated convertible notes, referred to as the 2009 convertible notes. The 2009 convertible notes, which bore interest at 10 percent per annum, were due

on September 3, 2011. Interest on the 2009 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2009 convertible notes were outstanding.

In 2010, ANI issued \$8,474,952 of secured subordinated convertible notes, referred to as the 2010 convertible notes. The 2010 convertible notes, which bore interest at 14 percent per annum, were due on September 3, 2011. Interest on the 2010 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2010 convertible notes were outstanding.

In 2011, ANI issued \$2,694,295 of secured subordinated convertible notes, referred to as the 2011 convertible notes, and consolidated all of the outstanding 2009 and 2010 convertible notes into 2011 convertible notes, which are collectively referred to as the consolidated 2011 convertible notes. The consolidated 2011 convertible notes, which bore interest at 14 percent per annum, were due on December 31, 2012. Interest on the consolidated 2011 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The consolidated 2011 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the consolidated 2011 convertible notes were outstanding.

On June 6, 2012, the holders converted all of the outstanding 2011 convertible notes and accrued interest into shares of ANI series D preferred stock. As of September 30, 2012, no convertible notes remained outstanding.

#### ***Net Cash Provided by (Used in) Operating Activities***

Net cash provided by operating activities was approximately \$422,000 for the nine months ended September 30, 2012 compared to \$1.9 million used in operating activities during the nine months ended September 30, 2011, an increase of \$2.3 million between the periods. This increase was due to changes in current assets and current liabilities and changes in net loss. Increases in current assets and decreases in current liabilities (in each case a use of cash) for the nine months ended September 30, 2012 totaled \$680,000 compared to \$1.9 million for the nine months ended September 30, 2011, a decrease of approximately \$1.2 million between the periods. Also, ANI's net loss from continuing operations, after adjusting for non-cash interest relating to convertible debt, decreased by \$1.1 million between the periods.

Net cash used in operating activities was \$3.1 million for the year ended December 31, 2011 compared to \$2.9 million for the year ended December 31, 2010, an increase of approximately \$193,000 between the periods. This increase was due to changes in current assets and current liabilities and changes in net loss. Increases in current assets and decreases in current liabilities (in each case a use of cash) in 2011 totaled \$3.0 million compared to approximately \$225,000 in 2010, an increase of \$2.7 million between the periods. Offsetting this increase was a \$2.5 million decrease in ANI's net loss from continuing operations, after adjusting for non-cash interest relating to convertible debt, between the periods.

#### ***Net Cash Used in Investing Activities***

Net cash used in investing activities was approximately \$77,000 for the nine months ended September 30, 2012, which related primarily to capital expenditures. Net cash used in investing

activities was approximately \$259,000 for the nine months ended September 30, 2011, which included capital expenditures and the acquisition in mid-2011 of Reglan® tablets.

Net cash used in investing activities was approximately \$288,000 for the year ended December 31, 2011 compared to approximately \$434,000 for the year ended December 31, 2010. Net cash used in investing activities decreased by approximately \$146,000 primarily due to decreases in capital equipment purchases, partially offset by an increase related to the acquisition in mid-2011 of Reglan® tablets.

#### ***Net Cash Provided by Financing Activities***

Net cash used in financing activities was approximately \$196,000 for the nine months ended September 30, 2012, which included approximately \$364,000 in increased borrowings under ANI's revolving line of credit, net of payment of debt issuance costs of approximately \$261,000 and approximately \$300,000 in note payable repayments. Net cash provided by financing activities was \$2.2 million for the nine months ended September 30, 2011, which included approximately \$950,000 in increased borrowings under ANI's revolving line of credit and \$1.8 million from the issuance of convertible notes, net of approximately \$575,000 in term loan repayments.

Net cash provided by financing activities was \$3.4 million for the year ended December 31, 2011, which included \$1.3 million in increased borrowings under ANI's revolving line of credit, \$2.7 million from the issuance of convertible notes, and approximately \$25,000 in notes payable issuances, net of approximately \$633,000 in term loan repayments. Net cash provided by financing activities was \$3.4 million for the year ended December 31, 2010, which included \$8.5 million from the issuance of convertible notes and approximately \$275,000 from the issuance of notes payable, net of \$2.4 million in decreased borrowings under ANI's revolving line of credit and \$3.0 million in term loan repayments.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2012 and 2011, and December 31, 2011 and 2010, ANI did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma condensed combined financial data is intended to show how the merger might have affected historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet, and was prepared based on the historical financial results reported by BioSante and ANI. The following should be read in conjunction with the audited and unaudited historical financial statements of each of BioSante and ANI and the notes thereto beginning on pages F-1 and F-47, respectively, and the sections entitled "BioSante's Management's Discussion and Analysis of Financial Condition and Results of Operations" and "ANI's Management's Discussion and Analysis of Financial Condition and Results of Operations", and the other information contained in this joint proxy statement/prospectus. The following information does not give effect to the reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

The merger will be accounted for as a reverse acquisition under the accounting rules for business combinations. Under the reverse acquisition method of accounting, ANI will be treated as the accounting acquiror and BioSante will be treated as the "acquired" company for financial reporting purposes because, immediately upon completion of the merger, ANI stockholders prior to the merger will hold a majority of the voting interest of the combined company. In addition, the seven member board of directors of the combined company will be comprised of five of the current members of the ANI board of directors; and therefore, ANI's current board of directors will possess majority control of the board of directors of the combined company. Members of the current management of ANI will be responsible for the management of the combined company and the majority of the combined company's activities will be activities related to ANI's current business.

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC. The pro forma adjustments reflecting the completion of the merger are based upon the reverse acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth in the notes to the unaudited pro forma condensed combined financial statements.

The unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the unaudited historical statements of operations of BioSante and ANI for their respective nine-month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective twelve months ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

The historical financial data has been adjusted to give pro forma effect to events that are (i) directly attributable to the merger, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition and certain other adjustments.

The unaudited pro forma condensed combined financial data is presented for illustrative purposes only and is not necessarily indicative of the financial condition or results of operations of future periods or the financial condition or results of operations that actually would have been realized had the

entities been combined during the periods presented. In addition, as explained in more detail in the accompanying notes to the unaudited pro forma condensed combined financial statements, the preliminary acquisition-date fair value of the identifiable assets acquired and liabilities assumed reflected in the unaudited pro forma condensed combined financial statements is subject to adjustment and may vary from the actual amounts that will be recorded upon completion of the merger.

**UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET**

	As of September 30, 2012			
	BioSante Historical	ANI Historical	Pro Forma Adjustments	Pro Forma Combined
	(in thousands)			
<b>ASSETS</b>				
<b>CURRENT ASSETS</b>				
Cash and cash equivalents	\$ 38,049	\$ 148	\$ —	\$ 38,197
Accounts receivable, net	—	5,623	—	5,623
Inventories, net	—	2,495	—	2,495
Prepaid expenses	534	402	—	936
	<u>38,583</u>	<u>8,668</u>	<u>—</u>	<u>47,251</u>
PROPERTY AND EQUIPMENT, NET	<u>1,185</u>	<u>4,793</u>	<u>—</u>	<u>5,978</u>
<b>OTHER ASSETS</b>				
Investments	3,414	—	—	3,414
Deposits	30	—	—	30
Intangible assets, net	—	98	19,535 (B)	19,633
	<u>\$ 43,212</u>	<u>\$ 13,559</u>	<u>19,535</u>	<u>76,306</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
<b>CURRENT LIABILITIES</b>				
Accounts payable	\$ 2,005	\$ 1,296	\$ —	\$ 3,301
Accrued compensation	464	—	3,900 (F)	4,364
Other accrued expenses	752	877	2,800 (E)	4,429
Returned goods reserve	—	388	—	388
Borrowings under line of credit	—	3,429	—	3,429
Convertible senior notes	7,593	—	—	7,593
Interest due on convertible senior notes	108	—	—	108
Current liabilities of discontinued operations	—	378	—	378
TOTAL LIABILITIES	<u>10,922</u>	<u>6,368</u>	<u>6,700</u>	<u>23,990</u>
Redeemable convertible preferred stock	—	46,155	(46,155)(D)	—
<b>STOCKHOLDERS' EQUITY</b>				
<b>Capital stock</b>				
Issued and outstanding:				
Class C common stock				—
Common stock	273,260	2	(2)(C)	—
			46,155 (D)	—
			(225,951)(A)	—
			6,154 (K)	—
Additional paid in capital		1,082	(1,082)(C)	—
	<u>273,260</u>	<u>1,084</u>	<u>(174,726)</u>	<u>99,618</u>
Accumulated deficit	(240,970)	(40,048)	240,970 (A)	(47,302)
			(1,100)(E)	—
			(6,154)(K)	—
TOTAL STOCKHOLDERS' EQUITY	<u>32,290</u>	<u>(38,964)</u>	<u>58,990</u>	<u>52,316</u>
	<u>\$ 43,212</u>	<u>\$ 13,559</u>	<u>\$ 19,535</u>	<u>\$ 76,306</u>

**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS**

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2012**

	<u>BioSante Historical</u>	<u>ANI Historical</u>	<u>Pro Forma Adjustments</u>	<u>Pro Forma Combined</u>
	(in thousands)			
<b>REVENUE</b>				
Licensing revenue	\$ —	\$ —	\$ —	\$ —
Royalty revenue	333	—	—	333
Product revenues	—	15,050	—	15,050
	<u>333</u>	<u>15,050</u>	<u>—</u>	<u>15,383</u>
<b>OPERATING EXPENSES</b>				
Cost of sales (excluding depreciation and amortization)	—	6,292	—	6,292
Salaries and benefits	4,802	3,516	—	8,318
Freight	—	243	—	243
Research and development	11,101	637	—	11,738
Selling, general and administrative	3,879	2,962	(514)(E)	6,327
Licensing expense	—	—	—	—
Depreciation and amortization	88	425	1,832(G)	2,345
	<u>19,870</u>	<u>14,075</u>	<u>1,318</u>	<u>35,263</u>
<b>OTHER</b>				
Convertible note fair value adjustment	(4,037)	—	—	(4,037)
Interest expense	(283)	(1,239)	—	(1,522)
Other income (expense)	—	(191)	—	(191)
Interest income	5	—	—	5
<b>NET LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX BENEFIT</b>				
TAX BENEFIT	(23,852)	(455)	(1,318)	(25,625)
Income tax benefit	122	—	—(I)	122
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<u>(23,730)</u>	<u>(455)</u>	<u>(1,318)</u>	<u>(25,503)</u>
<b>DISCONTINUED OPERATIONS</b>				
Gain on discontinued operations	—	104	—	104
<b>NET LOSS</b>	<u>\$ (23,730)</u>	<u>\$ (351)</u>	<u>\$ (1,318)</u>	<u>\$ (25,399)</u>
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<u>\$ (23,730)</u>	<u>\$ (455)</u>	<u>\$ (1,318)</u>	<u>\$ (25,503)</u>
<b>PREFERRED STOCK DIVIDENDS</b>	<u>—</u>	<u>(4,327)</u>	<u>4,327(J)</u>	<u>—</u>
<b>NET LOSS FROM CONTINUING OPERATIONS AVAILABLE TO COMMON SHAREHOLDERS</b>	<u>\$ (23,730)</u>	<u>\$ (4,782)</u>	<u>\$ 3,009</u>	<u>\$ (25,503)</u>
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<u>\$ (1.14)</u>	<u>—</u>	<u>—</u>	<u>\$ (0.52)</u>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	<u>20,841</u>	<u>—</u>	<u>27,915(H)</u>	<u>48,756</u>



**UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENTS OF OPERATIONS**

**FOR THE YEAR ENDED DECEMBER 31, 2011**

	<u>BioSante Historical</u>	<u>ANI Historical</u>	<u>Pro Forma Adjustments</u>	<u>Pro Forma Combined</u>
	(in thousands)			
<b>REVENUE</b>				
Licensing revenue	\$ 100	\$ —	\$ —	\$ 100
Royalty revenue	335	—	—	335
Product revenues	—	16,515	—	16,515
	<u>435</u>	<u>16,515</u>	<u>—</u>	<u>16,950</u>
<b>OPERATING EXPENSES</b>				
Cost of sales (excluding depreciation and amortization)	—	6,861	—	6,861
Salaries and benefits	8,234	4,352	—	12,586
Freight	—	253	—	253
Research and development	38,324	799	—	39,123
Selling, general and administrative	4,606	3,712	—	8,318
Licensing expense	50	—	—	50
Depreciation and amortization	148	533	2,442(G)	3,123
	<u>51,362</u>	<u>16,510</u>	<u>2,442</u>	<u>70,314</u>
<b>OTHER</b>				
Convertible note fair value adjustment	(23)	—	—	(23)
Interest expense	(682)	(2,254)	—	(2,936)
Other income (expense)	15	(385)	—	(370)
Interest income	8	—	—	8
<b>NET LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAX BENEFIT</b>				
TAX BENEFIT	<b>(51,609)</b>	<b>(2,634)</b>	<b>(2,442)</b>	<b>(56,685)</b>
Income tax benefit	—	—	—(I)	—
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<b>(51,609)</b>	<b>(2,634)</b>	<b>(2,442)</b>	<b>(56,685)</b>
<b>DISCONTINUED OPERATIONS</b>				
Gain on discontinued operations	—	206	—	206
<b>NET LOSS</b>	<b>\$ (51,609)</b>	<b>\$ (2,428)</b>	<b>\$ (2,442)</b>	<b>\$ (56,479)</b>
<b>NET LOSS FROM CONTINUING OPERATIONS</b>	<b>\$ (51,609)</b>	<b>\$ (2,634)</b>	<b>\$ (2,442)</b>	<b>\$ (56,685)</b>
<b>PREFERRED STOCK DIVIDENDS</b>	<b>—</b>	<b>(2,280)</b>	<b>2,280(J)</b>	<b>—</b>
<b>NET LOSS FROM CONTINUING OPERATIONS AVAILABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (51,609)</b>	<b>\$ (4,914)</b>	<b>\$ (162)</b>	<b>\$ (56,685)</b>
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<b>\$ (3.15)</b>			<b>\$ (1.28)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	<b>16,398</b>		<b>27,915(H)</b>	<b>44,313</b>

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION**

**1. Description of Transaction and Basis of Presentation**

*Description of Transaction*

On October 3, 2012, BioSante entered into the merger agreement with ANI. Pursuant to the terms and subject to the conditions set forth in the merger agreement, ANI will be merged with and into BioSante, and BioSante will survive as the continuing entity.

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI's certificate of incorporation, and all options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled without consideration therefor, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof.

Upon completion of the merger, ANI stockholders are expected to receive shares of BioSante common stock representing an aggregate of approximately 53 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, and thus will not be determined until that time. If BioSante has more than \$18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than \$18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each \$1.0 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In no event, however, will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI's obligations to complete the merger is BioSante's net cash as of the closing date being no less than \$17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement.

Pursuant to the terms of ANI's certificate of incorporation, (i) before any amounts are paid to the holders of shares of any other series of ANI preferred stock or ANI common stock, the holders of shares of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00 plus all declared but unpaid dividends; (ii) before any amounts are paid to the holders of shares of ANI series B preferred stock, ANI series A preferred stock or ANI common stock, the holders of shares of ANI series C preferred stock are entitled to receive an amount per share equal to \$110.00 plus all declared but unpaid dividends; (iii) before any amounts are paid to the holders of shares of ANI series A preferred stock or ANI common stock, the holders of shares of ANI series B preferred stock are entitled to receive an amount per share equal to \$110.00 plus all declared but unpaid dividends; (iv) before any amounts are paid to the holders of shares of ANI common stock, the holders of shares of ANI series A preferred stock are entitled to receive an amount per share equal to \$100.00 plus all declared but unpaid dividends; and (v) after payments have been made to all holders of ANI preferred

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION (Continued)**

**1. Description of Transaction and Basis of Presentation (Continued)**

stock, the remaining assets of ANI will be distributed ratably to the holders of ANI common stock, including holders of ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock who elect to convert into ANI common stock in lieu of receiving the stated dollar preference amounts described above, and ANI series D preferred stock. The stated value of each series of ANI preferred stock set forth above is subject to adjustment as provided in ANI's certificate of incorporation. The exchange ratios in the merger agreement reflect these preferential payments. As a result of such provisions, it is likely that holders of shares of ANI series A preferred stock, ANI series B preferred stock, ANI series C preferred stock or ANI common stock will not receive any shares of BioSante common stock in connection with the merger.

***Basis of Presentation***

The unaudited pro forma condensed combined financial statements were prepared in accordance with the regulations of the SEC and are intended to show how the merger might have affected the historical financial statements if the merger had been completed on January 1, 2011 for the purposes of the statements of operations and September 30, 2012 for the purposes of the balance sheet. The pro forma adjustments reflecting the completion of the merger are based upon the accounting rules for business combinations, specifically, the reverse acquisition method of accounting in accordance with GAAP, and upon the assumptions set forth herein. Based on the terms of the merger, ANI is deemed to be the accounting acquiror.

Under the reverse acquisition method of accounting, the identifiable assets acquired and liabilities assumed of BioSante will be recorded at the acquisition date fair values and added to those of ANI. The pro forma adjustments are preliminary and based on management's estimates of the fair value and useful lives of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the acquisition. These estimates are based on the most recently available information. To the extent there are significant changes to the combined company's business following completion of the merger, the assumptions and estimates set forth in the unaudited pro forma condensed combined financial statements could change significantly. The allocation is dependent upon certain valuation and other studies that will not be completed until following the merger. Accordingly, the pro forma purchase price adjustments are subject to further adjustments as additional information becomes available and as additional analyses and final valuations are conducted following completion of the merger. There can be no assurances that these additional analyses and final valuations will not result in material changes to the estimates of fair value set forth below under Note 2.

The unaudited pro forma condensed combined balance sheet as of September 30, 2012 combines the historical balance sheets of BioSante and ANI as of September 30, 2012 and gives pro forma effect to the merger as if it had been completed on September 30, 2012.

The unaudited pro forma condensed combined statements of operations for the nine months ended September 30, 2012 combine the historical statements of operations of BioSante and ANI for their respective nine month periods ended September 30, 2012 and gives pro forma effect to the merger as if it had been completed on January 1, 2011. The unaudited pro forma condensed combined statements of operations for the year ended December 31, 2011 combine the historical statements of operations of BioSante and ANI for their respective year ended December 31, 2011 and gives pro forma effect to the merger as if it had been completed on January 1, 2011.

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION (Continued)**

**1. Description of Transaction and Basis of Presentation (Continued)**

The unaudited pro forma condensed combined financial statements assume that BioSante's net cash, as defined in the merger agreement, will be \$18.0 million as of the determination date and an exchange ratio of 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and an exchange ratio of zero shares of BioSante common stock for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock. Such exchange ratios do not give any effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus but take into account shares of ANI series D preferred stock to be issued to certain of ANI's executive officers immediately prior to completion of the merger.

The exchange ratios, as such ratios are calculated pursuant to the formulas set forth in the merger agreement, are based on the number of shares of BioSante common stock and ANI capital stock outstanding as of immediately prior to completion of the merger, and in the case of BioSante, a certain percentage of the number of certain warrants to purchase shares of BioSante common stock outstanding as of such date, and will not be determined until that time. The exchange ratios will be adjusted upward or downward only as a result of changes to the outstanding capital stock of either or both of BioSante and ANI as of immediately prior to completion of the merger and changes to BioSante's net cash as of a determination date prior to completion of the merger. No adjustments to the exchange ratios will be made based on changes in the trading price of BioSante common stock or the value of ANI capital stock prior to completion of the merger. As a result, the value of the shares of BioSante common stock issued to ANI stockholders in connection with the merger could be substantially less or substantially more than the current market value of BioSante common stock. The following information does not give effect to the reverse stock split of BioSante common stock and BioSante class C special stock described in BioSante Proposal No. 2.

**2. Purchase Price**

A preliminary estimate of the purchase price is as follows (table in thousands):

Fair value of BioSante shares outstanding	\$ 46,158
Estimated fair value of vested BioSante stock options	67
Estimated purchase price	<u>\$ 46,225</u>

For pro forma purposes, the fair value of the BioSante common stock used in determining the purchase price was \$1.89 per share based on the closing price of BioSante common stock on September 30, 2012. The fair value of the BioSante stock options was determined by using the Black-Scholes option pricing model with the following assumption: (i) stock price of \$1.89, which is the value ascribed to the BioSante common stock in determining the purchase price, (ii) volatility of 90 percent; risk-free interest rate of 0.21 percent, and (iii) a weighted average expected life of 1.37 years. All outstanding BioSante options will fully vest upon completion of the merger. The combined company will expense all transaction costs as incurred.

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION (Continued)**

**2. Purchase Price (Continued)**

The estimated acquired tangible and intangible assets and liabilities assumed based on their estimated fair values as of September 30, 2012 comprises (table in thousands):

Cash and cash equivalents	\$ 38,049
Receivables and other current assets	534
Intangible assets	19,535
Other assets	4,629
Convertible senior notes, including interest	(7,701)
Other assumed liabilities	(8,821)
<b>Total</b>	<b>\$ 46,225</b>

The allocation of the purchase price is preliminary. The final determination of the purchase price allocation will be based on the fair values of assets, including identifiable intangible assets, acquired, and the fair values of liabilities assumed as of the date that the merger is completed. BioSante and ANI believe that the historical values of BioSante's current assets and current liabilities, excluding the convertible senior notes, approximate their fair value based on the short term nature of such items. The convertible senior notes historically have been recorded at fair value; and accordingly, no adjustment to the historical recorded value of the convertible senior notes is necessary. BioSante and ANI believe that the historical value of BioSante's investments represents fair value based upon current information known to BioSante and ANI, and the valuation performed by BioSante in 2011 when an impairment charge was recorded on BioSante's investment in Ceregene. BioSante's property and equipment consists substantially of a new asset, not yet put into use; and therefore, its historical cost is deemed to be its fair value. The only identifiable intangible assets are BioSante's developed technology, which consists primarily of its intellectual property related to BioSante's male testosterone gel and the GVAX cancer vaccines. The estimated fair values of the assets acquired and liabilities assumed will remain preliminary until the combined company completes a valuation of significant identifiable intangible assets acquired and determines the fair values of other assets and liabilities acquired. Based on such valuation, any excess of the purchase price over the fair value of assets and liabilities acquired will be allocated to goodwill, although at this time, based on preliminary valuation estimates, BioSante and ANI do not believe there will be any goodwill resulting from the merger. The final determination of the fair values is expected to be completed as soon as practicable after completion of the merger. The final amounts could differ from the amounts presented in the unaudited pro forma condensed combined financial statements, because the amounts allocated will not be determined until the date of the merger.

**3. Pro Forma Adjustments**

The pro forma adjustments are as follows:

- (A) Represents the elimination of BioSante's accumulated deficit and the adjustment to outstanding common stock to reflect the additional shares of BioSante common stock to be issued to ANI stockholders in the merger.
- (B) Represents the estimated fair value of BioSante's identifiable intangible assets, representing developed technology, acquired in the merger. BioSante's developed technology consists primarily of its intellectual property related to BioSante's male testosterone gel and the GVAX cancer vaccines. The estimated fair value of the male testosterone gel represents the

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION (Continued)**

**3. Pro Forma Adjustments (Continued)**

majority of the \$19.5 million estimated fair value of the developed technology, with the GVAX cancer vaccines representing approximately \$1.0 million of the total estimated fair value. These fair values estimates are based on a preliminary valuation that discounted the forecasted, estimated future net cash flows to be generated from the respective technologies. The final determination of the fair values is expected to be completed as soon as practicable after completion of the merger.

- (C) Represents the elimination of ANI's historical common stock equity accounts.
- (D) Represents the elimination and/or exchange of ANI preferred stock for BioSante common stock in connection with the merger. Pursuant to the terms of ANI's capital stock, only the ANI series D preferred stockholders are expected to receive shares of BioSante common stock in connection with the merger. See adjustment (H) below.
- (E) Reflects BioSante and ANI estimated transaction costs payable in cash that have not been incurred as of September 30, 2012. The amounts include \$1.7 million of anticipated costs for BioSante and \$1.1 million of anticipated costs for ANI. The \$1.7 million of anticipated BioSante costs consist of \$0.6 million investment banking firm transaction fees, \$0.8 million in legal, accounting and filing fees and \$0.3 million in insurance, which costs are included in assumed liabilities in allocating the purchase price. BioSante has also incurred \$0.2 million of transaction costs, principally legal fees, through September 30, 2012. The \$1.1 million of anticipated ANI costs consist of \$0.4 million of advisory/monitoring fees and \$0.7 million of legal and accounting fees. ANI has also incurred \$0.3 million of transaction costs, principally legal fees, through September 30, 2012.
- (F) Represents the accrual \$3.9 million of retention, change of control and severance obligations for certain employees of BioSante that will become due upon closing of the merger consisting of \$3.8 million for change of control and severance and \$0.1 million of retention.
- (G) Represents the amortization of BioSante's developed technology over an estimated useful life of eight years based on the weighted-average remaining life of the patents underlying such technology.
- (H) Represents the shares of BioSante common stock to be issued to holders of ANI series D preferred stock in connection with the merger at an assumed estimated exchange ratio of 10.3502. No fractional shares of BioSante common stock will be issued in connection with the merger and holders of ANI series D preferred stock will be entitled to receive cash in lieu thereof. Cash paid in lieu of fractional shares will be from existing cash balances which has not been reflected due to immateriality.
- (I) Represents the tax effect of the above pro forma adjustments as calculated at the statutory rate. The tax effect of the adjustments is determined to be zero because it relates to a non-deductible expense for tax purposes. In addition, the combined company will have available net operating loss (NOL) carryforwards and research and development carryforwards that may be utilized to offset any current income and related taxes. Utilization of the NOL and research and development carryforwards may be subject to substantial annual limitation due to ownership change limitations provided by Section 382 of the Code, as well as similar state provisions. It is expected that the combined company will continue to provide a full valuation allowance on its deferred tax assets.

**NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED  
FINANCIAL INFORMATION (Continued)**

**3. Pro Forma Adjustments (Continued)**

- (J) Represents the elimination of ANI preferred stock dividends as there will be no preferred stock outstanding after the merger.
- (K) Represents transaction bonuses due to certain members of ANI management upon the closing of the merger transaction which will be paid in shares of BioSante common stock as described in the section entitled "Management of the Combined Company Following the Merger—Executive Compensation—Transaction Bonus Agreements and Related Arrangements" beginning on page 268.

**MANAGEMENT OF THE COMBINED COMPANY FOLLOWING THE MERGER****Directors and Executive Officers of the Combined Company Following the Merger**

Pursuant to the terms of the merger agreement, the board of directors of the combined company will consist of five directors of ANI and two directors of BioSante, ANI's chairman of the board will serve as chairman of the board of the combined company and ANI's current executive officers will serve as executive officers of the combined company. Accordingly, the following five of BioSante's current seven directors will resign effective upon completion of the merger: Louis W. Sullivan, M.D., Edward C. Rosenow, III, M.D., John T. Potts, Jr., M.D., Stephen M. Simes and Stephen A. Sherwin, M.D. In addition, all of BioSante's current executive officers will resign from their respective positions at BioSante effective upon completion of the merger.

The following table lists the names and ages as of December 31, 2012 and positions of the individuals who are expected to serve as directors and executive officers of the combined company upon completion of the merger:

<u>Name</u>	<u>Age</u>	<u>Title</u>
Robert E. Brown, Jr.	62	Chairman of the Board
Arthur S. Przybyl	55	President, Chief Executive Officer and Director
Tracy L. Marshbanks, Ph.D.	49	Director
Thomas T. Penn	66	Director
Robert Schrepfer	41	Director
Fred Holubow	73	Director
Ross Mangano	67	Director
Charlotte C. Arnold	47	Vice President and Chief Financial Officer
James G. Marken	50	Vice President, Operations
Robert J. Jamnick	55	Vice President, Quality and Product Development

**Robert E. Brown, Jr.** has been a director of ANI since July 2010. Mr. Brown has been active in the venture capital and private equity business for over 30 years and has been the sole stockholder, director and President of MVP Management Company (MVP Management) since 2000. MVP Management conducts business as MVP Capital Partners (MVP Capital), and is the investment management company for Meridian Venture Partners II, L.P. (MVP II), a mid-sized venture capital and private equity firm focused on expansion capital and microcap buyout investments, and the owner of 12,477 shares of ANI common stock, 67,599 shares of ANI series A preferred stock, 13,638 shares of ANI series B preferred stock, 11,364 shares of ANI series C preferred stock and 1,376,596 shares of ANI series D preferred stock, representing approximately 57 percent of ANI capital stock. Mr. Brown is the Managing Partner of MVP II and the President and sole stockholder and sole director of Meridian Venture Partners II Co., the corporate general partner of the general partner of MVP II. Mr. Brown serves on the ANI board of directors as MVP II's designee. Mr. Brown co-founded MVP II in 2000 and its predecessor fund, Meridian Venture Partners, in 1987. Prior to 1987, Mr. Brown was a principal in a merchant banking firm active in both private equity and investment banking. Mr. Brown began his professional career as a certified public accountant with Arthur Andersen & Co. Subsequently, he worked for a subsidiary of The Penn Central Corporation as a financial analyst, and after graduation from law school, practiced corporate tax law at the firm of Morgan, Lewis & Bockius in Philadelphia. In his role at MVP Capital, Mr. Brown has served on the board of directors of numerous privately-held portfolio companies, including several healthcare related companies such as Implex Corporation, Dorland Data Networks, Omega Health Systems, Air Medical Group Holdings, and MCMC LLC. Mr. Brown holds an A.B. degree from Princeton University, an M.B.A. from the Wharton School of the University of Pennsylvania, and a J.D. from the Law School of the University of Pennsylvania.



**Arthur S. Przybyl** joined ANI in March 2009 as President and Chief Executive Officer. Mr. Przybyl is an experienced healthcare executive in a career that spans over 25 years and includes the management of both specialty pharmaceutical and medical device companies. Prior to joining ANI, Mr. Przybyl served as President and Chief Executive Officer of Akorn, Inc., a NASDAQ-listed specialty pharmaceutical company that manufactures and markets ophthalmic, liquid and lyophilized injectable, and vaccine drug products from August 2002 through January 2009. Prior to Akorn, Mr. Przybyl was President of privately-held Hearing Innovations, Inc. and President and Chief Operating Officer of NASDAQ-listed company Bioject, Inc., both medical device companies. During his career, Mr. Przybyl has held several sales and marketing management positions, including Senior Vice President, Sales and Marketing for International Medication Systems, Inc. and Director Corporate Marketing and National Accounts for LyphoMed, Inc., both specialty pharmaceutical companies. Mr. Przybyl was chosen to serve on the board of directors of the combined company because of his extensive experience as an executive in the healthcare industry, including as President and Chief Executive Officer of ANI. As a member of the executive team of the combined company, Mr. Przybyl will serve a vital function in the link between management and the board of directors of the combined company, enabling the board of directors to perform its oversight function with the benefits of management's perspective on the business.

**Tracy L. Marshbank, Ph.D.** has been a director of ANI since 2006, serving on both the Audit and Compensation Committees of the ANI board of directors during that period. Dr. Marshbanks is a Managing Director of First Analysis Corp. (First Analysis), a financial services firm, where he has been employed since 1999. First Analysis manages First Analysis Venture Operations and Research, L.L.C. (FAVOR), the indirect owner of 3,810 shares of ANI common stock, 30,762 shares of ANI series B preferred stock, 8,237 shares of ANI series C preferred stock and 394,680 shares of ANI series D preferred stock, representing an aggregate of approximately 17 percent of ANI capital stock. In his role at First Analysis, Dr. Marshbanks focuses on growth equity investments in private companies in the healthcare and the cleantech/environmental sectors and serves as an analyst having followed public companies within the chemical, life science tools, and medical technology industries. Prior to First Analysis, he was employed by Amoco Corp. in a number of positions ranging from Research and Development to Marketing. He has served on the boards of directors of other privately-held companies within healthcare, including manufacturers of medical devices and diagnostic tests. Dr. Marshbanks earned a B.S. and Ph.D. in Chemical Engineering from Colorado State University and Purdue University, respectively, in addition to an M.B.A., with a finance concentration, from the University of Chicago. Dr. Marshbanks holds Series 7 and 63 Securities Licenses as well as a Research Analyst Qualification (Series 86 & 87). Dr. Marshbanks was chosen to serve on the board of directors of the combined company because he brings investor and financial analyst experience and perspective to the board. In addition, he has exposure to the broader healthcare market and technical expertise related to manufacturing and process industries.

**Thomas T. Penn** has been a director of ANI since 2009. Mr. Penn is employed by MVP Management, of which he serves as Vice President. MVP Management conducts business as MVP Capital Partners. MVP Management is the investment management company for MVP II, of which Mr. Penn is a Partner and which is the owner of 12,477 shares of ANI common stock, 67,599 shares of ANI series A preferred stock, 13,638 shares of ANI series B preferred stock, 11,364 shares of ANI series C preferred stock and 1,376,596 shares of ANI series D preferred stock, representing approximately 57 percent of ANI capital stock. Mr. Penn serves on the ANI's board as MVP II's designee. Mr. Penn is also managing director at and 50 percent owner of Penn Venture I LLC, the general partner for Penn Venture Partners, L.P., an investment fund focused on investments in Central Pennsylvania, holding the managing director position since 2007. Previously, Mr. Penn served as chief executive officer of Tektagen, Inc. and as director of several privately held life sciences and healthcare companies. Mr. Penn was chosen to serve on the board of directors of the combined company primarily because of his significant experience as a director and executive officer in the life sciences industry.

**Robert Schrepfer** has been a director of ANI since July 2010. Since 2005, Mr. Schrepfer has served as Assistant Portfolio Manager at Healthcare Value Capital, LLC, an SEC-registered healthcare investment firm. Mr. Schrepfer co-manages the firm's private equity portfolio and oversees investments in healthcare services, devices and specialty pharmaceuticals. In addition, he is principal and founder of National Healthcare Analysis Group, LLC and serves as Chief Financial Officer of National Healthcare Analysis Partners 1, LP, a partnership that seeks to identify and pursue healthcare fraud. Between 2003 and 2005, Mr. Schrepfer was Managing Director at Bear Stearns & Co. Inc., providing sell side research coverage of the pharmaceuticals industry. Mr. Schrepfer served as Clinical Director and Director of Outcomes and Research at the Centers for Aquatic Rehabilitation from 1997 to 2001. Mr. Schrepfer received an M.B.A. in Finance and Health Sector Management from Duke University and an M.S. in Physical Therapy from the University of Indianapolis. He is currently a member of the Health Sector Advisory Council at Duke University. Mr. Schrepfer is a previous holder of Series 7 and 63 Securities Licenses as well as a Research Analyst Qualification (Series 86 & 87). Mr. Schrepfer was chosen to serve on the board of directors of the combined company because of his experience managing investments in specialty pharmaceuticals and other healthcare services companies and providing research coverage of the pharmaceuticals industry.

**Fred Holubow** has been a director of BioSante since 1999. Mr. Holubow is the Principal of Petard Risk Analysis and a General Partner of Starbow Partners, an investor in early stage healthcare ventures, a position he has held since January 2012. From 2001 to December 2011, Mr. Holubow served as a Managing Director of William Harris Investors, Inc., a registered investment advisory firm. From 1982 to 2001, Mr. Holubow served as Vice President of Pegasus Associates, a registered investment advisory firm he co-founded. He specializes in analyzing and investing in pharmaceutical and biotechnology companies. Mr. Holubow previously served on the boards of directors of the following public companies: Micrus Endovascular Corporation, ThermoRetec Corporation, Savient Pharmaceuticals, Inc. (formerly Bio-Technology General Corp.), Gynex Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc.

BioSante believes Mr. Holubow's qualifications to serve as a member of the board of directors of the combined company include his significant experience of analyzing and investing in pharmaceutical and biotechnology companies both in his current position as a Principal of Petard Risk Analysis and a General Partner of Starbow Partners and in his prior positions as a Managing Director of William Harris Investors and Vice President of Pegasus Associates. In addition, through his experience of serving on the boards of directors and more specifically the audit committees of several other public companies, Mr. Holubow has developed a substantial financial and accounting expertise with pharmaceutical and biotechnology companies, which he contributes to the BioSante board of directors, and more specifically, to the Audit and Finance Committee in his role as Chair of the Audit and Finance Committee.

**Ross Mangano** has been a director of BioSante since 1999. Mr. Mangano has been the President and a director of Oliver Estate, Inc., a management company specializing in investments in public and private companies, since 1971. Mr. Mangano in the past has served on the boards of directors of Cerprobe Corporation, Tower Federal Savings & Loan, Cypress Communications, Inc. and Mego Financial Corp.

BioSante believes Mr. Mangano's qualifications to serve as a member of the board of directors of the combined company include his significant general business experience as President of Oliver Estate, Inc. and his significant experience analyzing and investing in public and private companies. In addition, BioSante believes Mr. Mangano provides the board of directors of the combined company valuable business, leadership and management experience and insights into many aspects of the combined company's business.

**Charlotte C. Arnold** has served as ANI's Vice President and Chief Financial Officer since May 2009. In that role, Ms. Arnold leads ANI's finance and accounting department as well as information technology. Between March 2004 and May 2009, Ms. Arnold served as director of ANI. Ms. Arnold has more than 20 years of experience in finance, corporate development and operations. Before becoming ANI's Chief Financial Officer, Ms. Arnold was a Founding Partner at Laurel Capital, a growth equity and microcap buyout private equity firm, from October 2007 to March 2009. Prior to Laurel, Ms. Arnold was an employee and Vice President of MVP Management, where she was responsible for four platform investments, including the initial acquisition of ANI. Previously, Ms. Arnold was a Director with Ben Franklin Technology Partners, a nationally-known economic development organization and worked in the Entrepreneurial Services assurance practice of PricewaterhouseCoopers in Philadelphia. Ms. Arnold holds a B.A. degree from UCLA, an MBA from the Wharton School of Business, and is a certified public accountant.

**James G. Marken** serves as Vice President, Operations, a position he has held since March 2009. Mr. Marken joined ANI in March 2007 as General Manager of the Minnesota facilities. As Vice President, Operations, Mr. Marken has been principally responsible for the following areas: warehousing, pharmaceutical manufacturing, packaging, engineering/maintenance, calibrations and purchasing. Mr. Marken brings over 20 years of pharmaceutical industry experience to the combined company. Prior to joining ANI in March 2007, he worked for Solvay Pharmaceuticals as plant manager and in various departments including quality control, validation and manufacturing. Mr. Marken holds a B.S. degree in Chemistry from Bemidji State University.

**Robert J. Jammick** serves as Vice President, Quality and Product Development, a position he has held since July 2010. Mr. Jammick joined ANI in May 2007 as Director Quality Assurance/Quality Control for the Baudette facilities. Mr. Jammick came to ANI after a career spanning over 25 years at Solvay Pharmaceuticals, where he held various technical and managerial positions in quality assurance, quality control, technical services and research and development. From March 2009 to July 2010, Mr. Jammick served as Executive Director Global Quality of ANI. In his current position, Mr. Jammick is responsible for quality control, quality assurance, product development, regulatory affairs and technical services. Mr. Jammick holds a Bachelor's degree in Chemistry and Biology from Bemidji State University.

### **Director Independence**

Prior to completion of the merger, the BioSante board of directors will affirmatively determine which of the seven individuals that will serve as directors of the combined company is an "independent director" as defined under the Listing Rules of The NASDAQ Stock Market. The Listing Rules of The NASDAQ Stock Market provide a list of disqualifying criteria for the independence determination. For example, under these rules, a director who is, or during the past three years was, employed by the company or by any parent or subsidiary of the company, other than prior employment as an interim chairman or interim chief executive officer, would not be considered independent. No director qualifies as independent unless the board of directors affirmatively determines that the director does not have a material relationship with the listed company that would interfere with the exercise of independent judgment. Based on information provided by the directors and by BioSante and ANI with regard to each of the seven individuals expected to serve as a member of the board of directors of the combined company and such individual's business and personal activities as they may relate to BioSante, ANI, the combined company and their respective management, it is anticipated that all of the seven individuals that will serve as directors of the combined company will be "independent" other than Mr. Przybyl, Mr. Brown and Mr. Penn.

**Board Committees of the Combined Company**

The board of directors of the combined company will have the same committee structure as BioSante prior to the merger and therefore will have an Audit and Finance Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of these committees will operate under a charter that has been previously approved by the board of directors of BioSante and will have the composition and responsibilities described below. The board of directors of the combined company from time to time may establish other committees to facilitate the management of the company and may change the composition and the responsibilities of the existing committees.

The table below summarizes the anticipated membership of each of the three standing board committees of the combined company after the merger.

<u>Director</u>	<u>Audit and Finance</u>	<u>Compensation</u>	<u>Nominating and Corporate Governance</u>
Tracy L. Marshbanks, Ph.D.	Chair	Chair	Member
Robert Schrepfer	Member	Member	Chair
Fred Holubow	Member	—	—
Ross Mangano	—	Member	Member

***Audit and Finance Committee***

The primary responsibilities of the Audit and Finance Committee of the combined company will include:

- overseeing the combined company's accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the board of directors and reporting the results or findings of its oversight activities to the board;
- having sole authority to appoint, retain and oversee the work of the combined company's independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or or auditing matters and for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters;
- reviewing and pre-approving all audit services and permissible non-audit services to be performed for the combined company by its independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC; and
- overseeing the combined company's system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) a written code of ethics applicable to each of the combined company's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

The Audit and Finance Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Audit and Finance Committee of the combined company will consist of Mr. Holubow, Dr. Marshbanks and Mr. Schrepfer. It is expected that the board of directors of the combined company will determine that each anticipated member of the Audit and Finance Committee will qualify as "independent" for purposes of membership on audit committees pursuant to the Listing Rules of The NASDAQ Stock Market and the rules and regulations of the SEC and is "financially

literate" as required by the Listing Rules of The NASDAQ Stock Market. In addition, it is expected that the board of directors of the combined company will determine that Mr. Holubow qualifies as an "audit committee financial expert" as defined by the rules and regulations of the SEC and meets the qualifications of "financial sophistication" under the Listing Rules of The NASDAQ Stock Market as a result of his Masters in Business Administration in Finance, and his previous experience as an investment analyst and portfolio manager for over 40 years and as a former member of an audit committee of another public company.

### ***Compensation Committee***

The primary responsibilities of the Compensation Committee of the combined company will include:

- recommending to the board of directors for its determination the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to the combined company's chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors regarding any revisions to corporate goals and objectives with respect to compensation for the combined company's chief executive officer and other executive officers and establishing and leading a process for the full board of directors to evaluate the performance of the combined company's chief executive officer and other executive officers in light of those goals and objectives;
- administering the combined company's equity-based compensation plans applicable to any employee of the combined company and recommending to the board of directors specific grants of options and other awards for all executive officers and determining specific grants of options and other awards for all other employees, under the combined company's equity-based compensation plans;
- reviewing and discussing with the President and Chief Executive Officer and reporting periodically to the board of directors plans for executive officer development and corporate succession plans for the President and Chief Executive Officer and other key executive officers and employees; and
- annually reviewing and discussing with management the "Compensation Discussion and Analysis" section of the combined company's proxy statement in connection with the combined company's annual meeting of stockholders and based on such review and discussions make a recommendation to the board of directors as to whether the "Compensation Discussion and Analysis" section should be included in the combined company's proxy statement in accordance with applicable rules and regulations of the SEC and any other applicable regulatory bodies.

The Compensation Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Compensation Committee of the combined company will consist of Dr. Marshbanks, Mr. Mangano and Mr. Schrepfer.

### ***Nominating and Corporate Governance Committee***

The primary responsibilities of the Nominating and Corporate Governance Committee of the combined company will include:

- identifying individuals qualified to become board members;

- recommending director nominees for each annual meeting of the combined company's stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;
- being aware of the best practices in corporate governance and developing and recommending to the board of directors a set of corporate governance standards to govern the board of directors, its committees, the company and its employees in the conduct of the business and affairs of the combined company;
- developing and overseeing the annual board and board committee evaluation process; and
- establishing and leading a process for determination of the compensation applicable to the non-employee directors on the board.

The Nominating and Corporate Governance Committee will have the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

It is anticipated that the Nominating and Corporate Governance Committee of the combined company will consist of Mr. Schrepfer, Mr. Mangano and Dr. Marshbanks.

### **Certain Relationships and Related Transactions**

It is anticipated that the policies and procedures of the combined company with respect to the review, approval or ratification of related-person transactions will be substantially similar to BioSante's current policies and procedures on such matters.

#### ***BioSante Related Transactions***

The BioSante board of directors has delegated to the Audit and Finance Committee, pursuant to the terms of a written policy, the authority to review, approve and ratify related party transactions. If it is not feasible for the Audit and Finance Committee to take an action with respect to a proposed related party transaction, the BioSante board of directors or another committee of the BioSante board of directors, may approve or ratify it. No member of the BioSante board of directors or any committee may participate in any review, consideration or approval of any related party transaction with respect to which such member or any of his or her immediate family members is the related party.

BioSante's policy defines a "related party transaction" as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which BioSante (including any of its subsidiaries) were, are or will be a participant and in which any related party had, has or will have a direct or indirect interest.

Prior to entering into or amending any related party transaction, the party involved must provide notice to BioSante's finance department of the facts and circumstances of the proposed transaction, including:

- the related party's relationship to BioSante and his or her interest in the transaction;
- the material facts of the proposed related party transaction, including the proposed aggregate value of such transaction or, in the case of indebtedness, the amount of principal that would be involved;
- the purpose and benefits of the proposed related party transaction with respect to BioSante;
- if applicable, the availability of other sources of comparable products or services; and
- an assessment of whether the proposed related party transaction is on terms that are comparable to the terms available to an unrelated third party or to employees generally.

If BioSante's finance department determines the proposed transaction is a related party transaction and the amount involved will or may be expected to exceed \$10,000 in any calendar year, the proposed transaction is submitted to the Audit and Finance Committee for its prior review and approval or ratification. In determining whether to approve or ratify a proposed related party transaction, the Audit and Finance Committee will consider, among other things, the following:

- the purpose of the transaction;
- the benefits of the transaction to BioSante;
- the impact on a director's independence in the event the related party is a non-employee director, an immediate family member of a non-employee director or an entity in which a non-employee director is a partner, shareholder or executive officer;
- the availability of other sources for comparable products or services;
- the terms of the transaction; and
- the terms available to unrelated third parties or to employees generally.

Related party transactions that involve \$10,000 or less must be disclosed to the Audit and Finance Committee but are not required to be approved or ratified by the Audit and Finance Committee.

BioSante also produces quarterly reports to the Audit and Finance Committee of any amounts paid or payable to, or received or receivable from, any related party. These reports allow BioSante to identify any related party transactions that were not previously approved or ratified. In that event, the transaction will be promptly submitted to the Audit and Finance Committee for consideration of all the relevant facts and circumstances, including those considered when a transaction is submitted for pre-approval. Under BioSante's policy, certain related party transactions as defined under the policy, such as certain transactions not requiring disclosure under the rules of the SEC, will be deemed to be pre-approved by the Audit and Finance Committee and will not be subject to these procedures.

There were no related party transactions for BioSante during 2011, and as of the latest practicable date before the printing of this joint proxy statement/prospectus, there were no related party transaction for BioSante during 2012.

#### ***ANI Related Transactions***

ANI does not have a formal policy on related party transactions, but it conducts a review of all related party transactions for potential conflict of interest situations on an ongoing basis and all such transactions relating to directors and executive officers must be approved by the independent and disinterested members of the ANI board of directors. There were no related party transactions for ANI during 2009, 2010, 2011, and as of the latest practicable date before the printing of this joint proxy statement/prospectus, there were no related party transaction for ANI during 2012, except as described below:

#### ***Director and Executive Officer Compensation***

Please see "Management of the Combined Company Following the Merger—Director Compensation" and "—Executive Compensation" for information regarding the compensation of ANI's directors and those of its executive officers who will continue as executive officers of the combined company and for information regarding employment, bonus and other agreements ANI has in place with such directors and/or executive officers.

**Investments by Related Parties**

In 2009, ANI issued \$2,502,814 of secured subordinated convertible notes (the 2009 convertible notes) and related warrants. The 2009 convertible notes, which bore interest at 10 percent per annum, were due on September 3, 2011. Interest on the 2009 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2009 convertible notes were outstanding. Among the investors in the 2009 convertible notes were the following:

**2009 Convertible Notes**

<u>Investor</u>	<u>Affiliations with ANI</u>	<u>Principal Amount(1)</u>	<u>Shares of ANI Series D Preferred Stock Issued upon Conversion of:</u>		<u>Warrants Issued</u>
			<u>Principal</u>	<u>Interest</u>	
MVP II	Owns 56.7 percent of ANI capital stock  ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP II(2)	1,591,100	211,941	16,085	Common stock warrants: 12,477  Series D preferred stock warrants: 2,235
First Analysis	Owns 16.7 percent of ANI capital stock  ANI director Tracy L. Marshbanks, Ph.D. is managing director of First Analysis Corporation(3)	319,443	42,522	15,315	Common stock warrants: 3,809
Healthcare Value Master Fund, Ltd.	Owns 1.6 percent of ANI capital stock  ANI director Robert Schrepfer is employed by the investment advisor to HVMF but is not deemed to be an affiliate of ANI(4)	152,172	20,275	7,380	Common stock warrants: 1,841
Argentum Capital Partners II, L.P.	Owns 11.3 percent of ANI capital stock.	301,159	40,111	14,304	Common stock warrants: 2,693  Series D preferred stock warrants: 300

(1) Represents the largest aggregate principal amount outstanding since issuance.

(2) The notes were held by Meridian Venture Partners II, L.P. (MVP II). MVP II GP, L.P. (GP) is the general partner of MVP II. Meridian Venture Partners II, Co. (MVP Corp.), is the general partner of GP. MVP Management Company (MVP Management) d/b/a MVP Capital Partners, is the



management company for MVP II and also renders financial and business advisory services to several of the companies in which MVP II has invested. Robert E. Brown, Jr., a director of ANI, is the President, sole stockholder and sole director of MVP Corp, the sole stockholder, director and President of MVP Management, as well as a limited partner of GP and one of two principals of MVP II that are licensed by the Small Business Administration (SBA). SBA-licensed principals are charged with approving all investment-related decisions on behalf of small business investment companies licensed by the SBA, such as MVP II. Thomas T. Penn, a director of ANI, is a Vice President of MVP Corp, a Vice President and employee of MVP Management, a limited partner of GP and one of the two SBA-licensed principals of MVP II. Charlotte C. Arnold, ANI's Vice President and Chief Financial Officer, is a former employee and Vice President of MVP Management, and has a vested interest in 6 percent of GP's interest in MVP II. MVP Management has been receiving advisory and monitoring fees from ANI and will receive a fee at the closing of the merger, as further described below. Pursuant to the applicable provisions of the MVP II limited partnership agreement and to comply with applicable SBA regulations, 50 percent of all such fees received by MVP Management are paid over or credited to MVP II.

- (3) The notes were held by FA Private Equity Fund IV, L.P. (FAPEF IV), FA Private Equity Fund IV GmbH & Co. Beteiligungs KG (GmbH), The Productivity Fund IV, L.P. (Productivity Fund) and The Productivity Fund IV Advisors Fund, L.P. (Advisors Fund).

FA Private Equity Management IV, L.L.C. (FAPEM IV) is the sole general partner of FAPEF IV. FAVOR is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by FAPEF IV. Tracy L. Marshbanks, Ph.D., a director of ANI, is a managing director of First Analysis Corporation, which manages FAVOR.

FAPEM IV is the managing limited partner of GmbH. FAVOR is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by GmbH. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

First Analysis Management Company IV, L.L.C. (FAMC IV) is the sole general partner of Productivity Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Productivity Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

FAMC IV is the sole general partner of Advisors Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Advisors Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

- (4) The notes were held by Healthcare Value Master Fund, Ltd. (HVMF). Mr. Schrepfer is an employee of Healthcare Value Capital, LLC (HVC), the investment adviser to HVMF, but has no ownership interest in and does not serve as general partner or managing member of HVC or its affiliates. Therefore, Mr. Schrepfer is not deemed beneficially to own the securities of ANI held by HVMF. HVC has been receiving advisory fees from ANI and will receive a fee at the closing of the merger, as further described below.

In 2010, ANI issued \$8,474,952 of secured subordinated convertible notes (the 2010 convertible notes) and related warrants. The 2010 convertible notes, which bore interest at 14 percent per annum, were due on September 3, 2011. Interest on the 2010 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on ANI's ability to enter into certain transactions while the 2010 convertible notes were outstanding. Among the investors in the 2010 convertible notes were the following:

**2010 Convertible Notes**

Investor	Affiliations with ANI	Principal Amount(1)	Shares of ANI Series D Preferred Stock Issued upon Conversion of:		Warrants Issued
			Principal	Interest	
MVP II	Owns 56.7 percent of ANI capital stock  ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP II(2)	4,774,832	535,944	295,278	11,603
First Analysis	Owns 16.7 percent of ANI capital stock  ANI director Tracy L. Marshbanks, Ph.D. is managing director of First Analysis Corporation(3)	1,453,599	193,813	61,906	5,280
Healthcare Value Master Fund, Ltd.	Owns 1.6 percent of ANI capital stock  ANI director Robert Schrepfer is employed by the investment advisor to HVMF but is not deemed to be an affiliate of ANI(4)	673,223	89,763	28,268	1,475
Argentum Capital Partners II, L.P.	Owns 11.3 percent of ANI capital stock	927,135	123,618	38,405	2,725

(1) Please refer to footnote (1) to the table "2009 Convertible Notes."

(2) Please refer to footnote (2) to the table "2009 Convertible Notes."

(3) Please refer to footnote (3) to the table "2009 Convertible Notes."

(4) Please refer to footnote (4) to the table "2009 Convertible Notes."

In 2011, ANI issued \$2,694,295 of secured subordinated convertible notes (the 2011 convertible notes) and consolidated all of the outstanding 2009 and 2010 convertible notes into 2011 convertible notes (collectively the consolidated 2011 convertible notes). The consolidated 2011 convertible notes, which bore interest at 14 percent per annum, were due on December 31, 2012. Interest on the consolidated 2011 convertible notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The consolidated 2011 convertible notes were secured by a second lien on substantially all of ANI's assets and included financial covenants and limitations on

ANI's ability to enter into certain transactions while the consolidated 2011 convertible notes were outstanding. Among the investors in the 2011 convertible notes were the following:

**2011 Convertible Notes**

Investor	Affiliations with ANI	Principal Amount(1)	Shares of ANI Series D Preferred Stock Issued upon Conversion of:		Warrants Issued
			Principal	Interest	
MVP II	Owns 56.7 percent of ANI capital stock  ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP II(2)	1,590,649	212,087	31,425	—
First Analysis	Owns 16.7 percent of ANI capital stock  ANI director Tracy L. Marshbanks, Ph.D. is managing director of First Analysis Corporation(3)	493,637	65,819	10,025	—
Healthcare Value Master Fund, Ltd.	Owns 1.6 percent of ANI capital stock  ANI director Robert Schrepfer is employed by the investment advisor to HVMF but is not deemed to be an affiliate of ANI(4)	230,815	30,775	4,703	—
Argentum Capital Partners II, L.P.	Owns 11.3 percent of ANI capital stock.	343,480	45,797	6,979	—

(1) Please refer to footnote (1) to the table "2009 Convertible Notes."

(2) Please refer to footnote (2) to the table "2009 Convertible Notes."

(3) Please refer to footnote (3) to the table "2009 Convertible Notes."

(4) Please refer to footnote (4) to the table "2009 Convertible Notes."

In addition, under the related note purchase agreement, dated as of January 28, 2011, among ANI, Meridian Venture Partners II, L.P. and the other lenders party thereto, ANI agreed to pay to MVP Management an annual fee of \$160,000 for monitoring and advisory services and to HVC an annual fee of \$40,000 for advisory services. In 2011, ANI paid no such fees to MVP Management or HVC. In 2012, ANI paid \$240,000 in such fees to MVP Management and \$60,000 to HVC. The obligation of ANI to continue to pay such fees under the note purchase agreement will terminate upon the closing of the merger. However, upon closing of the merger, certain additional fees are payable to MVP and HVC, as further described under "—Monitoring and Advisory Fee Agreements" below.

On June 6, 2012, all of the then outstanding convertible notes and accrued interest were converted into shares of ANI series D preferred stock. As of September 30, 2012, no convertible notes remained outstanding.

### **Monitoring and Advisory Fee Agreements**

In contemplation of the merger, ANI entered into separate agreements with MVP Management and HVC as of October 3, 2012. ANI refers to these agreements as the monitoring and advisory fee agreements.

Under the monitoring and advisory fee agreements, ANI agreed to make the following payments at the closing of the merger:

- fees in the amount of \$350,000 to MVP Management and \$40,000 to HVC, which fees represent reasonable compensation and fair value for overall management, deal structuring, financial advisory and due diligence services provided by MVP Management and HVC, respectively, in connection with the merger agreement and the transactions contemplated thereby; and
- the accrued but unpaid portion (pro-rated through the closing date of the merger) of the monitoring and advisory fees owed to MVP Management and HVC, respectively, by ANI pursuant to Section 15.4 of the note purchase agreement, which are expected not to exceed \$120,000 for MVP Capital and \$30,000 for HVC, assuming a closing on or before March 31, 2013.

### **Director Compensation**

It is anticipated that at least initially the compensation to be paid to the combined company's directors after the merger will be substantially similar to the compensation currently paid to members of the BioSante board of directors. It is anticipated, however, that the cash and equity non-employee director compensation policies described below will be reviewed by the Nominating and Corporate Governance Committee of the board of directors of the combined company following completion of the merger and may be subject to change.

The principal elements of BioSante's director compensation program currently include:

- annual cash retainers;
- meeting fees; and
- long-term equity-based incentive compensation, in the form of stock options.

BioSante does not compensate directors who are employees of BioSante separately for serving on the BioSante board of directors. BioSante does, however, reimburse each member of the BioSante board of directors, including directors who are employees of BioSante, for out-of-pocket expenses incurred in connection with attending board and board committee meetings.

Currently, ANI reimburses its directors for all reasonable and necessary travel and other incidental expenses incurred in connection with their attendance at meetings of the ANI board of directors. ANI's directors do not receive compensation in connection with their board or committee service or attendance at meetings. Any board compensation to be received by Messrs. Brown and Penn after completion of the merger, under the terms of the MVP II limited partnership agreement, will be turned over to MVP Management, which in turn will forward in excess of 50 percent of that amount to MVP II or credit it against future management fees owed by MVP II to MVP Management. Similarly, any board compensation to be received by Dr. Marshbanks will be credited against any management fees paid by the First Analysis funds.

**Cash Compensation**

Under current arrangements, the cash compensation paid to BioSante's non-employee directors consists of the following described annual board and board committee cash retainers and meeting fees.

<u>Description</u>	<u>Annual Cash Retainer</u>
Board Member	\$ 25,000
Chairman of the Board (in addition to Board member retainer)	22,500
Audit and Finance Committee Chair	15,000
Compensation Committee Chair	10,000
Nominating and Corporate Governance Committee Chair	7,000
Audit and Finance Committee Member (other than Chair)	7,500
Compensation Committee Member (other than Chair)	5,000
Nominating and Corporate Governance Committee Member (other than Chair)	3,500

<u>Description</u>	<u>Meeting Fees</u>
Board Meeting (in person)	\$ 2,000
Board Meeting (telephonic)	1,000
Board Committee (in person or telephonic)	1,000

The annual cash retainers are paid on a quarterly basis in the beginning of each calendar quarter. For example, the retainers paid in the beginning of the first calendar quarter are for the period from January 1 through March 31. The meeting fees are paid in arrears after the end of each calendar quarter.

**Stock Options**

Under certain circumstances, each of BioSante's non-employee directors receives an automatic grant of options to purchase shares of BioSante common stock upon the director's initial election to the BioSante board of directors and on an annual basis on the last business day of March each year. In addition, BioSante's chairman of the board receives an additional automatic option grant. The options have a ten-year term and an exercise price equal to the fair market value of the BioSante common stock on the grant date. The initial options vest and become exercisable in four equal annual installments and the annual options vest and become exercisable in full on the one-year anniversary of the grant date. The table below sets forth the number of options granted to each of BioSante's non-employee directors as initial and annual grants and the additional option grant to BioSante's chairman of the board:

<u>Description</u>	<u>Number of Shares Underlying Option Grants</u>
New Board Member (initial grant)	50,000
Board Member (annual basis)	25,000
Chairman of the Board (annual basis)	10,000

Any options to be received by Messrs. Brown and Penn after completion of the merger will be held for the benefit of MVP Management.

**Indemnification Agreements**

BioSante has entered into, and it is anticipated that the combined company will enter into, agreements with all of its directors under which the combined company will be required to indemnify

them against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of the combined company's directors. The combined company will be obligated to pay these amounts only if the director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to the best interests of the combined company. With respect to any criminal proceeding, the combined company will be obligated to pay these amounts only if the director had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

**Director Compensation Table: Combined Company Directors from BioSante**

The table below sets forth the compensation paid to BioSante's directors who will continue as directors for the combined company for their service in 2012. All share and per share amounts have been retroactively adjusted to reflect the one-for-six reverse stock split effected on June 1, 2012.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)(1)(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Fred Holubow	\$ 68,500	\$ 12,790	\$ 0	\$ 81,290
Ross Mangano	68,000	12,790	0	80,790

- (1) Amounts reported in the "Option Awards" column represent the aggregate grant date fair value for option awards granted to each director in 2012 computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. The grant date fair value is determined based on BioSante's Black-Scholes option pricing model. The grant date fair value per share for the options granted on March 30, 2012 was \$3.07 and was determined using the following specific assumptions: risk free interest rate: 1.04 percent; expected life: 5.5 years; expected volatility: 97.20 percent; and expected dividend yield: 0 percent.
- (2) The following table provides information regarding the aggregate number of options to purchase shares of BioSante common stock outstanding at December 31, 2012 and held by each of the directors listed in the table:

<u>Name</u>	<u>Aggregate Number of Securities Underlying Options</u>	<u>Exercisable/ Unexercisable</u>	<u>Range of Exercise Price(s)</u>	<u>Range of Expiration Date(s)</u>
Fred Holubow	28,329	24,163/4,166	\$ 4.08 - 26.43	03/15/2016 - 03/29/2022
Ross Mangano	28,329	24,163/4,166	4.08 - 26.43	03/15/2016 - 03/29/2022

**Director Compensation Table: Combined Company Directors from ANI**

ANI's directors did not receive any compensation in connection with their board or committee service or attendance at meetings during the year ended December 31, 2012. It is ANI's policy, however, to reimburse directors for travel expenses incurred in connection with traveling to and from board meetings and related lodging.

As described in further detail under "—Certain Relationships and Related Transactions," under the note purchase agreement, dated as of January 28, 2011, among ANI, Meridian Venture Partners II, L.P. and the other lenders party thereto, ANI agreed to pay to MVP Management an annual fee of \$160,000 for monitoring and advisory services and to HVC an annual fee of \$40,000 for advisory services. In 2011, ANI paid no such fees to MVP Management or HVC. In 2012, ANI paid \$240,000 in such fees to MVP Management and \$60,000 to HVC. As described under "—Certain Relationships and Related Transactions," ANI directors Robert E. Brown, Jr. and Thomas T. Penn are affiliated with MVP Management and ANI director Robert Schrepfer is employed by HVC but is not

deemed to be an affiliate of ANI. The obligations of ANI to continue to pay such fees under the note purchase agreement will terminate upon the closing of the merger.

In contemplation of the merger, ANI entered into the monitoring and advisory fee agreements with MVP Management and HVC as of October 3, 2012. Under the monitoring and advisory fee agreements, ANI agreed to make the following payments at the closing of the merger:

- fees in the amount of \$350,000 to MVP Management and \$40,000 to HVC, which fees represent reasonable compensation and fair value for overall management, deal structuring, financial advisory and due diligence services provided by MVP Management and HVC, respectively, in connection with the merger agreement and the transactions contemplated thereby; and
- the accrued but unpaid portion (pro-rated through the closing date of the merger) of the monitoring and advisory fees owed to MVP Management and HVC, respectively, by ANI pursuant to Section 15.4 of the note purchase agreement, which are expected not to exceed \$120,000 for MVP Capital and \$30,000 for HVC, assuming a closing on or before March 31, 2013.

## Executive Compensation

It is anticipated that at least initially the compensation to be paid to the combined company's executive officers after the merger will be substantially similar to the compensation currently paid to such individuals by ANI. It is anticipated, however, that the compensation to be paid to the executive officers of the combined company after the merger will be reviewed by the Compensation Committee of the board of directors of the combined company following completion of the merger and may be subject to change.

### Summary Compensation Table

The table below provides summary information concerning all compensation awarded to, earned by or paid to ANI's principal executive officer, principal financial officer and other executive officers during the years ended December 31, 2012 and 2011. Except as indicated below, these individuals are expected to serve the combined company in the same capacities following completion of the merger.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u>	<u>Bonus(1)</u>	<u>All Other Compensation(2)</u>	<u>Total</u>
Arthur S. Przybyl <i>President and Chief Executive Officer</i>	2012	\$ 370,364	\$ 187,688	\$ 10,887	\$ 568,939
	2011	350,863	—	10,850	361,713
Charlotte C. Arnold <i>Vice President and Chief Financial Officer</i>	2012	239,376	97,020	887	337,283
	2011	225,750	—	850	226,600
James G. Marken <i>Vice President, Operations</i>	2012	242,784	88,036	887	331,707
	2011	234,300	—	850	235,150
Robert J. Jamnick <i>Vice President, Quality and Product Development</i>	2012	207,929	63,202	887	272,018
	2011	191,066	—	821	191,887

- (1) On April 5, 2012, the ANI board, after considering, among other things, the fact that ANI's executive officers did not receive bonuses for 2010 and 2011, resolved to pay special bonuses in the form of interests in the proceeds of an exit transaction. The terms of such bonuses, which are not included in the table above, were memorialized in the transaction bonus agreements described below. The bonus amounts for Mr. Marken do not include \$33,800 he received in 2011 and \$12,450 he received in 2012, as part of a bonus awarded to him in 2008.

- (2) The amounts shown in the "All Other Compensation" column for 2012 include the following with respect to each named executive officer:

<u>Name</u>	<u>Insurance Premiums(a)</u>	<u>Auto Allowance</u>
Arthur S. Przybyl	\$ 887	\$ 10,000
Charlotte C. Arnold	887	—
James G. Marken.	887	—
Robert J. Jamnick.	887	—

- (a) Includes premiums paid by ANI on behalf of the named executive officer for short- and long-term disability insurance, accident, death and disability insurance and basic life insurance.

### **Employment Agreements**

#### *Arthur S. Przybyl*

Mr. Przybyl currently serves as ANI's Chief Executive Officer. In February 2009, ANI entered into an employment letter agreement with Mr. Przybyl commencing on March 9, 2009. The term of the agreement is open-ended; therefore, Mr. Przybyl is free to resign for any reason or for no reason and ANI is free to conclude the at-will employment relationship with Mr. Przybyl at any time, with or without cause, subject to certain severance provisions described below.

Under the agreement, Mr. Przybyl's original annual base salary was \$325,000, subject to a 10 percent increase on the first anniversary of the letter agreement if ANI achieves positive earnings before interest, depreciation and amortization (EBITDA) during the first year of the letter agreement. Mr. Przybyl's current annual base salary is \$375,375. In addition to his salary, Mr. Przybyl receives an automobile allowance of \$10,000 per year, payable in equal monthly installments. Mr. Przybyl is also eligible for an annual cash bonus, the target of which is up to 50 percent of his base salary, based on the achievement of certain individual and corporate objectives, as determined by the ANI board of directors.

Pursuant to the agreement, as of March 9, 2009, Mr. Przybyl was to receive an option under ANI's 2005 Stock Option Plan to purchase 17,005 shares of ANI common stock at an exercise price of \$110.00 per share. The number of shares issuable upon exercise of the option and the exercise price have been adjusted for the one-for-ten reverse stock split in January 2011. This option was never granted.

The employment agreement also specifies that Mr. Przybyl was entitled to a one-time bonus upon a sale of ANI; however, Mr. Przybyl forfeited this one-time bonus in connection with the execution of the transaction bonus agreement described below.

Under the terms of the employment agreement, if Mr. Przybyl is terminated by ANI other than for cause, upon the receipt from him of a release in form and substance satisfactory to ANI, he is entitled to receive, in addition to unpaid salary and expenses and payment of accrued incentive compensation amounts, (i) an amount equal to his base salary for a period of 12 months, which amount may be paid, at ANI's election, either in a lump sum or by salary continuation, and a prorated portion of his targeted annual bonus to the extent that the corresponding objectives are achieved prior to the termination of employment and (ii) amounts or reimbursements for the premiums to continue health insurance coverage as in effect at the time of the termination of employment for a period of 12 months under the Consolidated Omnibus Budget Reconciliation Act (COBRA).



*Charlotte C. Arnold*

Ms. Arnold currently serves as ANI's Vice President and Chief Financial Officer. In May 2009, ANI entered into an employment letter agreement with Ms. Arnold commencing on May 14, 2009. The term of the agreement is as described above under "—Arthur S. Przybyl."

Under the agreement, Ms. Arnold's original annual base salary was \$210,000. Ms. Arnold's current annual base salary is \$242,550. Ms. Arnold is eligible for an annual cash bonus, the target of which is up to 40 percent of her base salary, based on the achievement of certain individual and corporate objectives, as determined by the ANI board of directors.

Pursuant to the agreement, as of May 14, 2009, Ms. Arnold was to receive an option under ANI's 2005 Stock Option Plan to purchase 3,250 shares of ANI common stock at an exercise price of \$110.00 per share. The number of shares issuable upon exercise of the option and the exercise price have been adjusted for the 1-for-10 reverse stock split in January 2011. This option was never granted.

The employment agreement furthermore specifies that Ms. Arnold was entitled to a one-time bonus upon a sale of ANI; however, Ms. Arnold forfeited this one-time bonus in connection with the execution of the transaction bonus agreement described below.

Under the terms of the employment agreement, if Ms. Arnold is terminated by ANI other than for cause, upon the receipt from her of a release in form and substance satisfactory to ANI, she is entitled to receive, in addition to unpaid salary and expenses and payment of accrued incentive compensation amounts, (i) an amount equal to her base salary for a period of 12 months, which amount may be paid, at ANI's election, either in a lump sum or by salary continuation, and a prorated portion of her targeted annual bonus to the extent that the corresponding objectives are achieved prior to the termination of employment and (ii) amounts or reimbursements for the premiums to continue health insurance coverage as in effect at the time of the termination of employment for a period of 12 months under COBRA.

*James G. Marken*

Mr. Marken currently serves as ANI's Vice President, Operations. On May 1, 2007 ANI entered into an employment agreement with Mr. Marken, for the period commencing on May 1, 2007 and ending on the second anniversary of such date. The term of the agreement is automatically extended for an additional year on each anniversary unless 90 days' prior written notice of non-extension is provided by either party.

Under the agreement, Mr. Marken's original annual base salary was \$147,000. Mr. Marken's current annual base salary is \$246,015. Mr. Marken is also eligible for an annual cash bonus, the target of up to 35 percent of his base salary, based on the achievement of certain corporate objectives. The corporate objectives will be determined by the Chief Executive Officer in consultation with Mr. Marken, while the achievement of such objectives will be determined by the Compensation Committee of the ANI board of directors.

Pursuant to the agreement, as of May 1, 2007, Mr. Marken was granted an option, under ANI's 2005 Stock Option Plan, as amended, to purchase 1,750 shares of ANI common stock at an exercise price of \$110.00 per share. The number of shares issuable upon exercise of the option and the exercise price have been adjusted for the one-for-ten reverse stock split in January 2011. The option, which has a term of ten years, vested monthly over 60 months. Mr. Marken forfeited this option in connection with the execution of the transaction bonus agreement described below.

Under the terms of the employment agreement, if Mr. Marken is terminated by ANI other than for cause or he resigns for good reason, he is entitled to receive, in addition to unpaid salary and expenses and payment of accrued incentive compensation amounts, (1) severance payments in the form

of a continuation of his base salary in effect immediately prior to the termination for a period of 12 months following the termination in exchange for a release of claims he may have against ANI, (2) any earned (with respect to his prior full year of employment), but unpaid bonus, and a prorated portion of the current year's bonus, determined by ANI in the ordinary course consistent with past practice; (3) continuing his participation through the severance period in any health benefits in which he was participating on the effective date of such termination; and (4) providing him any other benefits that have accrued or vested but have not been paid as of the effective date of such termination, all of which are payable in consideration for and only after he executes a mutual release of claims. If ANI elects not to renew Mr. Marken's employment agreement upon the expiration of the third renewal term after the expiration of the initial term or any successive renewal term, it shall be under no obligation to provide severance benefits. The third renewal term has passed.

Termination "with good reason" is defined as a termination by Mr. Marken for (1) any substantial diminution in his position or status, duties or authority with ANI; (2) any reduction in his base salary; (3) the relocation of ANI's principal office outside of a 50 mile radius of Baudette, Minnesota or ANI requiring Mr. Marken to be based at any place other than within a 50 mile radius of Baudette, Minnesota, except, in each instance, for reasonably required business travel from time to time; and (4) any material breach by ANI of any agreement or covenant made in the employment agreement, which breach is not cured within 30 days of written notice to ANI or is incapable of cure.

Termination "for good cause" is defined as a termination for (1) willful misconduct or gross negligence in the performance or intentional nonperformance of any of employee's material duties and responsibilities; (2) employee's continued and willful refusal promptly to follow any lawful direction of the Chief Executive Officer or the ANI board of directors; (3) employee's willful misconduct or gross negligence in the performance or intentional nonperformance of numerous of his duties and responsibilities (regardless of materiality), which in the aggregate, constitute material nonperformance; (4) employee's willful misrepresentation, fraud, alcohol or illegal drug abuse, or material misconduct with respect to the business or affairs of ANI, which materially and adversely affects the operations, prospects or reputation of ANI; (5) employee's conviction of a felony or other crime involving moral turpitude; (6) employee's material breach of any fiduciary duty owed to ANI or breach of the non-competition provisions or material breach of confidential information and trade secret provisions, which breach is not cured within thirty (30) days of written notice or is incapable of cure; or (7) any other willful and material breach that is not cured within thirty (30) days of written notice or is incapable of cure.

ANI did not execute an employment letter agreement with Robert J. Jamnick.

#### ***Transaction Bonus Agreements and Related Arrangements***

*Arthur S. Przybyl*

Pursuant to a transaction bonus agreement, dated September 22, 2012, as amended on December 28, 2012, between ANI and Mr. Przybyl, Mr. Przybyl is entitled to receive a bonus based on the net proceeds to the ANI stockholders from the consummation of a "change of control" transaction.

As defined in the agreement, a change of control occurs in connection with (a) any merger involving ANI where the holders of a majority of the issued and outstanding equity of the surviving entity are third parties; (b) the sale or transfer of a majority of ANI's equity interests to one or more third parties; (c) the sale or transfer of all or substantially all of ANI's assets to a third party; (d) completion of an initial public offering of ANI's stock, or (e) ANI becoming a publicly traded company through any other transaction, in each case with the result that net proceeds are available for distribution to the ANI stockholders.

Under the agreement, Mr. Przybyl agreed to forfeit any stock options or other equity right granted to him by ANI prior to the date of the agreement, including, without limitation, the transaction bonus issuable pursuant to his employment letter agreement, as described above.

Under the agreement, the aggregate transaction bonus payable to Mr. Przybyl by ANI will be as follows, based on the net proceeds (including contingency proceeds, if applicable) available for distribution to ANI stockholders: (i) if the net proceeds are between \$6,500,000 and \$16,499,999, the transaction bonus payment will equal 6 percent of the net proceeds, (ii) if the net proceeds are between \$16,500,000 and \$26,499,999, the transaction bonus payment will be \$600,000 plus 7.722 percent of the net proceeds over \$16,499,999 to \$26,499,999, and (iii) if the net proceeds are greater than \$26,499,999, the transaction bonus payment will be \$1,372,200 plus 7.722 percent of the net proceeds in excess of \$26,500,000.

The agreement originally provided that ANI would pay Mr. Przybyl's transaction bonus in two parts, as follows: (a) 100 percent of the closing date bonus would be paid within five days following the closing date of the change of control transaction and (b) 100 percent of the contingency bonus, if any, would be paid within five days following the 24-month anniversary of the closing date. In the current merger transaction, the bonus will be paid in shares of ANI series D preferred stock, which will automatically be converted into BioSante common stock at the completion of the merger. For Mr. Przybyl and Ms. Arnold, the agreements were amended on December 28, 2012 to provide for revised timing of the payout as described under "—Tax Withholding Arrangements" below.

Under the terms of the agreement, if Mr. Przybyl is discharged involuntarily, without cause (as defined in the agreement), or resigns from employment for good reason (as defined in the agreement), within 180 days prior to the closing date of the change of control transaction, he is still entitled to receive the transaction bonus payment.

The agreement acknowledges that the merger between BioSante and ANI qualifies as a change of control. The net proceeds of the merger are calculated as the product of (a) the average closing sale price of the BioSante common stock for the five trading days prior to the announcement of a signed merger agreement with ANI (which announcement occurred on October 4, 2012) and (b) the aggregate number of shares of BioSante common stock to be issued to the ANI stockholders in the merger.

The agreement and the right to receive a transaction bonus automatically terminates and is voided upon the earlier of (a) Mr. Przybyl's separation from service of ANI for any reason other than as specifically permitted in the agreement, and (b) the occurrence of a bankruptcy event (as defined in the agreement).

*Charlotte C. Arnold*

Pursuant to a transaction bonus agreement, dated September 22, 2012, as amended on December 28, 2012, between ANI and Ms. Arnold, Ms. Arnold is entitled to receive a bonus based on the net proceeds raised in connection with the consummation of a "change of control" transaction, including the proposed merger between BioSante and ANI.

Under the agreement, the aggregate transaction bonus payable to Mrs. Arnold by ANI will be as follows, based on the net proceeds (or contingency proceeds, if applicable) available for distribution to ANI stockholders: (i) if the net proceeds are between \$6,500,000 and \$16,499,999, the transaction bonus payment will equal 1.5 percent of the net proceeds, (ii) if the net proceeds are between \$16,500,000 and \$26,499,999, the transaction bonus payment will be \$150,000 plus 2.478 percent of the net proceeds over \$16,499,999 to \$26,499,999, and (iii) if the net proceeds are greater than \$26,499,999, the transaction bonus payment will be \$397,800 plus 2.478 percent of the net proceeds in excess of \$26,500,000.

The remaining terms of Ms. Arnold's agreement are substantially identical to the terms of Mr. Przybyl's agreement described above.

*James G. Marken*

Pursuant to a transaction bonus agreement, dated September 22, 2012, between ANI and Mr. Marken, Mr. Marken is entitled to receive a bonus based on the net proceeds raised in connection with the consummation of a "change of control" transaction, including the proposed merger between BioSante and ANI.

Under the agreement, the aggregate transaction bonus payable to Mr. Marken by ANI will be as follows, based on the net proceeds (or contingency proceeds, if applicable) available for distribution to ANI stockholders: (i) if the net proceeds are between \$6,500,000 and \$16,499,999, the transaction bonus payment will equal 1 percent of the net proceeds, (ii) if the net proceeds are between \$16,500,000 and \$26,499,999, the transaction bonus payment will be \$100,000 plus 1.855 percent of the net proceeds over \$16,499,999 to \$26,499,999, and (iii) if the net proceeds are greater than \$26,499,999, the transaction bonus payment will be \$285,000 plus 1.855 percent of the net proceeds in excess of \$26,500,000.

The remaining terms of Mr. Marken's agreement are substantially identical to the terms of Mr. Przybyl's agreement described above, with the timing of the bonus payout in the current merger transaction to be as described under "—Tax Withholding Arrangements" below.

*Robert J. Jamnick*

Pursuant to a transaction bonus agreement, dated September 22, 2012, between ANI and Mr. Jamnick, Mr. Jamnick is entitled to receive a bonus based on the net proceeds raised in connection with the consummation of a "change of control" transaction, including the proposed merger between BioSante and ANI.

Under the agreement, the aggregate transaction bonus payable to Mr. Jamnick by ANI will be as follows, based on the net proceeds (or contingency proceeds, if applicable) available for distribution to ANI stockholders: (i) if the net proceeds are between \$6,500,000 and \$16,499,999, the transaction bonus payment will equal 1 percent of the net proceeds, (ii) if the net proceeds are between \$16,500,000 and \$26,499,999, the transaction bonus payment will be \$100,000 plus 1.732 percent of the net proceeds over \$16,499,999 to \$26,499,999, and (iii) if the net proceeds are greater than \$26,499,999, the transaction bonus payment will be \$273,200 plus 1.732 percent of the net proceeds in excess of \$26,500,000.

The remaining terms of Mr. Jamnick's agreement are substantially identical to the terms of Mr. Przybyl's agreement described above, with the timing of the bonus payout in the current merger transaction to be as described under "—Tax Withholding Arrangements" below.

#### ***Tax Withholding Arrangements***

As described above, certain executive officers of ANI will be paid transaction bonuses at the closing of the merger. Even though the bonuses are to be paid in stock, the combined company will have to withhold amounts sufficient to meet its various state and federal tax withholding obligations, which are paid in cash. ANI and its executive officers expect to enter into the following arrangements to enable the combined company to make such withholdings:

*Mr. Przybyl and Ms. Arnold*

Immediately prior to closing of the merger, all of the shares of ANI series D preferred stock payable to Mr. Przybyl and Ms. Arnold pursuant to the transaction bonus arrangements referenced

above will be placed into a rabbi trust, which will remain in place until the expiration of the lock-up period that applies to Mr. Przybyl and Ms. Arnold. As a result of completion of the merger, those shares of ANI series D preferred stock will automatically convert into shares of BioSante common stock. There will be no taxes payable on the shares until they are released from the rabbi trust. The rabbi trust will provide that following the expiration of the lock-up period until at the latest March 5, 2014, shares will be released ratably on a weekly basis to a broker/dealer, who would, pursuant to a trading plan to be entered into by the executive and the broker/dealer pursuant to Rule 10b5-1 under the Exchange Act prior to closing of the merger, promptly sell a sufficient number of shares of BioSante common stock to pay the required tax withholding amounts on the released shares (expected to be one half of such shares). The combined company will calculate the amount of required tax withholding (including the employee portion of FICA, as well as income taxes) on the released shares on a weekly basis (based on the then current fair market value of such shares). After completing each sale, the broker/dealer will transfer sufficient sale proceeds to the combined company to satisfy the executive's tax withholding obligations and transfer any remaining released shares to or as directed by the executive. All such sales pursuant to the rabbi trust and such 10b5-1 plan must be completed by March 15, 2014. All such sales by the rabbi trust will be sold pursuant to Rule 144 under the Securities Act, including the applicable volume limitations.

*Messrs. Marken and Jamnick*

Immediately prior to closing of the merger, Messrs. Marken and Jamnick, who are not subject to a lock-up period, will receive shares of ANI series D preferred stock payable pursuant to the transaction bonus arrangements referenced above. As a result of the merger, those shares of ANI series D preferred stock will automatically convert into shares of BioSante common stock. All of these shares will be delivered to a broker/dealer who would, pursuant to a trading plan to be entered into by the executive and the broker/dealer pursuant to Rule 10b5-1 under the Exchange Act prior to closing of the merger, promptly sell a sufficient number of shares of BioSante common stock to pay the required tax withholding amounts on the released shares. The combined company will calculate the amount of required tax withholding (including the employee portion of FICA, as well as income taxes) on the released shares on a weekly basis (based on the then current fair market value of such shares). After completing each sale, the broker/dealer will transfer sufficient sale proceeds to the combined company to satisfy the executive's tax withholding obligations and transfer any remaining released shares to or as directed by the executive. All such sales will be sold pursuant to Rule 144 under the Securities Act, including the applicable volume limitations.

The following tables show, for each of the ANI executives, that number of shares of BioSante common stock corresponding to (i) an estimated gross bonus amount, (ii) an estimated amount of taxes to be withheld and (iii) an estimated net bonus amount to be delivered to the executive, in each case assuming \$1.848 per share market value of BioSante common stock and assuming (a) an exchange ratio of 10.5948 shares of BioSante common stock for each share of ANI series D preferred stock (corresponding to BioSante net cash of \$17.0 million), (b) an exchange ratio of 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock (corresponding to BioSante net cash of \$18.0 million) and (c) an exchange ratio of 9.4095 shares of BioSante common stock for each share of ANI series D preferred stock (corresponding to BioSante net cash of \$23.0 million or more). The assumed exchange ratios in the tables below do not give effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus. As explained in "The Merger Agreement—Merger Consideration and Adjustment", the exchange ratios are subject to potential adjustment depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger and thus will not be determined until that time.

*Assumed Exchange Ratio of 10.5948 Shares of BioSante Common Stock for Each Share of ANI Series D Preferred Stock*

<u>Executive</u>	<u>Estimated Gross Bonus Amount</u>	<u>Estimated Amount of Taxes to be Withheld</u>	<u>Estimated Net Bonus Amount</u>
Arthur S. Przybyl	1,843,399 shares	734,722 shares	1,108,677 shares
Charlotte C. Arnold	568,529 shares	219,102 shares	349,427 shares
James G. Marken	418,945 shares	154,172 shares	264,772 shares
Robert J. Jamnick	394,754 shares	145,693 shares	249,060 shares

*Assumed Exchange Ratio of 10.3502 Shares of BioSante Common Stock for Each Share of ANI Series D Preferred Stock*

<u>Executive</u>	<u>Estimated Gross Bonus Amount</u>	<u>Estimated Amount of Taxes to be Withheld</u>	<u>Estimated Net Bonus Amount</u>
Arthur S. Przybyl	1,790,806 shares	712,423 shares	1,078,383 shares
Charlotte C. Arnold	551,652 shares	211,203 shares	340,449 shares
James G. Marken	406,310 shares	149,743 shares	256,567 shares
Robert J. Jamnick	382,957 shares	141,588 shares	241,399 shares

*Assumed Exchange Ratio of 9.2508 Shares of BioSante Common Stock for Each Share of ANI Series D Preferred Stock*

<u>Executive</u>	<u>Estimated Gross Bonus Amount</u>	<u>Estimated Amount of Taxes to be Withheld</u>	<u>Estimated Net Bonus Amount</u>
Arthur S. Przybyl	1,554,438 shares	612,203 shares	942,235 shares
Charlotte C. Arnold	475,801 shares	182,238 shares	293,563 shares
James G. Marken	349,529 shares	129,842 shares	219,687 shares
Robert J. Jamnick	329,941 shares	122,976 shares	206,965 shares

**Indemnification Agreements**

BioSante has entered into, and it is anticipated that the combined company will enter into, agreements with all of its officers under which the combined company will be required to indemnify them against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of the combined company's officers. The combined company will be obligated to pay these amounts only if the officer acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to the best interests of the combined company. With respect to any criminal proceeding, the combined company will be obligated to pay these amounts only if the officer had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

**Outstanding Equity Awards at Fiscal Year End**

The table below provides information regarding outstanding equity awards held by the named executive officers of ANI as of December 31, 2012, including the value of the option awards.

<u>Name</u>	<u>Option Awards(1)</u>			
	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
Arthur S. Przybyl <i>President and Chief Executive Officer</i>	—	—	—	—
Charlotte C. Arnold <i>Vice President and Chief Financial Officer</i>	—	—	—	—
James G. Marken <i>Vice President, Operations</i>	—	—	—	—
Robert J. Jamnick <i>Vice President, Quality and Product Development</i>	—	—	—	—

- (1) All options shown were cancelled in connection with the execution of the transaction bonus agreements. Under the terms of the options, vesting occurred in 60 equal monthly installments. Upon the occurrence of a change in control, the options would have accelerated and become fully vested and immediately exercisable as of the date of the change in control. Option exercise prices and number of shares issuable upon exercise of the options have been adjusted to reflect ANI's one-for-ten reverse stock split on January 28, 2011.

**Compensation Committee Interlocks and Insider Participation**

It is anticipated that the compensation committee of the combined company will consist of Dr. Marshbanks, Mr. Mangano and Mr. Schrepfer. Each member of the compensation committee is an "outside" director as that term is defined in Section 162(m) of the Code and a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act. None of the combined company's executive officers serve as a member of the board of directors or compensation committee of any entity that has one or more executive officers who will serve on the combined company's board of directors or compensation committee following the merger.

**PRINCIPAL STOCKHOLDERS OF BIOSANTE**

The following table sets forth information known to BioSante with respect to the beneficial ownership of each class of BioSante capital stock as of December 31, 2012 for:

- each person known by BioSante to beneficially own more than five percent of any class of BioSante's voting securities;
- each of BioSante's directors;
- each of BioSante's executive officers; and
- all of BioSante's current directors and executive officers as a group.

The number of shares beneficially owned by a person includes shares subject to options held by that person that are currently exercisable or that become exercisable within 60 days of December 31, 2012. Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options currently exercisable or that become exercisable within 60 days of December 31, 2012 are outstanding for the purpose of computing the percentage of BioSante capital stock owned by such person or group. However, such unissued shares of BioSante capital stock are not deemed to be outstanding for calculating the percentage of BioSante capital stock owned by any other person. Except as otherwise indicated and subject to the voting agreements described under the section entitled "Voting and Other Ancillary Agreements," BioSante believes that the beneficial owners of BioSante capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. Unless otherwise indicated in the notes below, the address for each of the stockholders in the table below is c/o BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069.

Name and Address of Beneficial Owner	Shares Beneficially Owned(1)(2)					
	BioSante Common Stock		BioSante Class C Special Stock		BioSante Common Stock and Common Stock Equivalents	Percent of Total Voting Power(3)
	Number	Percent	Number	Percent		
Louis W. Sullivan, M.D.	35,481	*	16,666	25.6%	52,147	*
Stephen M. Simes	275,652(4)	1.1%	—	—	275,652	1.1%
Fred Holubow	34,372	*	—	—	34,372	*
Ross Mangano	418,397(5)	1.7%	—	—	418,397	1.7%
Edward C. Rosenow, III, M.D.	27,586	*	—	—	27,586	*
John T. Potts, Jr., M.D.	8,636(6)	*	—	—	8,636	*
Stephen A. Sherwin, M.D.	41,890	*	—	—	41,890	*
Phillip B. Donenberg	129,563	*	—	—	129,563	*
Michael C. Snabes, M.D., Ph.D.	54,373	*	—	—	54,373	*
Hans Michael Jebsen(7)	12,500	*	16,666	25.6%	29,166	*
Marcus Jebsen(8)	4,166	*	8,333	12.8%	12,499	*
Angela Ho(9)	1,219	*	16,666	25.6%	17,885	*
All directors and executive officers as a group (9 persons)	1,025,923(10)	4.1%	16,666	25.6%	1,042,589	4.2%

\* Represents beneficial ownership of less than one percent.



- (1) Includes for the persons listed below the following shares of BioSante common stock subject to options held by such persons that are currently exercisable or become exercisable within 60 days of December 31, 2012:

<u>Name</u>	<u>Shares of BioSante Common Stock Underlying Stock Options</u>
<b>Directors</b>	
Louis W. Sullivan, M.D.	27,498
Stephen M. Simes	241,942
Fred Holubow	24,163
Ross Mangano	24,163
Edward C. Rosenow, III, M.D.	24,163
John T. Potts, Jr., M.D.	7,707
Stephen A. Sherwin, M.D.	27,430
<b>Named Executive Officers</b>	
Stephen M. Simes	241,942
Phillip B. Donenberg	122,149
Michael C. Snabes, M.D., Ph.D.	54,373
<u>All directors and executive officers as a group (9 persons)</u>	<u>553,588</u>

- (2) Includes shares of BioSante common stock held by the following persons in securities brokerage accounts, which in certain circumstances under the terms of the standard brokerage account form may involve a pledge of such shares as collateral: Dr. Sullivan (1,666 shares), Mr. Simes (15,788 shares), Mr. Holubow (10,209 shares), Mr. Mangano (11,133 shares), Dr. Rosenow (3,333 shares), Dr. Sherwin (14,460 shares) and Mr. Donenberg (7,387 shares).
- (3) In calculating the percent of total voting power, the voting power of shares of BioSante common stock and shares of BioSante class C special stock is combined.
- (4) Mr. Simes's beneficial ownership includes 33,694 shares of BioSante common stock held by a trust and 16 shares of BioSante common stock held by Mr. Simes's child.
- (5) Mr. Mangano's beneficial ownership includes: (a) 321,610 shares of common stock held by JO & Co., of which Mr. Mangano is President; (b) 5,000 shares of common stock held by Oliver & Co., of which Mr. Mangano is the trustee; and (c) an aggregate of 39,998 shares of common stock held in various accounts, of which Mr. Mangano is an advisor and/or a trustee. Mr. Mangano has sole voting and investment power over these shares.
- (6) Includes 487 shares of BioSante common stock held in irrevocable trusts for Dr. Potts's children, as to which Dr. Potts disclaims any beneficial ownership.
- (7) The address of Hans Michael Jebsen is c/o Jebsen & Co. Ltd., 28/F Caroline Center, 28 Yun Ping Road, Causeway Bay, Hong Kong, China.
- (8) The address of Marcus Jebsen is c/o MF Jebsen International Ltd., 24/F Caroline Centre, 28 Yun Ping Road, Causeway Bay, Hong Kong.
- (9) The address of Angela Ho address is c/o Jet Asia Ltd., 39/F Shun Tak Center, 200 Connaught Road Central, Hong Kong, China.
- (10) The amount beneficially owned by all current directors and executive officers as a group includes 486,227 shares of BioSante common stock issuable upon the exercise of stock options held by these individuals, 62,513 shares of BioSante common stock held in trusts and 16 shares of BioSante common stock held by immediate family members of the directors and executive officers. See notes (1), (4), (5) and (6) above.

**PRINCIPAL STOCKHOLDERS OF ANI**

The following table sets forth information known to ANI with respect to the beneficial ownership of each class of ANI capital stock as of December 31, 2012 for:

- each person known by ANI to beneficially own more than five percent of any class of ANI's voting securities;
- each of ANI's directors;
- each of ANI's executive officers; and
- all of ANI's current directors and executive officers as a group.

The number of shares beneficially owned by a person includes shares subject to options or warrants held by that person that are currently exercisable or that become exercisable within 60 days of December 31, 2012. Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options or warrants currently exercisable or that become exercisable within 60 days of December 31, 2012 are outstanding for the purpose of computing the percentage of ANI capital stock owned by such person or group. However, such unissued shares of ANI capital stock are not deemed to be outstanding for calculating the percentage of ANI capital stock owned by any other person. Except as otherwise indicated in the footnotes below and subject to the voting agreements described under the section entitled "Voting and Other Ancillary Agreements," ANI believes that the beneficial owners of ANI capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. Unless otherwise indicated in the notes below, the address for each of the ANI stockholders in the table below is c/o ANIP Acquisition Company, 210 Main Street West, Baudette, Minnesota 56623.

Name and Address of Beneficial Owner	Shares Beneficially Owned(1)							
	ANI Common Stock		ANI Series A, B and C Preferred Stock(2)		ANI Series D Preferred Stock		ANI Common Stock and Common Stock Equivalents	Percent of Total Voting Power(3)
	Number	Percent	Number	Percent	Number	Percent		
Robert E. Brown, Jr.(4)	24,429	68.7%	92,600	42.9%	1,376,596	58.0%	1,493,625	56.9%
Arthur S. Przybyl	—	—	—	—	—	—	—	—
Tracy L. Marshbanks, Ph.D.(5)	3,810	16.1%	39,001	18.0%	394,680	16.6%	437,491	16.7%
Thomas A. Penn(4)	24,429	68.7%	92,600	42.9%	1,376,596	58.0%	1,493,625	56.9%
Robert Schrepfer(6)	—	—	—	—	—	—	—	—
Charlotte C. Arnold	—	—	—	—	—	—	—	—
James G. Marken	—	—	—	—	—	—	—	—
Robert J. Jamnick	—	—	—	—	—	—	—	—
Argentum Capital Partners II, L.P. (7)	2,788	11.8%	20,289	9.4%	272,239	11.5%	295,316	11.3%
Bannon Private Equity Fund Ltd.(8)	449	1.95%	7,293	3.4%	—	—	7,742	*
First Analysis Funds(9)	3,810	16.1%	39,001	18.0%	394,680	16.6%	437,491	16.7%
Healthcare Value Partners(10)	1,866	7.9%	13,661	6.3%	182,640	7.7%	198,167	7.6%
Liberty(11)	5,846	20.6%	34,651	16.0%	124,008	5.2%	164,505	6.3%
Meridian Venture Partners II, L.P. (12)	24,429	68.7%	92,600	42.9%	1,376,596	58.0%	1,493,625	56.9%
All directors and executive officers as a group (8 persons)(13)	28,239	79.4%	131,601	60.9%	1,771,276	74.6%	1,931,116	73.5%

\* Represents beneficial ownership of less than one percent.

- (1) Includes for the persons listed below the following shares of ANI common stock subject to warrants held by such persons that are currently exercisable or become exercisable within 60 days of December 31, 2012:

<u>Name</u>	<u>Shares of ANI Common Stock Underlying Warrants</u>
Bannon Private Equity Fund Ltd.	449
Liberty	4,831
Meridian Venture Partners II, L.P.	11,951

- (2) Includes for the persons listed below the following shares of ANI preferred stock held by such persons as of December 31, 2012:

<u>Name</u>	<u>Shares of ANI Series A Preferred Stock</u>	<u>Shares of ANI Series B Preferred Stock</u>	<u>Shares of ANI Series C Preferred Stock</u>
Argentum Capital Partners II, L.P.	—	16,004	4,285
Bannon Private Equity Fund Ltd.	5,088	925	1,280
First Analysis Funds	—	30,763	8,238
Healthcare Value Partners	—	9,116	4,545
Liberty	28,354	3,260	3,037
Meridian Venture Partners II, L.P.	67,598	13,638	11,364

- (3) In calculating the percent of total voting power, the voting power of shares of ANI common stock, shares of ANI series A preferred stock, ANI series B preferred stock and ANI series C preferred stock and shares of ANI series D preferred stock is combined.
- (4) These shares are held by Meridian Venture Partners II, L.P. (MVP II). MVP II GP, L.P. (GP) is the general partner of MVP II. Meridian Venture Partners II, Co. (MVP Corp.) is the general partner of GP. MVP Management Company (MVP Management) d/b/a MVP Capital Partners, is the management company for MVP II and also renders financial and business advisory services to several of the companies in which MVP II has invested. Robert E. Brown, Jr., a director of ANI, is the President, sole stockholder and sole director of MVP Corp, the sole stockholder, director and President of MVP Management, as well as a limited partner of GP and one of two principals of MVP II that are licensed by the Small Business Administration (SBA). SBA-licensed principals are charged with approving all investment-related decisions on behalf of small business investment companies licensed by the SBA, such as MVP II. Thomas T. Penn, a director of ANI, is a Vice President of MVP Corp, a Vice President and employee of MVP Management, a limited partner of GP and one of the two SBA-licensed principals of MVP II. As such, both Mr. Brown and Mr. Penn may be deemed to share voting and dispositive power with respect to the shares that are held of record by MVP II. Messrs. Brown and Penn disclaim beneficial ownership in such shares of capital stock except to the extent of their respective pecuniary interests therein. See footnote (12) below.
- (5) These shares are held by FA Private Equity Fund IV, L.P. (FAPEF IV), FA Private Equity Fund IV GmbH & Co. Beteiligungs KG (GmbH), The Productivity Fund IV, L.P. (Productivity Fund) and The Productivity Fund IV Advisors Fund, L.P. (Advisors Fund). We refer to these funds collectively as the First Analysis Funds.

FA Private Equity Management IV, L.L.C. (FAPEM IV) is the sole general partner of FAPEF IV. First Analysis Venture Operations and Research, L.L.C. (FAVOR) is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by FAPEF IV. Tracy L. Marshbanks, Ph.D., a director of ANI, is a managing director of First Analysis Corporation, which manages FAVOR.

FAPEM IV is the managing limited partner of GmbH. FAVOR is the ultimate managing member of FAPEM IV and, in that capacity, exercises voting and dispositive control over the shares held by GmbH. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

First Analysis Management Company IV, L.L.C. (FAMC IV) is the sole general partner of Productivity Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Productivity Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR.

FAMC IV is the sole general partner of Advisors Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Advisors Fund. Dr. Marshbanks is a managing director of First Analysis Corporation, which manages FAVOR. Dr. Marshbanks may therefore be deemed to share voting and dispositive power with respect to the shares that are held of record by the First Analysis Funds. Dr. Marshbanks disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. See footnote (9) below.

- (6) Does not include shares held by Healthcare Value Master Fund Ltd. (HVMF). While Mr. Schrepfer is an employee of Healthcare Value Capital, LLC (HVC), the investment adviser to HVMF, he does not have an ownership interest in, and does not serve as general partner or managing member of, HVC or its affiliates. Therefore, Mr. Schrepfer is not deemed to share voting or dispositive power with respect to the shares held by HVMF. See footnote (10) below.
- (7) Includes 2,788 shares of ANI common stock, 16,004 shares of ANI series B preferred stock and 4,285 shares of ANI series C preferred stock held by Argentum Capital Partners II, L.P. (ACP II). Argentum Investments, LLC is the managing member of Argentum Partners II, LLC, which is the general partner of ACP II. Walter H. Barandiaran and Daniel Raynor are co-managing members of Argentum Investments, LLC. Each of Messrs. Barandiaran and Raynor, and Argentum Investments, LLC and Argentum Partners II, LLC, may be deemed to beneficially own the shares of common stock held by ACP II. Each of Messrs. Barandiaran and Raynor disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. The business address of ACP II is 60 Madison Avenue, Suite 701, New York, NY 10010.
- (8) Includes 5,088 shares of ANI series A stock, 925 shares of ANI series B preferred stock and 1,280 shares of ANI series C preferred stock held by Bannan Private Equity Fund Ltd. (Bannan). See also footnote (1) for shares issuable upon exercise of warrants. Bannan is wholly-owned by Mercury Holdings LLC (Mercury). Arthur F. Bell, Jr. is the managing member of Mercury. The business address of Bannan, Mercury and Mr. Bell is 201 International Circle, Suite 400, Hunt Valley, Maryland 21030.
- (9) Includes: (i) 339 shares of ANI common stock, 9,874 shares of ANI series B preferred stock and 2,644 shares of ANI series C preferred stock held by Productivity Fund, (ii) 13 shares of ANI common stock, 381 shares of ANI series B preferred stock and 104 shares of ANI series C preferred stock held by Advisors Fund; (iii) 3,319 shares of ANI common stock, 19,688 shares of ANI series B preferred stock and 5,272 shares of ANI series C preferred stock held by FA PE Fund; and (iv) 138 shares of ANI common stock, 820 shares of ANI series B preferred stock and 220 shares of ANI series C preferred stock held by GmbH (collectively, the First Analysis Funds). FAMC UV is the sole general partner of each of Productivity Fund and Advisors Fund. FAVOR is the managing member of FAMC IV and, in that capacity, exercises voting and dispositive control over the shares held by Productivity Fund and Advisors Fund. FAPEM IV is the general partner of FAPEF IV and the managing limited partner of GmbH and, in those capacities, exercises voting and dispositive control over the shares held by FAPEF IV and GmbH. FAVOR, in turn, is the managing member of FAPEM UV. First Analysis Corporation is the manager of FAVOR and, in that capacity, may be deemed to share voting and dispositive power with respect to the shares that may be deemed to be beneficially owned by FAVOR. The business address for the First Analysis Funds, FAVOR, FAPEM IV and First Analysis Corporation is c/o First Analysis, 1 S. Wacker Drive, Suite 3900, Chicago, Illinois 60606.
- (10) Includes 9,116 shares of ANI series B stock and 4,545 shares of ANI series C preferred stock held by Healthcare Value Master Fund, Ltd. (HVMF), a Cayman Islands limited company. The investment adviser to HVMF is Healthcare Value Capital, LLC (HVC). Healthcare Value Capital General Partner, LLC (HVC GP) is the manager of HVMF. The managing members of HVC GP are Joseph Riccardo and Scott Shevick. The business address of HVMF, HVC, HVC GP and Messrs. Riccardo and Shevick is 400 Madison Avenue, Suite 10A, New York, New York 10017.
- (11) Includes: (i) 966 shares of ANI common stock, 27,730 shares of ANI series A preferred stock, 2,348 shares of ANI series B preferred stock and 2,885 shares of ANI series C preferred stock held by Liberty Ventures II, L.P. (LBII) and (ii) 49 shares of ANI common stock, 624 shares of ANI series A preferred stock, 913 shares of ANI series B preferred stock and 152 shares of ANI series C preferred stock held by Liberty Advisors, Inc. (LA). See also footnote (1) for shares issuable upon exercise of warrants. Liberty Venture Partners II, LLC (LLC) is the general partner of LBII and Thomas Morse, Carl Kopfinger and Maria Hahn are the managing members of LLC. The directors and officers of LA are Thomas Morse and Maria Hahn. Thomas Morse is the principal shareholder of LA. The business address of Liberty, LLC, LA and their respective control persons is 2001 Market Street, Suite 3820, Philadelphia, Pennsylvania 19103.
- (12) Includes 12,477 shares of common stock, 67,598 shares of ANI series A preferred stock, 13,638 shares of ANI series B preferred stock and 11,364 shares of ANI series C preferred stock held by Meridian Venture Partners

II, L.P. (MVP II). See also footnote (1) for shares issuable upon exercise of warrants. MVP II GP, L.P. (GP) is the general partner of MVP II. Meridian Venture Partners II, Co. (MVP Corp.) is the general partner of GP. MVP Management Company (MVP Management) d/b/a MVP Capital Partners, is the management company for MVP II and also renders financial and business advisory services to several of the companies in which MVP II has invested. Robert E. Brown, Jr., a director of ANI, is the President, sole stockholder and sole director of MVP Corp., the sole stockholder, director and President of MVP Management, as well as a limited partner of GP and one of two principals of MVP II that are licensed by the Small Business Administration (SBA). SBA-licensed principals are charged with approving all investment-related decisions on behalf of small business investment companies licensed by the SBA, such as MVP II. Thomas T. Penn, a director of ANI, is a Vice President of MVP Corp., a Vice President and employee of MVP Management, a limited partner of GP and one of the two SBA-licensed principals of MVP II.

- (13) The amount beneficially owned by all current directors and executive officers as a group includes 11,951 shares of ANI common stock issuable upon the exercise of warrants. See notes above.

## PRINCIPAL STOCKHOLDERS OF COMBINED COMPANY

The following table sets forth information as of December 31, 2012 with respect to the beneficial ownership of each class of capital stock of the combined company upon completion of the merger for:

- each person known by BioSante and ANI that is expected to beneficially own more than five percent of any class of voting securities of the combined company upon completion of the merger;
- each director of the combined company;
- each named executive officer of the combined company; and
- all directors and named executive officers of the combined company as a group.

Percentage of beneficial ownership is calculated based on 24,422,240 shares of BioSante common stock outstanding and 65,211 shares of BioSante class C special stock outstanding and 2,615,001 shares of ANI capital stock outstanding as of December 31, 2012. The percent of common stock and class C special stock of the combined company is based on 52,337,228 shares of common stock and 65,211 shares of class C special stock of the combined company outstanding upon completion of the merger and assumes that the exchange ratio for the ANI series D preferred stock is 10.3502 shares of BioSante common stock for each share of ANI series D preferred stock and the exchange ratio for the ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock is zero shares of BioSante common stock for each share of ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock (without giving effect to the proposed reverse stock split of BioSante common stock and BioSante class C special stock described elsewhere in this joint proxy statement/prospectus but giving effect to the anticipated issuance of an estimated 321,737 shares of ANI series D preferred stock to ANI's executive officers and an additional ANI employee in connection with the transaction bonus arrangements as described elsewhere in this joint proxy statement/prospectus).

The number of shares beneficially owned by a person includes shares subject to options and warrants held by that person that are currently exercisable or that become exercisable within 60 days of December 31, 2012. Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options and warrants currently exercisable or that become exercisable within 60 days of December 31, 2012 are outstanding for the purpose of computing the percentage of capital stock of the combined company owned by such person or group. However, such unissued shares of capital stock are not deemed to be outstanding for calculating the percentage of capital stock owned by any other person. Except as otherwise indicated and subject to the voting agreements described under the section entitled "Voting and Other Ancillary Agreements," BioSante and ANI believe that the beneficial owners of capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. Unless otherwise indicated in the notes below, the address

for each of the stockholders in the table below is c/o ANIP Acquisition Company, 210 Main Street West, Baudette, Minnesota 56623.

Name and Address of Beneficial Owner	Shares Beneficially Owned					
	Common Stock		Class C Special Stock		Common Stock and Common Stock Equivalents	Percent of Total Voting Power
	Number	Percent	Number	Percent		
<b>Five Percent Stockholders</b>						
Meridian Venture Partners II, L.P.(1)	14,248,043	27.2%	—	—	14,248,043	27.2%
First Analysis Funds(2)	4,085,016	7.8%	—	—	4,085,016	7.8%
Argentum Capital Partners II, L.P.(3)	2,817,728	5.4%	—	—	2,817,728	5.4%
Louis W. Sullivan, M.D.	35,481	*	16,666	25.6%	52,147	*
Hans Michael Jebsen(4)	12,500	*	16,666	25.6%	29,166	*
Marcus Jebsen(5)	4,166	*	8,333	12.8%	12,499	*
Angela Ho(6)	1,219	*	16,666	25.6%	17,885	*
Ross Mangano(7)	418,397	*	—	—	418,397	*
Fred Holubow	34,372	*	—	—	34,372	*
<b>Directors and Named Executive Officers</b>						
Robert E. Brown, Jr.(8)	14,248,043	27.2%	—	—	14,248,043	27.2%
Arthur S. Przybyl	—	—	—	—	—	—
Tracy L. Marshbanks, Ph.D.(9)	4,085,016	7.8%	—	—	4,085,016	7.8%
Thomas A. Penn(10)	14,248,043	27.2%	—	—	14,248,043	27.2%
Robert Schrepfer(11)	—	—	—	—	—	—
Fred Holubow	34,372	*	—	—	34,372	*
Ross Mangano(7)	418,397	*	—	—	418,397	*
Charlotte C. Arnold	—	—	—	—	—	—
James G. Marken	—	—	—	—	—	—
Robert J. Jamnick	—	—	—	—	—	—
All directors and executive officers as a group (10 persons)	18,785,828	35.9%	—	—	18,785,828	35.8%

\* Represents beneficial ownership of less than one percent.

- (1) See footnote 12 in the section entitled "Principal Stockholders of ANI."
- (2) See footnote 9 in the section entitled "Principal Stockholders of ANI."
- (3) See footnote 7 in the section entitled "Principal Stockholders of ANI."
- (4) See footnote 7 in the section entitled "Principal Stockholders of BioSante."
- (5) See footnote 8 in the section entitled "Principal Stockholders of BioSante."
- (6) See footnote 9 in the section entitled "Principal Stockholders of BioSante."
- (7) See footnote 5 in the section entitled "Principal Stockholders of BioSante."
- (8) See footnote 4 in the section entitled "Principal Stockholders of ANI."
- (9) See footnote 5 in the section entitled "Principal Stockholders of ANI."
- (10) See footnote 4 in the section entitled "Principal Stockholders of ANI."
- (11) See footnote 6 in the section entitled "Principal Stockholders of ANI."

## DESCRIPTION OF BIOSANTE CAPITAL STOCK

### Authorized and Outstanding Capital Stock

BioSante currently is authorized to issue 200.0 million shares of common stock, \$0.0001 par value per share, 4,687,684 shares of BioSante class C special stock, \$0.0001 par value per share, and 10.0 million shares of undesignated preferred stock, \$0.0001 par value per share. BioSante is seeking stockholder approval pursuant to this joint proxy statement/prospectus to effect a reverse stock split of BioSante's issued and outstanding common stock and class C special stock, pursuant to which any whole number of outstanding shares between and including two and five would be combined and reclassified into one share of BioSante common stock or BioSante class C special stock, as applicable (with the exact reverse stock split ratio within such range to be determined by BioSante and ANI prior to completion of the merger).

As of December 31, 2012, BioSante had 24.4 million shares of BioSante common stock outstanding. As of December 31, 2012, BioSante had an aggregate of 1.1 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding stock options granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan and the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan and an additional 1.0 million shares of BioSante common stock reserved for issuance pursuant to future grants under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan. As of December 31, 2012, BioSante had an aggregate of 4.7 million shares of BioSante common stock reserved for issuance upon the exercise of outstanding warrants. As of December 31, 2012, BioSante had an aggregate of 370,871 shares of BioSante common stock reserved for issuance upon the conversion of its outstanding convertible senior notes.

As of December 31, 2012, BioSante had 65,211 shares of BioSante class C special stock outstanding. Each share of BioSante class C special stock entitles its holder to one vote per share. Each share of BioSante class C special stock is exchangeable, at the option of the holder, for one share of BioSante common stock, at an exchange price of \$15.00 per share, subject to adjustment upon certain capitalization events. Holders of BioSante class C special stock are not entitled to receive dividends. Holders of BioSante class C special stock are not entitled to participate in the distribution of BioSante's assets upon any liquidation, dissolution or winding-up of BioSante. The holders of BioSante class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

As of the date of this joint proxy statement/prospectus, BioSante does not have any shares of preferred stock outstanding.

### Common Stock

For all matters submitted to a vote of BioSante stockholders, each holder of BioSante common stock is entitled to one vote for each share registered in the holder's name on BioSante's books. BioSante common stock does not have cumulative voting rights. The holders of a majority of the shares of BioSante common stock and BioSante class C special stock entitled to vote in any election of directors, voting together as a single class, can elect all of the directors standing for election, if they so choose. Subject to limitations under Delaware law and preferences that may be applicable to any then outstanding preferred stock, holders of BioSante common stock are entitled to receive ratably those dividends, if any, as may be declared by the BioSante board of directors out of legally available funds. Upon the liquidation, dissolution or winding up of BioSante, the holders of BioSante common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of BioSante's debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. All shares of outstanding BioSante common stock are fully paid and nonassessable. Holders of BioSante common stock do not have preemptive or subscription rights, and



they have no right to convert their BioSante common stock into any other securities. There are no redemption or sinking fund provisions applicable to the BioSante common stock. The rights, preferences and privileges of the holders of BioSante common stock are subject to the rights of the holders of any series of preferred stock which BioSante may designate in the future. BioSante's certificate of incorporation and bylaws do not restrict the ability of a holder of BioSante common stock to transfer the holder's shares of BioSante common stock.

### **Class C Special Stock**

Each share of BioSante class C special stock entitles its holder to one vote per share. Each share of BioSante class C special stock is exchangeable, at the option of the holder, for one share of BioSante common stock, at an exchange price of \$15.00 per share, subject to adjustment upon certain capitalization events. Holders of BioSante class C special stock are not entitled to receive dividends. Holders of BioSante class C special stock are not entitled to participate in the distribution of BioSante's assets upon any liquidation, dissolution or winding-up of BioSante. There are six record holders of BioSante class C special stock and they have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

### **Preferred Stock**

The BioSante board of directors is authorized, without approval of BioSante stockholders subject to any limitations prescribed by law and imposed by the Listing Rules of The NASDAQ Global Market, to issue up to an aggregate of 10.0 million shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions granted to or imposed upon the preferred stock, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences. The rights of the holders of BioSante common stock and BioSante class C special stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. The BioSante board of directors could authorize the issuance of shares of preferred stock with terms and conditions more favorable than the BioSante common stock or BioSante class C special stock and with rights that could adversely affect the voting power or other rights of holders of the BioSante common stock or BioSante class C special stock. Prior to issuance of shares of each series of undesignated preferred stock, the BioSante board of directors is required by the Delaware General Corporate Law and BioSante's certificate of incorporation to adopt resolutions and file a Certificate of Designations with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series. Issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of delaying, deferring or preventing a change in control of BioSante. BioSante has no present plans to issue any shares of preferred stock.

### **Anti-Takeover Effects of Provisions of BioSante's Certificate of Incorporation and Bylaws and Delaware Law**

Some provisions of BioSante's certificate of incorporation and bylaws and Delaware law contain provisions that could make the following transactions more difficult: an acquisition of BioSante by means of a tender offer; an acquisition of BioSante by means of a proxy contest or otherwise; or removal of BioSante's incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that BioSante stockholders may otherwise consider to be in their best interest or in BioSante's best interests, including transactions that might result in a premium over the market price for BioSante's shares.

These provisions, summarized below, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions also are designed to encourage persons seeking to acquire

control of BioSante to first negotiate with the BioSante board of directors. The BioSante board of directors believes that the benefits of increased protection of its potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure BioSante outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

### ***Certificate of Incorporation and Bylaws***

The following provisions in BioSante's certificate of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control or change in BioSante's management, including transactions that the BioSante stockholders may otherwise consider to be in their best interest or in BioSante's best interests, including transactions that might result in a premium over the market price for BioSante's shares.

- ***Authorized But Unissued Capital Stock.*** BioSante has shares of BioSante common stock, BioSante class C special stock and undesignated preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the Listing Rules of The NASDAQ Global Market. BioSante may use these additional shares for a variety of corporate purposes, including for future public offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on its capital stock. The existence of unissued and unreserved capital stock may enable the BioSante board of directors to issue shares to persons friendly to current management that could render more difficult or discourage a third-party attempt to obtain control of BioSante by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of BioSante's management. In addition, the ability to authorize undesignated preferred stock makes it possible for the BioSante board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of BioSante. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of BioSante.
- ***Stockholder Meetings.*** BioSante's bylaws provide that a special meeting of stockholders may be called only by BioSante's chairman of the board, president and chief executive officer, or by the BioSante board of directors.
- ***Requirements for Advance Notification of Stockholder Nominations and Proposals.*** BioSante's bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the BioSante board of directors or a committee of the BioSante board of directors.
- ***No Cumulative Voting Rights.*** BioSante's certificate of incorporation and bylaws do not provide for cumulative voting rights. The holders of a majority of the shares of BioSante common stock and BioSante class C special stock entitled to vote in any election of directors, voting together as a single class, can elect all of the directors standing for election, if they so choose.

### ***Delaware Anti-Takeover Law***

As a Delaware corporation, BioSante is subject to Section 203 of the Delaware General Corporation Law. This law prohibits a publicly-held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85 percent of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10 percent or more of the corporation's assets involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by the corporation of any of its stock to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

### **Limitation of Liability and Indemnification**

BioSante's certificate of incorporation contains certain provisions permitted under the Delaware General Corporation Law relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, except in circumstances involving wrongful acts, such as the breach of a director's duty of loyalty or acts or omissions that involve intentional misconduct or a knowing violation of law.

In addition, BioSante's certificate of incorporation contains provisions to indemnify BioSante's directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

### **Listing of BioSante Common Stock**

BioSante common stock is listed on The NASDAQ Global Market under the symbol "BPAX." The combined company expects to have its shares of common stock listed on The NASDAQ Global Market or The NASDAQ Capital Market under the symbol "ANIP."

### **Transfer Agent and Registrar**

The transfer agent and registrar for BioSante common stock is Computershare Investor Services, LLC.

## COMPARISON OF RIGHTS OF HOLDERS OF BIOSANTE STOCK AND ANI STOCK

Both BioSante and ANI are incorporated under the laws of the State of Delaware. Any differences, therefore, in the rights of BioSante stockholders and ANI stockholders arise primarily from differences in their respective certificates of incorporation and bylaws. Upon completion of the merger, the certificate of incorporation and bylaws of the combined company will be identical in all respects to BioSante's pre-merger certificate of incorporation, as amended to reflect the amendments described in this joint proxy statement/prospectus, which is referred to as the amended BioSante charter, and BioSante's bylaws, which are referred to as the BioSante bylaws. Consequently, after the effective time of the merger, the rights of the former ANI stockholders will be determined by reference to the amended BioSante charter and the BioSante bylaws. The following table compares the material differences between the current rights of ANI stockholders under ANI's certificate of incorporation and bylaws, which are referred to as the ANI charter and ANI bylaws, respectively, and the current rights of BioSante stockholders under BioSante's current certificate of incorporation, which is referred to as the BioSante charter, and BioSante bylaws, as well as the rights that those stockholders will have as stockholders of the combined company under the amended BioSante charter and BioSante bylaws following completion of the merger.

BioSante has filed copies of the BioSante charter and the BioSante bylaws with the SEC and the proposed amendments to the BioSante charter are attached as annexes to this joint proxy statement/prospectus. In addition, copies of the BioSante charter, the amended BioSante charter, the BioSante bylaws, the ANI charter and the ANI bylaws will be sent to holders of BioSante common stock or ANI common stock upon request. See "Where You Can Find More Information." Because this summary does not provide a complete description of these documents, BioSante and ANI urge you to read each of their charters and bylaws as well as the amended BioSante charter in their entirety.

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### ANI STOCKHOLDER RIGHTS

### BIOSANTE STOCKHOLDER RIGHTS

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#### Corporate Governance

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*Before the merger.* The rights of ANI stockholders currently are governed by Delaware law and the ANI charter and the ANI bylaws.

*Before the merger.* The rights of BioSante stockholders currently are governed by Delaware law and the BioSante charter and the BioSante bylaws.

*After the merger.* Upon completion of the merger, the rights of ANI stockholders who become BioSante stockholders in the merger will be governed by Delaware law, the amended BioSante charter and the BioSante bylaws.

*After the merger.* Upon completion of the merger, the rights of BioSante stockholders will be governed by Delaware law, the amended BioSante charter and the BioSante bylaws.

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**Authorized Capital**

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The authorized capital stock of ANI is 3,700,000 shares of common stock, \$0.10 par value per share, and 108,494 shares of series A convertible preferred stock, \$0.10 par value per share, 118,915 shares of series B convertible preferred stock, \$0.10 par value per share, 37,956 shares of series C convertible preferred stock, \$0.10 par value per share, and 3,400,000 shares of series D preferred stock, \$0.10 par value per share.

The authorized capital stock of BioSante, including a description of the preferential rights of the undesignated preferred stock, is set forth under "Description of BioSante Capital Stock—Authorized and Outstanding Capital Stock."

The BioSante charter provides, and upon completion of the merger the amended BioSante charter will provide, that the rights of the holders of BioSante common stock and BioSante class C special stock are subject to the rights and preferences of the BioSante preferred stock as the same may be designated from time to time by the BioSante board of directors. See "Description of BioSante Capital Stock—Preferred Stock."

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**Dividends**

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Under Delaware law, except as set forth in the certificate of incorporation, a corporation is generally permitted to declare and pay dividends out of surplus (defined as the excess, if any, of net assets over capital) or, if no surplus exists, out of net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. However, the directors of a corporation may not pay any dividends out of net profits if the capital of the corporation has been reduced to an amount less than the aggregate amount of capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets.

Under Delaware law, except as set forth in the certificate of incorporation, a corporation is generally permitted to declare and pay dividends out of surplus (defined as the excess, if any, of net assets over capital) or, if no surplus exists, out of net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. However, the directors of a corporation may not pay any dividends out of net profits if the capital of the corporation has been reduced to an amount less than the aggregate amount of capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets.

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**ANI STOCKHOLDER RIGHTS**

The ANI charter provides for cumulative and accruing cash dividends to be paid as follows (i) to holders of ANI series D preferred stock at a rate of 10 percent of the stated per share value per annum in preference and priority to dividends paid to holders of other classes of ANI preferred stock or ANI common stock, (ii) to holders of ANI series C preferred stock at a rate of 12 percent of the stated per share value per annum in preference and priority to dividends paid to holders of ANI series B preferred stock, ANI series A preferred stock or common stock, (iii) to holders of ANI series B preferred stock at a rate of 10 percent of the stated per share value per annum in preference and priority to dividends paid to holders of ANI series A preferred stock or ANI common stock, and (iv) to holders of ANI series A preferred stock at a rate of 10 percent of the stated per share value per annum in preference and priority to dividends paid to holders of common stock. The holders of ANI series A preferred stock, ANI series B preferred stock and ANI series C preferred stock waived the right to any dividends accrued prior to January 28, 2011.

Subject to the preferential rights of the preferred stock, the holders of common stock are entitled to receive, if and when declared by the board of directors, dividends out of the assets of the company payable in either cash, other property or shares of capital stock, equally among the holders of common stock on a pro rata basis.

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**BIOSANTE STOCKHOLDER RIGHTS**

The BioSante bylaws provide the BioSante board of directors may declare that the holders of shares of BioSante capital stock are entitled to receive, out of the assets of BioSante which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock.

The BioSante charter provides, and the amended BioSante charter upon completion of the merger will provide, the holders of common stock shall be entitled to receive dividends if and when declared by the board of directors and that the holders of BioSante class C special stock shall not be entitled to receive any dividends.

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**Rights on Liquidation**

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The ANI charter provides upon any liquidation, dissolution, or winding up of ANI, unless waived by a majority of the issued and outstanding preferred stock, that (i) before any amounts are paid to the holders of any other class of preferred stock or common stock, the holders of ANI series D preferred stock are entitled to receive an amount per share equal to \$30.00 (subject to adjustment) plus all declared but unpaid dividends, (ii) before any amounts are paid to the holders of ANI series B preferred stock, ANI series A preferred stock or ANI common stock, the holders of ANI series C preferred stock are entitled to receive an amount per share equal to \$110.00 (subject to adjustment) plus all declared but unpaid dividends, (iii) before any amounts are paid to the holders of ANI series A preferred stock or ANI common stock, the holders of ANI series B preferred stock are entitled to receive an amount per share equal to \$110.00 (subject to adjustment) plus all declared but unpaid dividends, (iv) before any amounts are paid to the holders of common stock, the holders of ANI series A preferred stock are entitled to receive an amount per share equal to \$100.00 (subject to adjustment) plus all declared but unpaid dividends and (v) after payments have been made to all holders of preferred stock, the remaining assets of ANI will be distributed ratably to the holders of ANI common stock and ANI series D preferred stock. If ANI's assets are insufficient to make payment in full to any class of preferred stock as set forth above, such assets should be distributed ratably in proportion to the preferential amount such holder of a class of preferred stock is otherwise entitled to receive.

The BioSante charter provides that upon a voluntary or involuntary liquidation, dissolution or winding up of BioSante, holders of common stock are entitled to receive all assets of BioSante available for distribution subject to any preferential liquidation right on any then outstanding preferred stock. The BioSante charter also sets forth that the BioSante board of directors may designate preferred stock and in connection with such designation fix liquidation rights.

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**Conversion Rights**

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The ANI charter provides that each share of ANI preferred stock is convertible at the option of the holder into one share of ANI common stock, subject to adjustment for additional issuances or deemed issuances of ANI common stock. In addition, the ANI charter provides that each share of ANI preferred stock will be converted into ANI common stock at the then effective applicable conversion rate (i) upon the closing of a firmly underwritten public offering of ANI common stock by ANI which generates not less than \$50,000,000 of gross proceeds and imputes a valuation of ANI of not less than \$100,000,000, (ii) with respect to each series of ANI preferred stock, upon the vote of at least the applicable percentage of holders of the then outstanding shares of such series, which percentage is 60 percent for the ANI series A preferred stock, 50 percent for the ANI series B preferred stock, 55 percent for the ANI series C preferred stock and 65 percent for the ANI series D preferred stock or (iii) on the date that all shares of ANI series D preferred stock are mandatorily converted into ANI common stock.

The BioSante charter sets forth that the BioSante board of directors may designate preferred stock and in connection with such designation fix conversion rights.



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**Voting Rights**

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Subject to the exceptions described below, the ANI charter provides that the preferred stock and common stock vote as a single class on an as converted to common stock basis.

The ANI charter provides that, for as long as 1,000,000 shares of ANI series D preferred stock remain outstanding, the following corporate actions require separate approval of at least 65 percent of the then outstanding shares ANI series D preferred stock: (i) issuance of new securities of any kind, (ii) amendments to the ANI charter or ANI bylaws that adversely affect the rights or privileges of the ANI series D preferred stock, (iii) any increase or decrease in the number of shares of authorized ANI preferred stock, (iv) stock repurchases in excess of \$50,000, (v) declaration and/or payment of dividends, (vi) liquidation or dissolution, other than a change in control transaction, and (viii) a change in control transaction.

Any change in control transaction that is not approved by at least 65 percent of the ANI series D preferred stock must be approved by at least 50 percent of each of the ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock, each voting as a separate class for so long as the requisite number of ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock remain outstanding.

The BioSante common stock and BioSante class C special stock are the only outstanding classes of BioSante voting securities and will be the only outstanding classes of BioSante voting securities upon completion of the merger. Under Delaware law and the BioSante charter, and upon the completion of the merger, under the amended BioSante charter, each share of BioSante common stock and BioSante class C special stock will be entitled to one vote on all matters submitted to stockholders.

Generally, under Delaware law, the approval of any merger or consolidation or a sale of all or substantially all of a corporation's assets requires the affirmative vote of a majority of the total votes represented by the outstanding stock of the corporation entitled to vote on such matter.

Under Delaware law, the BioSante charter, and upon completion of the merger the amended BioSante charter, may be amended by the adoption of a resolution of the BioSante board of directors, followed by the vote of a majority of the outstanding voting power entitled to vote thereon and a majority of the outstanding stock of each class entitled to vote thereon as a separate class. The BioSante charter provides, and upon completion of the merger the amended BioSante charter will provide, that charter amendments may be made in accordance with the default positions of Delaware law.

The ANI charter provides that, for as long as 18,977.50 shares of ANI series C preferred stock remain outstanding, the holders of at least 55 percent of the then outstanding shares of ANI series C preferred stock must approve any amendment to the ANI charter or ANI bylaws that adversely affect the rights and privileges of the ANI series C preferred stock or any reclassification of the ANI common stock, ANI series A preferred stock or ANI series B preferred stock to be senior or equal to the ANI series C preferred stock. The ANI charter also provides the holders of ANI series C preferred stock the right to vote as a separate class on the following corporate actions, for so long as 18,977.50 shares of ANI series C preferred stock remain outstanding, if such actions were not approved by at least 65 percent of the then outstanding shares of ANI series D preferred stock: (i) the issuance of any new securities senior or equal to the ANI series C preferred stock, (ii) any increase or decrease in the number of shares of authorized ANI preferred stock, (iii) stock repurchases in excess of \$50,000, (iv) declaration and/or payment of dividends, and (v) liquidation or dissolution, other than a change in control transaction.

The ANI charter provides that the holders of at least 50 percent of the then outstanding shares of ANI series B preferred stock must approve any amendment to the ANI charter or ANI bylaws that adversely affect the rights and privileges of the ANI series B preferred stock or any reclassification of the common stock or ANI series A preferred stock to be senior or equal to the ANI series B preferred stock. The ANI charter also provides the holders of ANI series B preferred stock the right to vote as a separate class on the following corporate actions, for so long as 40,381.30 shares of ANI series B preferred stock remain outstanding, if such actions were not approved by at least 65 percent of the then outstanding shares of ANI series D preferred stock: (i) the issuance of any new securities senior or equal to the ANI series B preferred stock, (ii) stock repurchases in excess of \$50,000, (iii) declaration and/or payment of dividends, and (iv) liquidation or dissolution, other than a change in control transaction.

No ANI corporate action requires a separate class vote of the ANI common stock.

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**Number of Directors**

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The ANI bylaws provide that the number of directors will be fixed, from time to time, as determined by action of the ANI board of directors or stockholders. The ANI board of directors currently consists of five directors.

The BioSante bylaws provide that the number of directors will not be less than one, as determined by action of the BioSante board of directors or BioSante stockholders at an annual or special meeting. The BioSante board of directors currently consists of seven directors.

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**Classification of Board of Directors**

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The ANI bylaws provide for one class of directors, meaning each director stands for election on an annual basis.

The BioSante bylaws provide for one class of directors, meaning each director stands for election on an annual basis.

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**Removal of Directors**

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The ANI bylaws provide that a director may be removed from office with or without cause upon the affirmative vote of the holders of at least a majority of the total voting power of the then outstanding shares of ANI capital stock entitled to vote.

The BioSante bylaws provide that a director may be removed from office with or without cause upon the affirmative vote of the holders of at least a majority of the total voting power of the then outstanding shares of BioSante capital stock entitled to vote.

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**Vacancies on the Board of Directors**

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The ANI bylaws provide that vacancies occurring on the board of directors may be filled by the vote of a majority of the ANI stockholders. Any director chosen in accordance with the preceding sentence will hold office until his or her successor has been elected and qualified.

The BioSante bylaws provide that a vacancy occurring on the board of directors may be filled by the affirmative vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director. Any director chosen in accordance with the preceding sentence will hold office until the next election of directors or until such director's successor has been duly elected and qualified, or until such director's earlier resignation or removal.

The ANI stockholders' agreement provides that the ANI board shall consist of two directors designated by Meridian Venture Partners II, L.P., one director designated by First Analysis Corporation, one director designated by Healthcare Value Master Fund Ltd. and ANI's chief executive officer.

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**Board Quorum**

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The ANI bylaws provide that a majority of the entire ANI board of directors will constitute a quorum for the transaction of business, but if at any meeting of the ANI board of directors there is less than a quorum present, the majority of those present may adjourn the meeting from time to time, until a quorum is present.

The BioSante bylaws provide that a majority of the authorized number of directors will constitute a quorum for the transaction of business, but if at any meeting of the BioSante board of directors there is less than a quorum present, the majority of those present may adjourn the meeting from time to time, until a quorum is present.

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**Stockholder Quorum**

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The ANI bylaws provide that the presence in person or by proxy at a meeting of the holders of shares representing a majority of the voting power of the issued and outstanding stock entitled to vote thereat constitutes a quorum. In the absence of a quorum, the stockholders so present or represented by proxy may vote to adjourn the meeting from time to time until a quorum is present.

The BioSante bylaws provide that the presence in person or by proxy at a meeting of the holders of shares representing one-third of the capital stock issued and outstanding and entitled to vote thereat constitutes a quorum. In the absence of a quorum, the chairman of the board or the stockholders so present may adjourn the meeting from time to time until a quorum is present.

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**Stockholder Action by Written Consent**

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The ANI bylaws provide that any action required or permitted to be taken at a meeting of ANI stockholders may be taken without a meeting if a consent in writing, setting forth the action to be taken, is signed by the holders of outstanding stock having at least the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted.

The BioSante bylaws provide that any action required or permitted to be taken at a meeting of BioSante stockholders may be taken without a meeting, without prior notice and without a vote, if the holders of outstanding stock having at least the minimum number of votes that would be necessary to authorize or take such action at a meeting entitled to vote thereon were present and voted.

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**Special Meetings of Stockholders**

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Under Delaware law, a special meeting of ANI stockholders may be called by the ANI board of directors or by any other person authorized to do so in the ANI charter or bylaws and the written notice of the special meeting must set forth the purpose or purposes for which the meeting is called. The ANI bylaws provide that special meetings of ANI stockholders may be called by the ANI board of directors or chairman of the board of directors.

Under Delaware law, a special meeting of BioSante stockholders may be called by the BioSante board of directors or by any other person authorized to do so in the BioSante charter or bylaws and the written notice of the special meeting must set forth the purpose or purposes for which the meeting is called. The BioSante bylaws provide that special meetings of stockholders may be called by the chairman of the board, the president and chief executive officer, the chief financial officer, or the BioSante board of directors. The business to be transacted at a special meeting of BioSante stockholders must be limited to the purposes stated in the notice of meeting.

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**Stockholder Proposals**

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The ANI bylaws provide that the order of business at all meetings of the stockholders will be determined by the chairman of the meeting.

The BioSante bylaws provide that a BioSante stockholder wishing to bring business before the annual BioSante stockholders' meeting must provide timely written notice to BioSante's corporate secretary. To be timely, the notice must be delivered to or mailed and received by BioSante not less than 90 days nor more than 120 days before the one year anniversary of the date on which BioSante first mailed its proxy statement to BioSante stockholders in connection with the previous year's annual meeting. However, if the date of the annual meeting has changed by more than 30 days from the anniversary date of the prior year's meeting, notice by the BioSante stockholder to be timely must be received not later than the 10<sup>th</sup> day following the date on which the first public announcement of the date of the annual meeting was made.

A BioSante stockholder's notice to BioSante regarding the proposal of business to be brought before an annual meeting must contain certain required information as described in the BioSante bylaws, including, among other things:

- a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting;
- a description of any material interest of the BioSante stockholder in such business;
- the name and address of the BioSante stockholder making the proposal;
- the class and number of shares owned beneficially or of record by such BioSante stockholder; and
- a representation that the BioSante stockholder intends to appear in person or by proxy at the meeting to bring the proposed business before the meeting.

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**Stockholder Nominations**

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The ANI charter or bylaws do not provide guidelines for the submission of stockholder nominations and proposals by ANI stockholders.

The BioSante bylaws provide that BioSante stockholders wishing to nominate candidates for election to the BioSante board of directors at an annual meeting must give proper and timely written notice to BioSante's corporate secretary. To be timely, the notice must be delivered to or mailed and received by BioSante within the timeframe described under "Stockholder Proposals" above with respect to the submission of BioSante stockholder proposals.

A BioSante stockholder's notice to BioSante regarding director nominations must contain certain required information as described in the BioSante bylaws, including, among other things:

- the name, age, business address and residence address of the nominee;
- the principal occupation or employment of the nominee;
- the class and number of shares of capital stock of BioSante owned beneficially or of record by the nominee;
- any other information concerning the nominee that would be required under the rules of the SEC in a proxy statement soliciting proxies for the election of such nominee; and
- as to the stockholder giving the notice, the name and record address of the stockholder, the class and number of shares of BioSante which are owned beneficially or of record by such BioSante stockholder, a description of all arrangements between such stockholder and the nominee, and a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the person named in its notice.

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**Amendment of Bylaws**

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The ANI bylaws may be amended or repealed or new bylaws may be adopted by the ANI stockholders at any annual or special meeting or, if the certificate of incorporation so provides, by the board of directors. Any bylaw made by the board of directors may be amended or repealed by the stockholders at any annual or special meeting of stockholders.

The BioSante bylaws may be rescinded, altered, amended or repealed by BioSante board of directors, but BioSante stockholders may rescind, alter, amend or repeal any bylaws made by the board of directors, and may enact bylaws.

**Limitation of Liability**

The ANI charter provides that no director will be personally liable to the corporation or ANI stockholders for monetary damages for breaches of fiduciary duty as a director, except for a director's acts or omissions that:

- were in breach of the director's duty of loyalty to the corporation or ANI stockholders;
- were not in good faith or involved intentional misconduct or a knowing violation of the law;
- resulted in a violation of section 174 of the Delaware General Corporation Law for unlawful payment of a dividend or unlawful stock purchases or redemptions; or
- involved transactions from which the director derived an improper personal benefit.

The BioSante charter provides, and the amended BioSante charter upon completion of the merger will provide, that no director will be personally liable to the corporation or BioSante stockholders for monetary damages for breach of fiduciary duty as a director, except for a director's acts or omissions that:

- were in breach of the director's duty of loyalty to the corporation or BioSante stockholders;
- were not in good faith or involved intentional misconduct or a knowing violation of the law;
- resulted in a violation of section 174 of the Delaware General Corporation Law for unlawful payment of a dividend or unlawful stock purchases or redemptions; or
- involved transactions from which the director derived an improper personal benefit.

The BioSante charter further provides, and the amended BioSante charter upon completion of the merger will provide, that if Delaware law is amended to authorize corporations to further eliminate or limit the liability of a director, then the liability of a director will be eliminated or limited to the fullest extent permitted by Delaware law, as amended.

**Indemnification**

The ANI charter and bylaws collectively provide that the corporation will indemnify its directors, officers, employees or agents for any proceedings in which they are involved by reason of the fact that they are or were a director or officer of corporation to the fullest extent permitted by Delaware law.

In addition, the ANI bylaws provide that ANI may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation against any expense, liability or loss incurred by such person in any such capacity, whether or not the corporation would have the power to indemnify such person against such liability under the bylaws.

The BioSante charter provides, and the amended BioSante charter upon completion of the merger will provide, that the corporation will indemnify its directors and officers, or any person serving at the request of BioSante as a director, officer, employee or agent of any other company or enterprise for any proceedings in which they are involved by reason of the fact that they are or were a director or officer of corporation to the fullest extent permitted by Delaware law.

As described above under "The Merger Agreement—Certain Covenants," BioSante has agreed to provide, for a period of six years after the effective date of the merger, officers' and directors' liability insurance covering acts or omissions occurring before the effective time of the merger by each officer or director of BioSante or its subsidiaries covered by BioSante's current officers' and directors' liability insurance policy.

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**Certain Business Combinations / Anti-takeover Provisions**

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Under Delaware law, a privately held corporation is not subject to section 203 of the DGCL, which generally protects publicly held Delaware corporations from unfair transactions and tactics by persons who acquire large blocks of stock without prior board approval, unless its certificate of incorporation otherwise provides. ANI has not made this election and is therefore not subject to the restrictions of section 203 of the DGCL.

Under Delaware law, a corporation can elect not to be governed by section 203 of the DGCL, which generally protects publicly held Delaware corporations from unfair transactions and tactics by persons who acquire large blocks of stock without prior board approval. BioSante has not made this election and is therefore subject to the restrictions of section 203 of the DGCL.

In general, section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested" stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination or the transaction by which the person became an interested stockholder is approved in a prescribed manner. A "business combination" includes certain mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to exceptions, an "interested" stockholder is a person who, alone or together with his affiliates and associates, owns 15 percent or more of the corporation's voting stock. These provisions could have the effect of delaying, deferring or preventing a change in control of BioSante or reducing the price that certain investors might be willing to pay in the future for BioSante common stock.



## LEGAL MATTERS

The validity of the shares of BioSante common stock offered by this joint proxy statement/prospectus has been passed upon for BioSante by Oppenheimer Wolff & Donnelly LLP. The material U.S. federal income tax consequences of the merger have been passed upon for BioSante by Oppenheimer Wolff & Donnelly LLP and for ANI by SNR Denton US LLP.

## EXPERTS

The financial statements of BioSante Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and for each of the three years in the period ended December 31, 2011, included in the joint proxy statement/prospectus, which is part of this registration statement, and the effectiveness of BioSante Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports appearing herein. Such financial statements have been so included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

The financial statements of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. at December 31, 2011 and 2010, and for each of the two years in the period ended December 31, 2011 included in this registration statement of BioSante and the related joint proxy statement/prospectus of BioSante and ANI have been audited by Stout, Causey & Horning, P.A., independent registered public accounting firm, as set forth in their report appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## FUTURE BIOSANTE STOCKHOLDER PROPOSALS AND DIRECTOR NOMINATIONS

### BioSante Stockholder Proposals

Stockholder proposals intended to be presented in BioSante's proxy materials relating to its next annual meeting of stockholders must have been received by BioSante on or before December 12, 2012, unless the date of the meeting is delayed by more than 30 calendar days, and must satisfy the requirements of the proxy rules promulgated by the SEC.

Any other stockholder proposals to be presented at BioSante's next annual meeting of stockholders must be given in writing to BioSante's Corporate Secretary and received at BioSante's principal executive offices not later than January 10, 2013 nor earlier than December 11, 2012. The proposal must contain specific information required by BioSante's bylaws, a copy of which may be obtained by writing to BioSante's Corporate Secretary or accessing the SEC's EDGAR filing database at [www.sec.gov](http://www.sec.gov). If a proposal is not timely and properly made in accordance with the procedures set forth in BioSante's bylaws, it will be defective and may not be brought before the meeting. If the proposal nonetheless is brought before the meeting and the Chair of the meeting does not exercise the power and duty to declare the proposal defective, the persons named in the proxy may use their discretionary voting with respect to the proposal.

### BioSante Director Nominations

In accordance with procedures set forth in BioSante's bylaws, BioSante stockholders may propose nominees for election to the BioSante board of directors only after providing timely written notice to BioSante's Corporate Secretary. To be timely, a BioSante stockholder's notice to BioSante's Corporate Secretary must have been delivered to or mailed and received at BioSante's principal executive offices on or before January 7, 2013 but not earlier than December 8, 2012; provided, however, that in the event that the annual meeting of stockholders is called for a date that is not within 30 days before or after the anniversary date of the immediately preceding annual meeting of stockholders, notice by the BioSante stockholder in order to be timely must be so received not later than the close of business on

the 10th day following the day on which such notice of the date of the annual meeting of stockholders was mailed or such public disclosure of the date of the annual meeting of stockholders was made, whichever first occurs.

The notice must set forth, among other things:

- the nominee's name, age, business address and residence address;
- the nominee's principal occupation or employment;
- the class and number of shares of BioSante capital stock which are beneficially owned by the nominee; and
- any other information concerning the nominee required under the rules of the SEC in a proxy statement soliciting proxies for the election of directors.

Submissions must be made by mail, courier or personal delivery. E-mailed submissions will not be considered. The Nominating and Corporate Governance Committee will consider only those stockholder recommendations whose submissions comply with these procedural requirements. The Nominating and Corporate Governance Committee will evaluate candidates recommended by stockholders in the same manner as those recommended by others.

#### **WHERE YOU CAN FIND MORE INFORMATION**

BioSante is a public company and files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document BioSante files at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. BioSante's SEC filings are also available to the public at the SEC's web site at <http://www.sec.gov>.

BioSante's common stock is listed on The NASDAQ Global Market. Reports and other information concerning BioSante also may be inspected at the offices of the NASDAQ OMX Group, Inc., 9600 Blackwell Road, Rockville, MD 20850 or on the NASDAQ OMX Group, Inc. website at <http://www.nasdaq.com>.

BioSante also files annual audited and interim unaudited financial statements, proxy statements and other information with the Ontario, Alberta and British Columbia Securities Commissions. Copies of these documents that are filed through the System for Electronic Document Analysis and Retrieval "SEDAR" of the Canadian Securities Administrators are available at its web site <http://www.sedar.com>.

In addition, BioSante maintains a website that contains information, including copies of reports, proxy statements and other information it files with the SEC. The address of BioSante's website is [www.biosantepharma.com](http://www.biosantepharma.com). Information contained on BioSante's website or that can be accessed through BioSante's website does not constitute a part of this joint prospectus/prospectus. BioSante has included its website addresses only as inactive textual references and does not intend it to be an active link to its website.

BioSante has filed a registration statement on Form S-4 with the SEC for the common stock offered under this joint proxy statement/prospectus. This joint proxy statement/prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information that is not contained in this joint proxy statement/prospectus. Whenever BioSante makes reference in this joint proxy statement/prospectus to

any of its contracts, agreements or other documents, you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. You may:

- inspect a copy of the Form S-4 registration statement, including the exhibits and schedules, without charge at the public reference room;
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC; or
- obtain a copy from the SEC website.

**You should rely only on the information contained in this joint proxy statement/prospectus to vote your shares at the special meetings. Neither BioSante nor ANI has authorized anyone to provide you with information that differs from that contained in this joint proxy statement/prospectus. This joint proxy statement/prospectus is dated January , 2013. You should not assume that the information contained in this joint proxy statement/prospectus is accurate as of any date other than that date, and neither the mailing of this joint proxy statement/prospectus to stockholders nor the issuance of shares of BioSante common stock in the merger shall create any implication to the contrary.**

**INDEX TO BIOSANTE'S FINANCIAL STATEMENTS**

BIOSANTE FINANCIAL STATEMENTS

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BIOSANTE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

<a href="#">Condensed Balance Sheet as of September 30, 2012</a>	<a href="#">F-32</a>
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
BioSante Pharmaceuticals, Inc.  
Lincolnshire, Illinois

We have audited the internal control over financial reporting of BioSante Pharmaceuticals, Inc. (the "Company") as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2011 of the Company and our report dated March 13, 2012 (December 11, 2012 as to the effects of the reverse stock split described in Note 2) expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Chicago, Illinois  
March 13, 2012

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
BioSante Pharmaceuticals, Inc.  
Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (the "Company") as of December 31, 2011 and 2010, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of BioSante Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 13, 2012 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Chicago, Illinois  
March 13, 2012 (December 11, 2012 as to the effects of the reverse stock split described in Note 2)

## BIOSANTE PHARMACEUTICALS, INC.

## Balance Sheets

December 31, 2011 and 2010

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 57,225,234	\$ 38,155,251
Prepaid expenses and other assets	801,147	2,469,879
	<u>58,026,381</u>	<u>40,625,130</u>
PROPERTY AND EQUIPMENT, NET	861,364	635,776
<b>OTHER ASSETS</b>		
Investments	3,405,807	3,405,807
Deposits	86,203	99,937
	<u>\$ 62,379,755</u>	<u>\$ 44,766,650</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 3,150,677	\$ 4,864,217
Accrued compensation	1,597,329	526,022
Other accrued expenses	2,479,697	1,681,956
Current portion of Convertible Senior Notes	—	1,111,132
	<u>7,227,703</u>	<u>8,183,327</u>
Long-term Convertible Senior Notes	17,336,760	17,436,201
<b>TOTAL LIABILITIES</b>	<u>24,564,463</u>	<u>25,619,528</u>
<b>STOCKHOLDERS' EQUITY</b>		
Capital stock		
Issued and outstanding		
2011—65,214; 2010—65,214 Class C special stock	391	391
2011—18,269,754; 2010—13,565,188 Common stock	224,387,346	154,110,672
	<u>224,387,737</u>	<u>154,111,063</u>
Accumulated deficit	(217,239,148)	(165,630,644)
	<u>7,148,589</u>	<u>(11,519,581)</u>
	<u>\$ 31,713,052</u>	<u>\$ 14,099,947</u>

See accompanying notes to the financial statements.

## BIOSANTE PHARMACEUTICALS, INC.

## Statements of Operations

Years ended December 31, 2011, 2010 and 2009

	Year Ended December 31,		
	2011	2010	2009
<b>REVENUE</b>			
Licensing revenue	\$ 100,000	\$ 115,807	\$ —
Grant revenue	—	51,870	116,389
Royalty revenue	335,160	2,306,560	1,141,665
	<u>435,160</u>	<u>2,474,237</u>	<u>1,258,054</u>
<b>EXPENSES</b>			
Research and development	44,182,260	39,705,502	13,680,573
General and administration	6,981,490	5,940,360	5,373,945
Acquired in-process research and development	—	—	9,000,000
Excess consideration paid over fair value	—	—	20,192,194
Licensing expense	50,000	268,750	299,616
Depreciation and amortization	148,240	167,986	137,280
	<u>51,361,990</u>	<u>46,082,598</u>	<u>48,683,608</u>
<b>OTHER</b>			
Convertible note fair value adjustment	(23,427)	(1,870,916)	33,163
Investment impairment charge	—	(286,000)	—
Interest expense	(681,573)	(688,083)	(147,025)
Other income	15,000	244,479	—
Interest income	8,326	12,665	11,648
<b>NET LOSS</b>	<u>\$ (51,608,504)</u>	<u>\$ (46,196,216)</u>	<u>\$ (47,527,768)</u>
Loss per common share:			
Basic	\$ (3.15)	\$ (4.21)	\$ (8.40)
Diluted	\$ (3.15)	\$ (4.21)	\$ (8.40)
Weighted average number of common and common equivalent shares outstanding:			
Basic	16,397,618	10,985,291	5,658,608
Diluted	<u>16,397,618</u>	<u>10,985,291</u>	<u>5,658,608</u>

See accompanying notes to the financial statements.



**BIOSANTE PHARMACEUTICALS, INC.**

**Statements of Stockholders' Equity**

**Years ended December 31, 2011, 2010 and 2009**

	Class C Special Shares		Common Stock		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount		
<b>Balance, January 1, 2009</b>	<b>65,214</b>	<b>\$ 391</b>	<b>4,507,127</b>	<b>\$ 85,732,688</b>	<b>\$ (71,906,660)</b>	<b>\$ 13,826,419</b>
Issuance of common shares						
Stock option expense	—	—	—	1,254,503	—	1,254,503
Stock warrant expense	—	—	—	64,103	—	64,103
Registered direct offering of common shares and warrants, net	—	—	1,000,000	11,352,751	—	11,352,751
Issuance of common shares pursuant to Cell Genesys, Inc. transaction	—	—	3,369,967	6,133,340	—	6,133,340
Credit equity financing facility	—	—	—	60,343	—	60,343
Net loss	—	—	—	—	(47,527,768)	(47,527,768)
<b>Balance, December 31, 2009</b>	<b>65,214</b>	<b>\$ 391</b>	<b>8,877,094</b>	<b>\$ 104,597,728</b>	<b>\$ (119,434,428)</b>	<b>\$ (14,836,309)</b>
Issuance of common shares						
Stock option exercise	—	—	222	2,014	—	2,014
Stock option expense	—	—	—	992,757	—	992,757
Stock warrant expense	—	—	—	65,529	—	65,529
Registered direct offerings of common shares and warrants, net	—	—	4,687,871	48,452,644	—	48,452,644
June 1, 2012 Fractional Share Adjustment	—	—	1	—	—	—
Net loss	—	—	—	—	(46,196,216)	(46,196,216)
<b>Balance, December 31, 2010</b>	<b>65,214</b>	<b>\$ 391</b>	<b>13,565,188</b>	<b>\$ 154,110,672</b>	<b>\$ (165,630,644)</b>	<b>\$ (11,519,581)</b>
Issuance of common shares						
Stock option exercise	—	—	3,194	32,442	—	32,442
Warrant exercises—various	—	—	1,458	24,062	—	24,062
Stock option expense	—	—	—	1,177,683	—	1,177,683
Stock warrant expense	—	—	—	204,980	—	204,980
Underwritten offering of common shares, net	—	—	2,666,666	44,961,137	—	44,961,137
Registered direct offering of common shares and warrants, net	—	—	2,033,247	23,876,370	—	23,876,370
June 1, 2012 Fractional Share Adjustment	—	—	1	—	—	—
Net loss	—	—	—	—	(51,608,504)	(51,608,504)
<b>Balance, December 31, 2011</b>	<b>65,214</b>	<b>\$ 391</b>	<b>18,269,754</b>	<b>\$ 224,387,346</b>	<b>\$ (217,239,148)</b>	<b>\$ 7,148,589</b>

See accompanying notes to the financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**
**Statements of Cash Flows**
**Years ended December 31, 2011, 2010 and 2009**

	Year Ended December 31,		
	2011	2010	2009
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>			
Net loss	\$ (51,608,504)	\$ (46,196,216)	\$ (47,527,768)
Adjustments to reconcile net loss to net cash (used in) operating activities			
Acquired in-process research and development	—	—	9,000,000
Excess consideration paid over fair value	—	—	20,192,194
Depreciation and amortization	148,240	167,986	137,280
Employee and director stock-based compensation	1,177,683	992,757	1,254,503
Stock warrant expense—noncash	204,980	65,529	64,103
Loss on disposal of equipment	367,502	4,583	—
Investment impairment charge	—	286,000	—
Other non-cash items	—	(65,807)	60,739
Convertible note fair value adjustment	23,427	1,870,916	(33,163)
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	1,682,466	(365,332)	(30,263)
Accounts payable and accrued liabilities	134,103	3,142,078	(1,548,535)
<b>Net cash used in operating activities</b>	<b>(47,870,103)</b>	<b>(40,097,506)</b>	<b>(18,430,910)</b>
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>			
Redemption of short term investments	—	—	3,026,334
Proceeds from sale of fixed assets	—	3,075	—
Purchase of fixed assets	(719,925)	(63,441)	(165,724)
<b>Net cash (used in) provided by investing activities</b>	<b>(719,925)</b>	<b>(60,366)</b>	<b>2,860,610</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>			
Cash paid for transaction related costs	—	—	(2,431,252)
Cash received in transaction	—	—	24,746,346
Cash paid for convertible note repayment	(1,234,000)	—	—
Proceeds from common stock option exercises	32,442	2,014	—
Proceeds from common stock warrant exercises	24,062	—	—
Proceeds from issuance of common stock by underwritten offering	44,961,137	—	—
Proceeds from issuance of common stock by registered direct offering	23,876,370	48,452,644	11,352,751
<b>Net cash provided by financing activities</b>	<b>67,660,011</b>	<b>48,454,658</b>	<b>33,667,845</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>19,069,983</b>	<b>8,296,786</b>	<b>18,097,545</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>38,155,251</b>	<b>29,858,465</b>	<b>11,760,920</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 57,225,234</b>	<b>\$ 38,155,251</b>	<b>\$ 29,858,465</b>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION</b>			
Interest paid, including acquired accrued interest	\$ 688,000	\$ 688,000	\$ 248,388
<b>Noncash Investing and Financing Activities:</b>			
Investment—non-cash	\$ —	\$ 65,807	\$ —
Liabilities acquired through Cell Genesys transaction	\$ —	\$ —	\$ 18,487,298
Shares issued for Cell Genesys transaction	\$ —	\$ —	\$ 36,800,043
Investment aquired through Cell Genesys transaction	\$ —	\$ —	\$ 3,486,000
Other assets acquired in Cell Genesys transaction	\$ —	\$ —	\$ 293,658
Purchase of fixed assets on account, non-cash investing activity	\$ 21,405	\$ —	\$ —

See accompanying notes to the financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2011**

**1. DESCRIPTION OF BUSINESS**

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The Company's products, either approved or in human clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III clinical development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva); (3) GVAX cancer vaccines, a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and are currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers; (4) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (5) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals), our licensee.

The Company's lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. The Company continues to analyze the data from the two pivotal LibiGel Phase III efficacy trials first reported on December 14, 2011. Initial analysis of the efficacy data from these trials shows that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD. However, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel's results were not shown to be statistically different from placebo. The LibiGel Phase III safety study, which completed enrollment in June 2011, continues and will continue during further analysis of the LibiGel efficacy data and until a final strategic decision has been made. It is the Company's objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study.

The Company's corporate strategy always has included product development of high value medically-needed pharmaceutical products. In light of recently announced top-line results from the Company's two pivotal LibiGel Phase III efficacy trials, the Company is assessing its corporate strategy. The Company is determining LibiGel's path forward and potential alternative strategies to utilize the continuing LibiGel Phase III cardiovascular events and breast cancer safety study. The Company also has expanded its efforts to explore new product development projects through in-licensing and mergers and acquisitions. In addition, a full review of the Company's GVAX cancer vaccine portfolio is underway.

On January 31, 2012, the Company received a notice from the Listing Qualifications Department of The NASDAQ Stock Market indicating that, for the last 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum \$1.00 per share required for continued inclusion on The NASDAQ Global Market under NASDAQ Listing Rule 5450(a)(1). The notification letter stated that pursuant to NASDAQ Listing Rule 5810(c)(3)(A), the Company will be afforded 180 calendar days, or until July 30, 2012, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company's common stock must maintain a

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**1. DESCRIPTION OF BUSINESS (Continued)**

minimum bid closing price of at least \$1.00 per share for a minimum of 10 consecutive business days. If the Company does not regain compliance by July 30, 2012, the Company may transfer its common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if the Company meets the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, the Company also would need to provide NASDAQ written notice of its intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not indicate its intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for the Company to cure the deficiency, the Company will not be eligible for the second 180-day grace period and its common stock will be subject to delisting, which delisting determination the Company may appeal to a hearings panel at that time.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of Presentation*

These financial statements are expressed in U.S. dollars. The Company is organized into one operating and one reporting segment.

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (generally accepted accounting principles). The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The Company does not have items of other comprehensive income for years ended December 31, 2011, 2010 or 2009; and therefore, has not presented comprehensive income.

On June 1, 2012, the Company effected a one-for-six reverse split of its outstanding common stock and class C special stock. All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

On October 14, 2009, the Company acquired 100 percent of the common stock of Cell Genesys, Inc. (Cell Genesys) in a direct merger transaction, with the Company being the surviving corporation. The primary reason the Company merged with Cell Genesys was the Company's need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for the Company to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been the Company's primary method for raising additional financing. Effective October 14, 2009, the balance sheet and net loss of the Company reflect the purchase price allocation and charges resulting from the purchase price allocation related to the merger, which included adjustments to carrying values of the acquired net assets based on their estimated fair values as of that date.

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Reclassifications*

Certain amounts in the 2010 and 2009 financial statements have been reclassified to conform to their presentation in the 2011 financial statements. Specifically, in the statement of cash flows, the changes related to Accounts receivable in the amounts of \$64,645 and \$285,838 for the years ended December 31, 2010 and 2009, respectively, have been combined into the Prepaid expenses and other assets line item within the net cash used in operating activities section.

*Cash and Cash Equivalents*

The Company generally considers all instruments with original maturities of three months or less to be cash equivalents. Interest income on invested cash balances is recognized on the accrual basis as earned.

As of December 31, 2011, all of the Company's cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account, a U.S. Treasury money market fund or a certificate of deposit. As of December 31, 2010, all of the Company's cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account in order to ensure maximum safety of principal.

*Fair Value of Financial Instruments*

The carrying value of certain of the Company's financial instruments, including cash equivalents, accounts receivable and accounts payable, approximate fair value due to their short maturities. Other information about the Company's assets and liabilities recorded at fair value is included in Note 14, "Fair Value Measurements."

*Property and Equipment*

Property and equipment that currently is being used in the Company's operations is stated at cost less accumulated depreciation and amortization. Depreciation is computed primarily on a straight line basis over the estimated useful lives of the respective assets, typically five and seven years for software and computer equipment and 10 years for non-computer equipment.

*Long-Lived Assets*

Long-lived assets are reviewed for possible impairment whenever events indicate that the carrying amount of such assets may not be recoverable. If such a review indicates an impairment, the carrying amount of such assets is reduced to estimated recoverable value.

*Convertible Senior Notes*

The Company assumed two series of 3.125% convertible senior note obligations with an aggregate principal balance of \$22,016,000, which contain certain redemption, repurchase and conversion adjustment features as a result of its transaction with Cell Genesys. The Company made an irrevocable election to account for these convertible senior notes at fair value commencing from the date of the merger, resulting in recognition of a single liability for the convertible senior notes which are reported

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

at fair value at each reporting date. Subsequent changes in the carrying value of the convertible senior notes are reflected in fair value adjustment in the accompanying statements of operations.

*Research and Development*

Research and development costs are charged to expense as incurred. Direct government grants are recorded as an offset to the related research and development costs when the Company has complied with the conditions attached to the grant and there is reasonable assurance that the funds will be received.

*Legal Costs*

For ongoing matters, legal costs are charged to expense as incurred.

*Basic and Diluted Net Loss Per Share*

The basic and diluted net loss per share is computed based on the weighted average number of the shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic loss per share is computed by dividing loss available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The computation of diluted loss per share does not include the Company's stock options, warrants or convertible debt as such securities have an antidilutive effect on loss per share.

*Stock-Based Compensation*

The Company recognizes stock-based compensation expense granted to employees generally on a straight-line basis over the estimated service period of the award, or when certain performance-based vesting provisions occur, for awards that contain these features. The Company also has granted options to non-employees in exchange for services. Expense related to such grants is recognized within the Company's statements of operations in accordance with the nature of the service received by the Company.

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue and are re-measured until the counterparty's performance under the arrangement is complete.

*Revenue Recognition*

The Company has entered into various licensing agreements that have generated license revenue or other upfront fees and which also may involve subsequent milestone payments earned upon completion of development milestones by the Company or upon the occurrence of certain regulatory actions, such as the filing of a regulatory application or the receipt of a regulatory approval. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

license agreement. Non-refundable license fees that meet these criteria and are due to the Company upon execution of an agreement are recognized as revenue immediately.

Milestones, in the form of additional license fees, typically represent non-refundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified clinical development activities and/or regulatory submissions and/or approvals, or as sales-based milestone payments. Revenues from milestone payments that meet the criteria in the preceding paragraph are recognized when the milestone is achieved.

Additionally, royalty revenue based upon sales of products under license is recorded when such royalties are earned and are deemed collectible, which is generally in the quarter when the related products are sold.

*Income Taxes*

Deferred tax assets or liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates. A valuation allowance is provided against deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is not more likely than not. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2011 and 2010.

*Investments*

The investments balance of \$3,405,807 as of December 31, 2011 and 2010 consists of the Company's investments that are recorded using the cost method, and substantially represents the Company's investment in Ceregene, Inc., a privately held biotechnology company (Ceregene). As a result of the Company's merger with Cell Genesys, the Company acquired a minority investment in Ceregene. The Company has recorded its investment using the cost method, as no active market exists for this investment, and the Company does not possess significant influence over operating and financial policies of Ceregene, although the Company by virtue of its stock ownership of Ceregene has the right to designate one member on the Ceregene board of directors. During 2010, the Company recorded a \$286,000 impairment on this investment. Such impairment was based on a third-party investment in Ceregene in 2010.

The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest the investment may not be recoverable. The fair value of the cost method investments are not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investments and it is not practicable to estimate the fair value of the investments.

*Recent Accounting Pronouncements*

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-04, "*Amendments to Achieve Common Fair Value Measurement and Disclosure*"

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS).*" This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. The Company will adopt this guidance at the beginning of its first quarter of 2012. Adoption of this guidance is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

**3. LIQUIDITY AND CAPITAL RESOURCES**

Substantially all of the Company's revenue to date has been derived from upfront, milestone and royalty payments earned on licensing transactions and from subcontracts. The Company's business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. The Company has not introduced commercially any products. If and when the Company's products for which it has not entered into marketing relationships receive FDA approval, the Company may begin to incur other expenses, including sales and marketing related expenses if it chooses to market the products itself.

During 2011, the Company raised approximately \$68.9 million in net proceeds, after deducting placement agent fees, underwriters' discounts, commissions and other offering expenses, through the sale of common stock in an underwritten public offering and common stock and warrants in a registered direct offering, as more fully described in Note 9, "Stockholders' Equity."

As of December 31, 2011, the Company had \$57.2 million of cash and cash equivalents. Absent the receipt of any additional licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as the Company continues to use cash to fund its operations, including in particular its LibiGel Phase III safety study if the Company decides to continue such study. As of March 12, 2012, the Company has \$11.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 outstanding. In February 2012, the Company issued an aggregate of approximately 1.9 million shares of its common stock to one of the holders of the Company's 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of \$9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest. Assuming the Company continues its LibiGel Phase III safety study, the Company expects its cash and cash equivalents as of December 31, 2011 to meet its liquidity requirements through mid 2013. If the Company terminates its LibiGel Phase III safety study and assuming that the Company does so during the second quarter of 2012 and assuming no other corporate product development and activities, the Company expects its cash and cash equivalents to meet its liquidity requirements through late 2014. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

The Company's future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of the Company's preclinical and clinical development programs, including in particular if the Company decides to continue its LibiGel Phase III safety study;



**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**3. LIQUIDITY AND CAPITAL RESOURCES (Continued)**

- whether the Company in-licenses additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to the Company's products;
- the Company's ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licensings;
- the Company's ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments that the Company may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of the Company's products;
- the outstanding principal amount of the Company's 3.125% convertible senior notes due May 1, 2013 that are scheduled to mature and become due and payable on May 1, 2013 and the Company's ability to avoid a "fundamental change" or an "event of default" under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- the Company's operating expenses;
- the success, progress, timing and costs of the Company's business development efforts to implement business collaborations, licenses and other business combinations or transactions, and the Company's efforts to evaluate various strategic alternatives available with respect to its products and the Company; and
- the resolution of the Company's pending purported class action litigation.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing arrangements. If the Company raises additional funds by issuing equity securities, the Company's stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company's operations or the Company's ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under the Company's existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. In addition, from time to time, the Company may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**3. LIQUIDITY AND CAPITAL RESOURCES (Continued)**

equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company's available cash and cash equivalents, the Company's liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company's stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company's existing stockholders and/or decrease the Company's cash balance. A significant decrease in the Company's cash balance may impair the Company's ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

The announcement of the results of the Company's LibiGel Phase III efficacy trials has significantly depressed the trading price of the Company's common stock and if the Company terminates its LibiGel Phase III safety study, the trading price of the Company's common stock could be depressed further and affect adversely the Company's ability to raise additional capital. The decrease in the trading price of the Company's common stock has resulted in the bid price for the Company's common stock failing to meet the minimum \$1.00 per share required for continued inclusion on The NASDAQ Global Market. The Company has until July 30, 2012 to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company's common stock must maintain a minimum bid closing price of at least \$1.00 per share for a minimum of 10 consecutive business days. If the Company does not regain compliance by July 30, 2012, the Company may transfer its common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if the Company meets the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, the Company also would need to provide NASDAQ written notice of the Company's intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not indicate its intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for the Company to cure the deficiency, the Company will not be eligible for the second 180-day grace period and its common stock will be subject to delisting, which delisting determination the Company may appeal to a hearings panel at that time. A delisting of the Company's common stock from NASDAQ or even the transfer of the Company's common stock listing to The NASDAQ Capital Market could result in further decreases in the trading price of the Company's common stock and, among other things, could harm the Company's ability to raise financing.

In addition, the announcement of the results of the Company's LibiGel Phase III efficacy trials has resulted in pending purported class action litigation of which the Company, along with its President and Chief Executive Officer, are defendants, which litigation is described in more detail in Note 13, "Commitments and Contingencies". While the Company believes the actions are without merit and intends to defend the actions vigorously, such litigation could divert management's attention, harm the Company's business and/or reputation and result in significant liabilities, as well as harm the Company's ability to raise financing.

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****3. LIQUIDITY AND CAPITAL RESOURCES (Continued)**

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the future value of the Company, the Company loses the NASDAQ listing of its common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to cut its operating costs further or the Company may be forced to explore other strategic alternatives, such as selling or merging the Company or winding down its operations and liquidating the Company. In such case, the Company's stockholders could lose some or all of their investment.

**4. ACQUISITION OF NET ASSETS OF CELL GENESYS**

On October 14, 2009, the Company acquired 100 percent of the common stock of Cell Genesys in a direct merger transaction. The merger was accounted as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys were recorded by the Company as of the completion of the merger based on their estimated fair values. As Cell Genesys had ceased substantially its operations prior to the date of the transaction, the merger was not considered to be a business combination, and the allocation of the purchase price did not result in recognition of goodwill. The total purchase price is allocated to the acquired assets and assumed liabilities of Cell Genesys based on their estimated relative fair values as of the merger closing date. The table below displays the purchase price of the merger.

Fair value of BioSante common stock issued (3,369,967 shares)	\$ 36,800,043
Transaction costs of BioSante	2,431,252
<b>Total purchase price</b>	<b>\$ 39,231,295</b>

The total purchase price was allocated as follows:

Cash	\$ 24,746,346
Investment in Ceregene	3,486,000
In-process research and development	9,000,000
Receivables, equipment and other assets	293,658
Accounts payable and accrued liabilities	1,777,323
Convertible senior notes	16,709,580
<b>Total net assets acquired</b>	<b>\$ 19,039,101</b>

In addition to the \$24.7 million in cash acquired, the Company obtained, as a result of the merger, the rights to all in-process research and development of Cell Genesys, which included a portfolio of cancer vaccines and other technologies. The \$9.0 million value attributed to this portfolio was expensed as of the date of the acquisition as acquired in-process technology, as it was considered to have no alternative future use. The \$20.2 million representing the premium of the total value of consideration in excess of fair values of the net assets acquired also was expensed as of the date of the acquisition.

In addition, as a result of the merger, the Company assumed \$1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 and \$20.8 million in aggregate

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**4. ACQUISITION OF NET ASSETS OF CELL GENESYS (Continued)**

principal amount of 3.125% convertible senior notes due May 1, 2013 issued by Cell Genesys. As a result of the merger and in accordance with the terms of the indentures governing the 3.125% convertible senior notes due May 1, 2013 as supplemented by supplemental indentures entered into between the Company and the trustees thereunder, such notes became convertible into an aggregate of 931,093 shares of the Company's common stock at a conversion price of \$22.32 per share, in each case subject to adjustments for stock dividends, stock splits, and other similar events. For more details see Note 7, "Convertible Senior Notes."

**5. LICENSE AGREEMENTS**

*Gel Products*

The Company licensed the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). Under the agreement, Antares granted the Company an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories. Under the agreement, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology. The patents covering the formulations used in these gel products are expected to expire in 2022 and 2028. The Company's male testosterone gel was developed and is fully-owned by the Company and is not covered under the Antares license.

*GVAX Cancer Vaccine Technology*

The Company owns development and commercialization rights to its GVAX cancer vaccine technology as a result of its transaction with Cell Genesys. The original core patent applications covering the cancer vaccine technology were licensed exclusively to Cell Genesys from Johns Hopkins University and The Whitehead Institute for Biomedical Research in 1992. Rights to additional patents and patent applications were licensed from Johns Hopkins University in 2001. The patents are expected to expire between 2012 and 2026. Under the various agreements, the Company is required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology.

*The Pill Plus*

The Company licensed the technology underlying its triple component contraceptive, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently is marketed. The patents covering the technology underlying The Pill Plus are expected to expire in 2016.

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****5. LICENSE AGREEMENTS (Continued)***Other License Agreements*

The Company has entered into several other license agreements in which the Company has out-licensed certain of the rights and technologies the Company has licensed. Under these agreements, the Company typically is entitled to receive royalty payments on any sales of the products and, in some cases, may be entitled to receive certain development and regulatory milestones.

**6. PROPERTY AND EQUIPMENT**

Property and equipment, net of accumulated depreciation at December 31, 2011 and 2010 consists of the following:

	<u>2011</u>	<u>2010</u>
Computer equipment	\$ 520,647	\$ 417,840
Office equipment	388,659	163,653
Equipment	378,147	500,130
	<u>1,287,453</u>	<u>1,081,623</u>
Accumulated depreciation and amortization	<u>(426,089)</u>	<u>(445,847)</u>
	<u>\$ 861,364</u>	<u>\$ 635,776</u>

There was no construction in progress as of December 31, 2011 or December 31, 2010.

**7. CONVERTIBLE SENIOR NOTES**

As a result of the Company's merger with Cell Genesys, the Company assumed liabilities related to two series of convertible senior notes of Cell Genesys—\$1,234,000 aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 (the 2011 Notes) and \$20,782,000 aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes and collectively with the 2011 Notes, the Notes). The conversion features of the Notes were adjusted for the exchange ratio used in the merger, as described in Note 9, "Stockholders' Equity."

Immediately prior to November 1, 2011, the Company repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued interest thereon through such date. As of December 31, 2011, the 2013 Notes remained outstanding. In February 2012, the Company issued 1.9 million shares of its common stock to one of the holders of the 2013 Notes in exchange for cancellation of an aggregate of \$9.0 million principal amount of such notes, including accrued and unpaid interest. The \$11.8 million principal amount of the remaining 2013 Notes are exchangeable at the option of the holder or upon certain specified events into an aggregate of approximately 0.5 million shares of the Company's common stock at a conversion price of \$22.32 per share. The 2013 Notes are our general, unsecured obligations, ranking equally with all of the Company's existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of the Company's existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of the Company's subsidiaries. The 2013 Notes are subject to repurchase by the Company at each holder's option, if a fundamental change (as defined in

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****7. CONVERTIBLE SENIOR NOTES (Continued)**

the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by the Company, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of the Company's common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of December 31, 2011, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company's other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

From time to time, the Company may purchase, exchange or restructure its outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company's available cash and cash equivalents, the Company's liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company's stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company's existing stockholders and/or decrease the Company's cash balance. A significant decrease in the Company's cash balance may impair the Company's ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of December 31, 2011, with changes in the fair value of the Notes occurring since December 31, 2010, reflected in fair value adjustment in the statements of operations. The fair value of the Notes is based on Level 2 inputs. The recorded fair value of the Notes of an aggregate of \$17,336,760 as of December 31, 2011 differs from their total stated principal amount of \$20,782,000 by \$3,445,240. The recorded value of the Notes of an aggregate of \$18,547,333 as of December 31, 2010 differs from their total stated principal amount of \$22,016,000 by \$3,468,667. The Company recorded fair value adjustments of \$(23,427) and \$(1,870,916) related to the Notes for the years ended December 31, 2011 and 2010, respectively, to increase its recorded liability and corresponding expense in 2011 and 2010.

For the year ended December 31, 2010, approximately \$184,000 of the fair value adjustment was attributable to the change in instrument specific credit risk. There was no significant change in the fair value of the convertible senior notes due to a change in instrument specific credit risk for the years ended December 31, 2011 or 2009. The change in the aggregate fair value of the Notes due to instrument specific credit risk was estimated by calculating the difference between the December 31, 2010 fair value of the Notes as recorded and what the fair value of the convertible notes would have

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****7. CONVERTIBLE SENIOR NOTES (Continued)**

been on December 31, 2010 if the December 31, 2009 discount rate continued to be used in the calculation. The instrument specific credit risk for the year ended December 31, 2010 has increased the fair value of the Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk-free borrowing rate.

The Company establishes the value the convertible senior notes based upon contractual terms of the notes, as well as certain key assumptions.

The assumptions as of December 31, 2011 were:

	<u>2013 Notes</u>
Average risk-free rate	0.19%
Volatility of BioSante common stock	77.4%
Discount rate for principal payments in cash	18.5%

The assumptions as of December 31, 2010 were:

	<u>2013 Notes</u>	<u>2011 Notes</u>
Average risk-free rate	0.82%	0.29%
Volatility of BioSante common stock	78.7%	61.0%
Discount rate for principal payments in cash	17.0%	17.0%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a Ca and Caa3 rating for long-term corporate obligations as assigned by Moody's Investors Service. Volatility is based on the historical fluctuations in the Company's stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate is based on observed yields as of the measurement date of one-year, two-year and three-year U.S. Treasury Bonds.

The following table represents the scheduled maturities of required principal payments by year related to the convertible senior notes at December 31, 2011:

2012	\$	—
2013		20,782,000
Total	\$	<u>20,782,000</u>

**8. INCOME TAXES**

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company's U.S. and state tax returns remain subject to examination for the year ended 1998 and all subsequent periods due to the availability of tax loss and credit carryforwards. The Company determined there are no uncertain tax positions existing as of December 31, 2011 or 2010.

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****8. INCOME TAXES (Continued)**

The components of the Company's net deferred tax asset at December 31, 2011 and 2010 were as follows:

	2011	2010
Net operating loss carryforwards	\$ 63,969,813	\$ 46,071,206
Tax basis in intangible assets	4,095,269	4,452,360
Deferred financing costs for tax	7,010,462	7,001,619
Research & development credits	8,266,610	5,796,148
Stock option expense	2,754,981	2,310,405
Other	448,140	25,955
	<u>86,545,275</u>	<u>65,657,693</u>
Valuation allowance	<u>(86,545,275)</u>	<u>(65,657,693)</u>
	<u>\$ —</u>	<u>\$ —</u>

The Company has no current tax provision due to its current and accumulated losses, which result in net operating loss carryforwards. At December 31, 2011, the Company had approximately \$169,456,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2018-2031 and their utilization in future years may be limited as prescribed by Section 382 of the United States Internal Revenue Code. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, and other items have generated deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, which is the amount management believes is more likely than not to be realized. Additionally, the Company has provided a full valuation allowance against \$8,266,610 of research and development credits, which are available to reduce future income taxes, if any in the future. The research and development credits expire in the years 2018-2031.

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate of 34.5% to pre-tax income as follows:

	2011	2010	2009
Tax at U.S. federal statutory rate	\$ (17,804,934)	\$ (15,937,695)	\$ (16,397,080)
State taxes, net of federal benefit	(1,677,276)	(1,501,377)	(1,544,652)
Research and development credits	(1,537,863)	(966,941)	(515,235)
Other, net	132,491	133,932	17,718
Change in valuation allowance	20,887,582	18,272,081	18,439,249
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>



**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**9. STOCKHOLDERS' EQUITY**

*Authorized and Outstanding Capital Stock*

The Company is authorized to issue 200,000,000 shares of common stock, \$0.0001 par value per share, 4,687,684 shares of class C special stock, \$0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.0001 par value per share.

No shares of preferred stock were outstanding as of December 31, 2011 or 2010.

There were 65,214 shares of class C special stock issued and outstanding as of December 31, 2011 and 2010. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of the Company's common stock, at an exchange price of \$15.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of the Company's assets upon any liquidation, dissolution or winding-up of the Company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

There were 18,269,754 and 13,565,188 shares of common stock issued and outstanding as of December 31, 2011 and 2010, respectively. The Company has presented the par values of its common stock and the related additional paid in capital on a combined basis for all periods presented.

*Underwritten Public Offering*

On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 2.7 million shares of its common stock at a purchase price of \$18.00 per share, resulting in net proceeds of approximately \$45.0 million, after underwriters' discounts, commissions and offering expenses.

*Registered Direct Offerings*

On March 8, 2011, the Company completed a registered direct offering of 2,033,247 shares of its common stock and warrants to purchase an aggregate of 711,636 shares of its common stock at a purchase price of \$12.3678 per share to institutional investors for gross proceeds of \$25.1 million. The offering resulted in net proceeds to the Company of \$23.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of \$13.50 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 40,665 shares of the Company's common stock at an exercise price of \$15.48 per share, which warrants are exercisable immediately and will expire on June 9, 2014.

On March 8, 2010, the Company completed a registered direct offering of an aggregate of 1,734,104 shares of its common stock and warrants to an aggregate of 867,052 shares of its common stock, at a purchase price of \$10.38 per share to funds affiliated with two institutional investors resulting in net proceeds to the Company of approximately \$17.5 million, after deducting placement agent fees and other offering expenses. The warrants are exercisable beginning on September 9, 2010, have an exercise price of \$12.48 per share and will expire on September 8, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 34,682 shares

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**9. STOCKHOLDERS' EQUITY (Continued)**

of the Company's common stock at an exercise price of \$12.96 per share, which warrants are exercisable beginning on September 8, 2010 and will expire on June 9, 2014.

On June 23, 2010, the Company completed a registered direct offering of 1,189,061 shares of its common stock and warrants to purchase an aggregate of 594,530 shares of its common stock at a purchase price of \$12.615 per share to funds affiliated with certain institutional investors for gross proceeds of \$15.0 million. The offering resulted in net proceeds to the Company of approximately \$14.1 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately, have an exercise price of \$14.70 per share and will expire on June 23, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 35,671 shares of the Company's common stock at an exercise price of \$15.78 per share, which warrants are exercisable immediately and will expire on June 9, 2015.

On December 31, 2010, the Company completed a registered direct offering of 1,764,706 shares of its common stock and warrants to purchase an aggregate of 882,353 shares of its common stock at a purchase price of \$10.20 per share to funds affiliated with certain institutional investors for gross proceeds of \$18.0 million. The offering resulted in net proceeds to the Company of approximately \$16.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately, have an exercise price of \$12.00 per share and expire on December 30, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 52,941 shares of the Company's common stock at an exercise price of \$12.75, which warrants are exercisable immediately and will expire on June 9, 2015.

*Acquisition of Net Assets of Cell Genesys*

In October 2009, the Company acquired Cell Genesys in a direct merger. As a result of the merger, each share of common stock of Cell Genesys issued and outstanding immediately prior to the effective time of the merger was converted into the right to receive 0.0305 of a share of the Company's common stock. In the aggregate, the Company issued approximately 3.4 million shares of its common stock to former Cell Genesys stockholders in connection with the merger. All options to purchase shares of Cell Genesys common stock, other than certain designated options held by certain of Cell Genesys's former officers (Assumed Options), became fully vested and exercisable until immediately prior to the effective time of the merger. At the effective time of the merger, such unexercised options other than the Assumed Options terminated. The Assumed Options were assumed by the Company and will remain outstanding following the merger, but converted into and became options to purchase shares of the Company's common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.0305 exchange ratio. As a result of the merger, the Assumed Options converted into options to purchase an aggregate of 39,071 shares of the Company's common stock at a weighted average exercise price of \$118.38 per share. All warrants to purchase shares of Cell Genesys common stock which by their terms survived the merger (Assumed Warrants) were assumed by the Company, but were converted into and became warrants to purchase shares of the Company's common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.0305 exchange ratio. As a result of the merger,

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****9. STOCKHOLDERS' EQUITY (Continued)**

these Assumed Warrants converted into warrants to purchase an aggregate of 65,874 shares of the Company's common stock at a weighted average exercise price of \$235.62 per share.

For additional discussion regarding the merger with Cell Genesys and the assets and liabilities acquired, see Note 4, "Acquisition of Net Assets of Cell Genesys."

*Convertible Senior Notes*

See Note 7, "Convertible Senior Notes" for information regarding the convertible senior notes assumed in the Cell Genesys merger.

*Warrants*

As of December 31, 2011, warrants to purchase an aggregate of 3,794,741 shares of the Company's common stock were outstanding and exercisable as of December 31, 2011:

<u>Issue Date</u>	<u>Number of Underlying Shares Of Common Stock</u>	<u>Per Share Exercise Price</u>	<u>Expiration Date</u>
December 15, 2008	50,000	\$ 24.00	June 14, 2014
July 21, 2009	30,000	\$ 12.00	July 20, 2012
August 13, 2009	400,000	\$ 15.00	August 12, 2014
August 13, 2009	40,000	\$ 15.00	June 9, 2014
October 14, 2009	65,874	\$ 235.62	April 1, 2012
March 8, 2010	867,052	\$ 12.48	September 8, 2015
March 8, 2010	34,682	\$ 12.96	June 9, 2014
June 23, 2010	594,530	\$ 14.70	June 23, 2015
June 23, 2010	35,671	\$ 15.78	June 9, 2015
November 22, 2010	30,000	\$ 12.00	November 21, 2013
December 30, 2010	882,353	\$ 12.00	December 30, 2015
December 30, 2010	52,941	\$ 12.75	June 9, 2015
March 8, 2011	670,971	\$ 13.50	March 8, 2014
March 8, 2011	40,665	\$ 15.48	June 9, 2014

During 2011, the Company issued warrants to purchase an aggregate of 711,636 shares of the Company's common stock in connection with the March 2011 registered direct offering as described above. During 2011, warrants to purchase an aggregate of 1,458 shares of common stock were exercised and warrants to purchase an aggregate of 151,868 shares of the Company's common stock expired unexercised.

During 2010, the Company issued warrants to purchase an aggregate of 2,467,230 shares of the Company's common stock in connection with registered direct offerings as described above, and warrants to purchase 30,000 shares of the Company's common stock as compensation for investor relations services as described below. During 2010, no warrants were exercised and warrants to purchase an aggregate of 127,291 shares of the Company's common stock expired unexercised.

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**9. STOCKHOLDERS' EQUITY (Continued)**

During 2009, the Company issued warrants to purchase an aggregate of 440,000 shares of the Company's common stock in connection with a registered direct offering, warrants to purchase an aggregate of 65,874 shares of the Company's common stock in connection with the Cell Genesys merger, and warrants to purchase 30,000 shares of the Company's common stock as compensation for investor relations services as described below. During 2009, no warrants were exercised and warrants to purchase an aggregate of 89,166 shares of the Company's common stock expired unexercised.

In 2011, 2010 and 2009, the Company issued warrants to purchase 0, 30,000 and 30,000 shares of the Company's common stock, respectively, in consideration for various investor relations services. The warrants became exercisable on a ratable basis over a twelve-month period from the date of grant. The Company uses the Black-Scholes pricing model to value these types of warrants and remeasures the awards each quarter until the measurement date is established. For the years ended December 31, 2011, 2010 and 2009, the Company recorded \$204,980, \$65,529 and \$64,103, respectively, in non-cash general and administrative expense pertaining to consultant warrants.

**10. STOCK-BASED COMPENSATION**

The Company has two stockholder-approved equity-based compensation plans under which stock options have been granted—the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan except with respect to options outstanding under the 1998 Plan. As of December 31, 2011, the number of shares of the Company's common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan, was 1,000,000 plus the number of shares subject to options outstanding under the 1998 Plan as of the effective date of the 2008 Plan but only to the extent that such outstanding options are forfeited, expire or otherwise terminate without the issuance of such shares. Of such authorized shares, 3,416 shares had been issued and 587,666 shares were subject to outstanding stock options as of December 31, 2011.

Outstanding employee stock options generally vest over a period of three or four years and have 10-year contractual terms. Upon exercise of an option, the Company issues new shares of its common stock. From time to time, the Company grants employee stock options that have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. None of these options were outstanding as of December 31, 2011. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan and the 2008 Plan was \$1,177,683, \$992,757 and \$1,254,503 for the years ended December 31, 2011, 2010 and 2009, respectively. No income tax benefit was recognized in the Company's statements of operations for stock-based compensation arrangements due to the Company's net loss position.

The weighted average fair value of the options at the date of grant for options granted during 2011, 2010 and 2009 was \$7.32, \$6.66 and \$6.24 per share, respectively. The fair value of each option

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**10. STOCK-BASED COMPENSATION (Continued)**

grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2011	2010	2009
Expected option life (years)	5.5 - 6.25	6.00	6.00
Risk-free interest rate	1.175% - 2.57%	2.42%	2.74%
Expected stock price volatility	69.07% - 72.16%	76.05%	76.75%
Dividend yield	—	—	—

The Company uses the simplified method to estimate the life of options. The risk-free interest rate used is the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company calculated a volatility rate based on the closing price for its common stock at the end of each calendar month as reported by the NASDAQ Global Market. The Company has not in the past issued a cash dividend nor does it have any current plans to do so in the future; and therefore, an expected dividend yield of zero was used.

The following table summarizes the stock option compensation expense for employees and non-employees recognized in the Company's statements of operations for each period:

	2011	2010	2009
Research and development	\$ 423,925	\$ 325,208	\$ 361,773
General and administrative	753,758	667,549	892,730
Total stock-based compensation expense	<u>\$ 1,177,683</u>	<u>\$ 992,757</u>	<u>\$ 1,254,503</u>

A summary of activity under the Plans during the year ended December 31, 2011 is presented below:

<u>Options</u>	<u>Option Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding December 31, 2010	619,572	\$ 22.14	6.74	\$ 162,892
Granted	346,541	\$ 11.40		
Exercised	3,194	\$ 10.14		
Forfeited or expired	56,059	\$ 17.70		
Outstanding December 31, 2011	<u>906,860</u>	<u>\$ 18.36</u>	6.97	\$ 0
Exercisable at December 31, 2011	<u>474,671</u>	<u>\$ 25.14</u>	5.40	\$ 0
Vested or expected to vest at December 31, 2011	<u>879,777</u>	<u>\$ 18.36</u>	6.95	\$ 0

There is no aggregate intrinsic value of the Company's outstanding and exercisable options as of December 31, 2011.

As of December 31, 2011, there was \$2,089,729 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plans. The cost is expected to be recognized over a weighted-average period of 2.76 years.

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements (Continued)**

**December 31, 2011**

**10. STOCK-BASED COMPENSATION (Continued)**

The intrinsic value of options exercised during the year ended December 31, 2011 and 2010 was \$22,106 and \$974, respectively. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position. The total fair value of shares vested during the years ended December 31, 2011, 2010 and 2009 was \$667,171, \$764,921 and \$788,461, respectively.

**11. RETIREMENT PLAN**

The Company offers a discretionary 401(k) Plan to all of its employees. Under the 401(k) Plan, employees may defer income on a tax-exempt basis, subject to limitations under the Internal Revenue Code of 1986, as amended. Under the 401(k) Plan, the Company may make discretionary matching contributions. Company contributions expensed in 2011, 2010 and 2009 totaled \$211,494, \$179,349 and \$117,969, respectively.

**12. LEASE ARRANGEMENTS**

The Company has entered into lease commitments for rental of its office space which expires in 2014. The future minimum lease payments during 2012, 2013 and 2014 are \$236,747, \$248,632 and \$41,718, respectively.

Rent expense amounted to \$424,294, \$338,588 and \$325,093 for the years ended December 31, 2011, 2010 and 2009, respectively.

**13. COMMITMENTS AND CONTINGENCIES**

*Antares Pharma, Inc. License*

The Company's license agreement with Antares Pharma, Inc. requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. In 2011, 2010 and 2009, the Company paid or accrued \$335,160, \$152,228 and \$63,749, respectively, to Antares as a result of royalties generated by Elestrin revenues. Pursuant to a separate agreement with Antares and related to the December 2009 license amendment with Azur Pharma International II Limited (now known as Jazz Pharmaceuticals, in light of Jazz Pharmaceuticals' acquisition of Azur), the Company paid Antares an aggregate of \$268,750 in February 2010, which is recorded in licensing expense.

*Wake Forest License*

In April 2002, the Company exclusively in-licensed from Wake Forest University Health Sciences and Cedars-Sinai Medical Center three issued U.S. patents claiming triple component therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and obtained an option to license the patents for triple component contraception. The financial terms of the license include an upfront payment by the Company in exchange for exclusive rights to the license and regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed. In July 2005, the Company exercised the option for an exclusive license for the three U.S. patents for triple component contraception. The financial terms of this license include an upfront payment, regulatory milestone

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****13. COMMITMENTS AND CONTINGENCIES (Continued)**

payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed.

Future minimum maintenance payments due under this agreement are as follows:

<u>Year</u>	<u>Minimum Amount Due</u>
2012	\$ 80,000
2013	80,000
2014	80,000
2015	80,000
2016	40,000
Thereafter	80,000

Under the terms of the license agreement with the Wake Forest University Health Sciences and Cedars-Sinai Medical Center, the Company has the right to terminate the license at any time.

The Company has agreed to indemnify, hold harmless and defend Wake Forest University Health Sciences and Cedars-Sinai Medical Center against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation as no events occurred that would require indemnification.

*Aptar Pharma—Gel Filling Machine*

The Company currently has a commitment with Aptar Pharma to purchase a gel filling machine for \$842,740. As of December 31, 2011, the Company has paid \$337,096 resulting in a remaining obligation of \$505,644.

*Pending Litigation*

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming the Company and the Company's President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act. A substantially similar complaint was filed in the same court on February 21, 2012. The plaintiffs seek to represent a class of persons who purchased the Company's securities between February 8, 2010 and December 15, 2011, and seek unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. BioSante believes the actions are without merit and intends to defend the actions vigorously. Additional lawsuits may be filed and, at this time, because the litigation is in its early stages, the Company is unable to predict the outcome of these lawsuits, the possible loss or range of loss, if

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****13. COMMITMENTS AND CONTINGENCIES (Continued)**

any, associated with their resolution or any potential effect they may have on BioSante's operations. Failure by the Company to obtain a favorable resolution of the lawsuits, however, could have a material effect on the Company's financial condition, results of operations, cash flows or its operations.

**14. FAIR VALUE MEASUREMENTS**

The Company accounts for its convertible senior notes and U.S. Treasury money market fund at fair value. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.

Financial assets and liabilities recorded at fair value on a recurring basis as of December 31, 2011 and 2010 are classified in the table below in one of the three categories described above:

<u>Description</u>	<u>December 31, 2011 Balance</u>	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
<b>Assets:</b>				
Money market fund	\$ 55,465,507	—	\$ 55,465,507	—
Total assets	<u>\$ 55,465,507</u>	<u>—</u>	<u>\$ 55,465,507</u>	<u>—</u>
<b>Liabilities:</b>				
2013 Notes	\$ 17,336,760	—	\$ 17,336,760	—
Total liabilities	<u>\$ 17,336,760</u>	<u>—</u>	<u>\$ 17,336,760</u>	<u>—</u>



**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****14. FAIR VALUE MEASUREMENTS (Continued)**

<u>Description</u>	<u>December 31, 2010 Balance</u>	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
<b>Assets:</b>				
Money market fund	\$ 21,729,230	—	\$ 21,729,230	—
Total assets	\$ 21,729,230	—	\$ 21,729,230	—
<b>Liabilities:</b>				
2011 Notes	\$ 1,111,132	—	\$ 1,111,132	—
2013 Notes	17,436,201	—	17,436,201	—
Total liabilities	\$ 18,547,333	—	\$ 18,547,333	—

The Company made an election to record the values of the 2011 Notes and 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately pursuant to ASC 825. The fair values of the 2011 Notes and 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company's stock, and the current borrowing rates for similar companies. See Note 7, "Convertible Senior Notes" for more information and disclosures regarding key assumptions used in this fair value determination.

**15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

Selected quarterly data for 2011 and 2010 is as follows:

	2011			
	First	Second	Third	Fourth
Revenue	\$ 57,000	\$ 81,003	\$ 182,784	\$ 114,373
Research and development expenses	14,864,420	11,116,323	11,500,053	6,701,465
General and administrative expenses	1,593,557	1,989,103	1,675,268	1,723,562
Licensing expense	0	0	50,000	0
Operating loss	(16,442,921)	(13,064,942)	(13,028,207)	(8,340,710)
Net loss	(17,250,676)	(14,975,231)	(12,733,691)	(6,648,906)
<b>Loss per share:</b>				
Basic and diluted	\$ (1.20)	\$ (0.96)	\$ (0.72)	\$ (0.36)

**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements (Continued)****December 31, 2011****15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED) (Continued)**

	2010			
	First	Second	Third	Fourth
Revenue	\$ 2,279,874	\$ 0	\$ 51,331	\$ 143,032
Research and development expenses	9,426,870	8,657,606	9,716,091	11,904,935
General and administrative expenses	1,498,252	1,540,200	1,534,417	1,367,491
Licensing expense	268,750	0	0	0
Operating loss	(8,959,419)	(10,240,352)	(11,240,177)	(13,168,413)
Net loss	(10,540,419)	(10,794,351)	(11,589,711)	(13,271,735)
Loss per share:				
Basic and diluted	\$ (1.14)	\$ (1.02)	\$ (0.96)	\$ (1.08)

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**BIOSANTE PHARMACEUTICALS, INC.****Condensed Balance Sheets****September 30, 2012 (Unaudited)**

	September 30, 2012
<b>ASSETS</b>	
<b>CURRENT ASSETS</b>	
Cash and cash equivalents	\$ 38,049,095
Prepaid expenses and other assets	534,037
	<u>38,583,132</u>
<b>PROPERTY AND EQUIPMENT, NET</b>	<u>1,184,764</u>
<b>OTHER ASSETS</b>	
Investments	3,413,762
Deposits	30,088
	<u>\$ 43,211,746</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>	
<b>CURRENT LIABILITIES</b>	
Accounts payable	\$ 2,004,814
Accrued compensation	463,942
Other accrued expenses	860,094
Current portion of convertible senior notes	7,593,216
	<u>10,922,066</u>
Long-term convertible senior notes	—
<b>TOTAL LIABILITIES</b>	<u>10,922,066</u>
<b>STOCKHOLDERS' EQUITY</b>	
Capital stock	
Issued and outstanding	
2012—65,211 Class C special stock	65
2012—24,422,240 Common stock	273,259,171
	<u>273,259,236</u>
Accumulated deficit	(240,969,556)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u>32,289,680</u>
	<u>\$ 43,211,746</u>

See accompanying notes to the condensed financial statements.

**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Operations****Nine Months Ended September 30, 2012 and 2011 (Unaudited)**

	Nine Months Ended September 30,	
	2012	2011
<b>REVENUE</b>		
Licensing revenue	\$ —	\$ 100,000
Royalty revenue	333,163	220,787
	<u>333,163</u>	<u>320,787</u>
<b>EXPENSES</b>		
Research and development	14,454,258	37,480,873
General and administration	5,327,711	5,257,853
Depreciation and amortization	87,548	118,132
	<u>19,869,517</u>	<u>42,856,858</u>
<b>OTHER</b>		
Convertible note fair value adjustment	(4,037,797)	(1,929,000)
Interest expense	(283,348)	(516,000)
Other income	—	15,000
Interest income	5,300	6,472
	<u>(23,852,199)</u>	<u>(44,959,599)</u>
<b>LOSS BEFORE INCOME TAX BENEFIT</b>		
Income tax benefit	121,791	—
	<u>\$ (23,730,408)</u>	<u>\$ (44,959,599)</u>
<b>NET LOSS</b>		
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<u>\$ (1.14)</u>	<u>\$ (2.86)</u>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	<u>20,841,417</u>	<u>15,744,738</u>

See accompanying notes to the condensed financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**
**Condensed Statements of Cash Flows**
**Nine Months Ended September 30, 2012 and 2011 (Unaudited)**

	Nine Months Ended September 30,	
	2012	2011
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>		
Net loss	\$ (23,730,408)	\$ (44,959,599)
Adjustments to reconcile net loss to net cash (used in) operations		
Depreciation and amortization	87,548	118,132
Loss on disposal of fixed assets	117,794	367,274
Employee & director stock-based compensation	852,468	886,564
Stock warrant expense—noncash	—	180,759
Convertible note fair value adjustment	4,037,797	1,929,000
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other assets	323,225	1,539,903
Accounts payable and accrued liabilities	(3,807,074)	2,993,059
<b>Net cash (used in) operating activities</b>	<b>(22,118,650)</b>	<b>(36,944,908)</b>
<b>CASH FLOWS (USED IN) INVESTING ACTIVITIES</b>		
Purchase of investment	(7,955)	—
Purchase of fixed assets	(528,742)	(645,603)
<b>Net cash (used in) investing activities</b>	<b>(536,697)</b>	<b>(645,603)</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>		
Fractional share payout	(658)	—
Proceeds from common stock option exercises	—	32,442
Proceeds from warrants exercised	211,068	24,063
Proceeds from issuance of common stock by underwritten public offering	—	45,102,584
Proceeds from issuance of common stock by registered direct offerings	3,268,798	23,876,370
<b>Net cash provided by financing activities</b>	<b>3,479,208</b>	<b>69,035,459</b>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(19,176,139)</b>	<b>31,444,948</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>57,225,234</b>	<b>38,155,251</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 38,049,095</b>	<b>\$ 69,600,199</b>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION</b>		
Interest paid	\$ 184,094	\$ 344,000
<b>Noncash investing and financing activities</b>		
Shares issued for convertible senior notes and accrued interest	\$ 13,881,052	\$ —
Unpaid costs associated with registered direct offering	\$ 7,933	\$ —
Unpaid costs associated with underwritten public offering	\$ —	\$ 141,447
Purchase of fixed assets on account, non-cash investing activity	\$ —	\$ 59,016

See accompanying notes to the condensed financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)**

**1. DESCRIPTION OF BUSINESS**

The corporate strategy of BioSante Pharmaceuticals, Inc. (the Company) is to develop high value medically-needed pharmaceutical products and to implement strategic alternatives with respect to its products and the Company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies.

The Company's products, either approved or in clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III clinical development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva); (3) GVAX cancer vaccines, a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and which are currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers; (4) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (5) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Meda Pharmaceuticals Inc. (Meda), the Company's licensee.

**2. BASIS OF PRESENTATION**

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of September 30, 2012, the results of operations for the nine months ended September 30, 2012 and 2011, and the cash flows for the nine months ended September 30, 2012 and 2011, in conformity with accounting principles generally accepted in the United States of America (GAAP). Operating results for the nine month period ended September 30, 2012 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2012. The Company does not have items of other comprehensive income for the nine month period ended September 30, 2012 or 2011; and therefore, has not presented comprehensive income.

These unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2011, 2010 and 2009 and related notes contained elsewhere in this joint proxy statement/prospectus.

On June 1, 2012, the Company effected a one-for-six reverse split of its outstanding common stock and class C special stock. These unaudited interim condensed financial statements give retroactive effect to the reverse stock split.

**3. LIQUIDITY AND CAPITAL RESOURCES**

Substantially all of the Company's revenue to date has been derived from upfront, milestone and royalty payments earned on licensing transactions and from subcontracts. The Company's business operations to date have consisted mostly of licensing and research and development activities. The Company itself has not introduced commercially any products. To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**3. LIQUIDITY AND CAPITAL RESOURCES (Continued)**

received from its 2009 merger with Cell Genesys, Inc. (Cell Genesys), to fund its ongoing business operations and short-term liquidity needs.

As of September 30, 2012, the Company had \$38,049,095 of cash and cash equivalents. As of September 30, 2012, the Company had outstanding \$8,277,850 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. In August 2012, the Company completed an offering of an aggregate of 2,359,932 shares of the Company's common stock and warrants to purchase an aggregate of 1,179,966 shares of the Company's common stock, resulting in net proceeds of \$3,268,798, after deducting placement agent fees and other offering expenses. See Note 7, "Stockholders' Equity," for additional discussion regarding the August 2012 registered direct offering.

Absent the receipt of any additional licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as the Company continues to use cash to fund its operations. Assuming the Company's pending merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI) is completed during the first quarter of 2013 (see Note 10, "Subsequent Events"), the Company expects its cash and cash equivalents as of September 30, 2012 to meet the Company's liquidity requirements through at least the Company's anticipated closing of the merger, including the requirement under our merger agreement to have at least \$17 million of net cash (as defined in the merger agreement) available upon the closing of the merger. If the Company's pending merger with ANI is not completed, the Company will need to reevaluate its strategic alternatives, which may include a sale of the company, liquidation of the company or other strategic transaction. The Company's liquidity position will be dependent upon the strategic alternative selected; however, assuming the Company does not enter into another strategic transaction, and assuming the Company decides not to commence the two new efficacy trials for LibiGel, the Company expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet the Company's liquidity requirements for at least the next 3-5 years. Additional financing would be required should the Company decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing arrangements. If the Company raises additional funds by issuing equity securities, the Company's stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company's operations or the Company's ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to attempt to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under the Company's existing license agreements. In addition, from time to time, the Company may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company's available cash and cash equivalents, the Company's liquidity requirements, contractual restrictions and other factors. Such purchases, exchanges

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**3. LIQUIDITY AND CAPITAL RESOURCES (Continued)**

or restructurings could dilute the percentage ownership of the Company's stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company's existing stockholders and/or decrease the Company's cash balance. A significant decrease in the Company's cash balance, together with an inability to raise additional financing when needed, may impair the Company's ability to complete its proposed merger with ANI, execute other strategic alternatives or leave the Company without sufficient cash remaining for operations.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the Company's business and future prospects, the future value of the Company and/or economic and market conditions deteriorate. In addition, the Company's ability to raise additional financing is limited by the terms of its agreement and plan of merger with ANI. See Note 10, "Subsequent Events." If adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to reduce its operating costs or the Company may be forced to complete other strategic alternatives, such as winding down its operations and liquidating the Company. In such case, the Company's stockholders could lose some or all of their investment.

**4. BASIC AND DILUTED NET LOSS PER SHARE**

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company's outstanding options, warrants and convertible debt are antidilutive; accordingly, such securities are excluded from the computation of diluted net loss per share and there is no difference between basic and diluted net loss per share amounts.

**5. CONVERTIBLE SENIOR NOTES**

The Company has outstanding 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes). The aggregate principal amount of the 2013 Notes outstanding at September 30, 2012 was \$8,277,850. In February 2012, the Company issued 1,868,055 shares of its common stock to one of the holders of the 2013 Notes in exchange for the cancellation of \$9,000,000 in aggregate principal amount of such notes and the related accrued and unpaid interest of \$79,024. In July 2012, the Company issued an aggregate of 1,784,070 shares of its common stock to two of the holders of the 2013 Notes in exchange for the cancellation of \$3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of \$20,686. Non-cash fair value adjustments of \$(2,545,530) and \$(611,621) were recorded during the first and third quarters of 2012 as a result of the cancellation of such notes. The fair value adjustment recorded upon the cancellation of the 2013 Notes is primarily attributable to the time value effect of settling these obligations at a date prior to the stated maturity of the 2013 Notes.

The remaining \$8,277,850 aggregate principal amount of the 2013 Notes are exchangeable at the option of the holder or upon certain specified events into an aggregate of approximately 370,871 shares



**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**5. CONVERTIBLE SENIOR NOTES (Continued)**

of the Company's common stock at a conversion price of \$22.32 per share. The 2013 Notes are general, unsecured obligations of the Company and are described in Note 7 to the Company's financial statements for the year ended December 31, 2011. As of September 30, 2012, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company's other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

As described in Note 3, "Liquidity and Capital Resources," from time to time, the Company may purchase, exchange or restructure its outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer.

The Company has elected to record the 2013 Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the 2013 Notes to their fair value as of September 30, 2012, with changes in the fair value of the 2013 Notes occurring since December 31, 2011, reflected in fair value adjustment in the unaudited condensed statements of operations. As described in Note 9, "Fair Value Measurements," the fair value of the 2013 Notes is based on Level 2 inputs. The recorded fair value of the 2013 Notes of an aggregate of \$7,593,216 as of September 30, 2012 differs from their total stated aggregate principal amount of \$8,277,850 as of such date by \$684,634. During the nine months ended September 30, 2012, the Company recorded a fair value adjustment of \$(4,037,797) related to the 2013 Notes that were converted to common stock during 2012 or that remained outstanding as of September 30, 2012, that for the nine months ended September 30, 2012 increased the recorded liability and corresponding expense. For the nine months ended September 30, 2011, the Company recorded a fair value adjustment of \$(1,929,000) that increased the recorded liability and corresponding expense, respectively.

For the nine months ended September 30, 2012 and 2011, approximately \$(41,000) and \$230,000, respectively, of the fair value adjustment was attributable to the change in instrument specific credit risk. The change in the aggregate fair value of the 2013 Notes due to instrument specific credit risk for the nine months ended September 30, 2012 was estimated by calculating the difference between the September 30, 2012 fair value of the 2013 Notes as recorded and what the fair value of the 2013 Notes would have been on September 30, 2012 if the December 31, 2011 discount rate continued to be used in the calculation.

The instrument specific credit risk for both periods has increased the fair value of the 2013 Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk-free borrowing rate.

The Company establishes the value of the 2013 Notes based upon contractual terms of the 2013 Notes, as well as certain key assumptions.

**BIOSANTE PHARMACEUTICALS, INC.****SEPTEMBER 30, 2012****NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)****5. CONVERTIBLE SENIOR NOTES (Continued)**

The assumptions as of September 30, 2012 were:

Average risk-free rate	0.14%
Volatility of BioSante common stock	90.0%
Discount rate for principal payments in cash	19.6%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a Ca and Caa3 rating for long-term corporate obligations as assigned by Moody's Investors Service. Volatility is based on the historical fluctuations in the Company's stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate is based on observed yields as of the measurement date of six month and one-year U.S. Treasury Bonds.

**6. STOCK-BASED COMPENSATION**

The Company typically grants options to purchase shares of the Company's common stock to existing employees and non-employee directors on an annual basis during the first quarter of each year and to new employees and non-employee directors throughout the year on or around the date their employment or service with the Company commences. All options are granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the 2008 Plan). As of September 30, 2012, approximately 981,272 shares of the Company's common stock remain available for issuance under the 2008 Plan.

During the nine months ended September 30, 2012, the Company granted options under the 2008 Plan to purchase an aggregate of 358,582 shares of the Company's common stock to certain employees of the Company and the Company's non-employee directors with a weighted average exercise price of \$4.08 per share. Options to purchase an aggregate of 105,781 shares of the Company's common stock expired and were cancelled during the nine months ended September 30, 2012. Options are granted at an exercise price equal to the closing price of the Company's common stock on the date of the grant. No options were exercised during the nine months ended September 30, 2012.

No warrants were granted during the nine months ended September 30, 2012, other than the warrants issued in conjunction with the Company's August 2012 offering described in Note 7, "Stockholders' Equity".

**7. STOCKHOLDERS' EQUITY**

During the nine months ended September 30, 2012, the Company issued an aggregate of 3,652,125 shares of its common stock to holders of the 2013 Notes in exchange for the cancellation of \$12,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of \$99,710. See Note 5, "Convertible Senior Notes" for information regarding the 2013 Notes.

In August 2012, the Company completed an offering of 2,359,932 shares of its common stock and warrants to purchase an aggregate of 1,179,966 shares of its common stock at a purchase price of \$1.4725 per share to one institutional investor for gross proceeds of \$3,475,000. The offering resulted in net proceeds to the Company of \$3,268,798, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continue for a period of 5 years, at an exercise price of \$1.50 per share. The number of shares issuable upon exercise of the warrants and the exercise

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**7. STOCKHOLDERS' EQUITY (Continued)**

price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities. On September 20, 2012, warrants from the August 2012 offering to purchase an aggregate of 140,712 shares of common stock were exercised resulting in proceeds of \$211,068 to the Company.

On May 30, 2012, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation to effect a reverse split of the Company's outstanding shares of common stock and class C special stock in the discretion of the Company's Board of Directors at an exchange ratio of not less than one-for-two and not more than one-for-ten. On June 1, 2012, the Board of Directors of the Company effected a one-for-six reverse split of the Company's outstanding shares of common stock and class C special stock. No fractional shares were issued as a result of the reverse stock split, and stockholders who otherwise would have been entitled to a fractional share received, in lieu thereof, a cash payment based on the closing sale price of BioSante's common stock on June 1, 2012. The total cash payment for fractional shares was \$658. The reverse stock split did not change the number of authorized shares of the Company's common stock or class C special stock or the par value of the Company's common stock or class C special stock, but because the number of authorized shares of the Company's common stock and class C special stock was not affected, the effect of the reverse stock split was to increase the number of authorized but unissued shares of the Company's common stock and class C special stock. The primary purpose of the reverse stock split was to increase the Company's ability to maintain the listing of its common stock on The NASDAQ Global Market.

**8. COMMITMENTS AND CONTINGENCIES**

*Aptar Pharma—Gel Packaging Machine*

The Company has a commitment with Aptar Pharma to purchase a gel packaging machine for \$844,740. As of September 30, 2012, the Company had paid Aptar \$804,132. The remaining obligation of \$40,608 is due upon the shipment, assembly and calibration of the machine at a location designated by the Company. In light of the Company's pending merger with ANI (see Note 10, "Subsequent Events"), the Company is evaluating the future plans for this gel packaging machine.

*Pending Litigation*

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming the Company and the Company's President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased the Company's securities between February 10, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. The Company

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**8. COMMITMENTS AND CONTINGENCIES (Continued)**

believes the action is without merit and intends to defend the action vigorously. On October 10, 2012, the District Court entered an order setting the dates on which the plaintiff's consolidated amended complaint is due and establishing a briefing schedule on the defendants' anticipated motion to dismiss. On November 6, 2012, plaintiff filed a consolidated amended complaint; the Company and Mr. Simes intend to file motions to dismiss the consolidated amended complaint on or before December 21, 2012.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption *Weinstein v. BioSante Pharmaceuticals, Inc. et al.*, naming the Company's directors as defendants and the Company as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in the Company's corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and entered a stipulation and order setting the dates on which the plaintiff's consolidated amended complaint is due and establishing a briefing schedule on defendants' anticipated motions to dismiss. The Company expects a similar scheduling order to be entered in the action pending in Illinois state court.

The lawsuits are in their early stages; and, therefore, the Company is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on the Company's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on the Company's operations, including its financial condition, results of operations, or cash flows.

The Company is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with reasonable assurance and that may not be known for extended periods of time.

**9. FAIR VALUE MEASUREMENTS**

The Company accounts for its convertible debt and U.S. Treasury money market fund at fair value. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

## BIOSANTE PHARMACEUTICALS, INC.

SEPTEMBER 30, 2012

## NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)

## 9. FAIR VALUE MEASUREMENTS (Continued)

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.

Financial assets and liabilities recorded at fair value on a recurring basis as of September 30, 2012 are classified in the table below in one of the three categories described above:

Description	September 30, 2012 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market fund	\$ 36,957,469	—	\$ 36,957,469	—
Total assets	<u>\$ 36,957,469</u>	<u>—</u>	<u>\$ 36,957,469</u>	<u>—</u>
<b>Liabilities:</b>				
2013 Notes	7,593,216	—	7,593,216	—
Total liabilities	<u>\$ 7,593,216</u>	<u>—</u>	<u>\$ 7,593,216</u>	<u>—</u>

The Company made an election to record the values of the 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately. The fair values of the 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company's stock, and the current borrowing rates for similar companies. See Note 6, "Convertible Senior Notes" for more information and disclosures regarding key assumptions used in this fair value determination.

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**10. SUBSEQUENT EVENTS**

*Agreement and Plan of Merger*

On October 3, 2012, the Company entered into an agreement and plan of merger (the Merger Agreement) with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Merger Agreement, ANI will merge with and into the Company, with the Company continuing as the surviving company (the Merger). At the effective time of the Merger, each outstanding share of capital stock of ANI will be converted into the right to receive a number of shares of the Company's common stock, if any, as determined pursuant to the exchange ratios described in the Merger Agreement and the provisions of ANI's certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the Merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the Merger. No fractional shares of the Company's common stock will be issued in connection with the Merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following the consummation of the transactions contemplated by the Merger Agreement, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of the Company are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the Merger Agreement depending upon the amount of the Company's "net cash", as defined in the Merger Agreement and generally consisting of the Company's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current Company stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The Merger Agreement provides that, immediately following the effective time of the Merger, the board of directors of the combined company will consist of five former directors of ANI and two former directors of the Company, and ANI's current executive officers are expected to serve as executive officers of the combined company. In connection with the Merger, the Company will seek to amend its certificate of incorporation to: (i) effect a reverse split of its common stock at a ratio between the range of one-for-two and one-for-five, as determined by the Company and ANI, which is intended to ensure that the listing requirements of The NASDAQ Global Market or The NASDAQ Capital Market are satisfied; and (ii) change the name of the Company to "ANI Pharmaceuticals, Inc." or another name as designated by ANI (together, the Charter Amendments). No fractional shares of the Company's common stock will be issued in connection with the reverse split and holders of the Company's common stock will be entitled to receive cash in lieu thereof.

Consummation of the Merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the Merger Agreement and the transactions contemplated thereby by both the Company's and ANI's stockholders and the approval of the Charter Amendments by the Company's stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by the Company with the Securities and Exchange Commission to register the shares of the Company's common stock to be issued in connection with the Merger, which will contain a joint proxy statement/

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**10. SUBSEQUENT EVENTS (Continued)**

prospectus; (iii) approval for the listing of shares of the Company's common stock to be issued in the Merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iv) written opinions of counsel that the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (v) other customary closing conditions. In addition, the obligation of ANI to effect the Merger is subject to a condition that the Company's net cash, as calculated pursuant to the terms of the Merger Agreement, be no less than \$17.0 million immediately prior to the effective time of the Merger.

Each of the Company and ANI have made customary representations, warranties and covenants in the Merger Agreement, including among others, covenants that (i) each party will conduct its business in the ordinary course consistent with past practice during the interim period between the execution of the Merger Agreement and the consummation of the Merger; (ii) each party will not engage in certain kinds of transactions or take certain actions during such period; (iii) ANI will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the Merger Agreement and the transactions contemplated thereby and the board of directors of ANI will recommend that its stockholders adopt and approve the Merger Agreement, subject to certain exceptions; and (iv) the Company will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the Merger Agreement and the transactions contemplated thereby and the approval of the Charter Amendments and the Company's board of directors will recommend that the Company's stockholders adopt and approve the Merger Agreement and approve the charter amendments, subject to certain exceptions. Each of the Company and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for the Company in the event of the Company's receipt of a "superior proposal."

The Merger Agreement contains certain termination rights in favor of each of ANI and the Company in certain circumstances. If the Merger Agreement is terminated due to certain triggering events specified in the Merger Agreement, the Company will be required to pay ANI a termination fee of up to \$1.0 million or ANI will be required to pay the Company a termination fee of up to \$750,000. The Merger Agreement also provides that under specified circumstances, the Company may be required to reimburse ANI up to \$500,000 for ANI's expenses in connection with the transaction. Any expenses paid by the Company will be credited against the \$1.0 million termination fee if the termination fee subsequently becomes payable by the Company.

*Voting Agreements*

Concurrently and in connection with the execution of the Merger Agreement, certain of ANI's stockholders, who collectively hold approximately 90 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into voting agreements with the Company, pursuant to which each stockholder agreed to vote its shares of ANI capital stock in favor of the Merger, the Merger Agreement and the transactions contemplated by the Merger Agreement and against certain transactions or certain actions that would delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement. In addition, one of the stockholders of ANI, who holds approximately 57 percent of the outstanding shares of ANI capital stock as of the close of

**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**10. SUBSEQUENT EVENTS (Continued)**

business on October 3, 2012, has agreed to vote in favor of the election of the two directors designated by the Company at the first annual meeting of stockholders following the completion of the Merger.

In addition, certain of the Company's stockholders, directors and officers, who collectively hold approximately two percent of the outstanding shares of the Company's capital stock as of the close of business on October 3, 2012, entered into voting agreements with ANI, pursuant to which each stockholder agreed to vote its shares of the Company's capital stock in favor of the Merger, the Merger Agreement and the transactions contemplated by the Merger Agreement and the charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement.

*Lock-Up Agreements*

Concurrently and in connection with the execution of the Merger Agreement, ANI's chief executive officer and chief financial officer and certain stockholders of ANI, who collectively hold approximately 85 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into lock-up agreements with the Company, pursuant to which each stockholder will be subject to a six-month lock-up on the sale of shares of the Company's common stock received in the Merger.

*Contingent Value Rights Agreement*

The Company has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to its existing stockholders immediately prior to the completion of the Merger. The Company expects that one CVR will be issued for each share of the Company's common stock outstanding as of the record date to be set at a date prior to the completion of the Merger. However, the CVRs will not be certificated and will not be attached to the shares of the Company's common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event the Company receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to the Company's LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between the Company and an as of yet unidentified third party, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to the Company's LibiGel program, as determined pursuant to the CVR agreement, and will not exceed \$40 million in the aggregate.

*Employee Reduction Implications*

As a result of the conclusion of the Company's LibiGel Phase III cardiovascular events and breast cancer safety study, as announced by the Company in September 2012, and considering the Company's October 4, 2012 announcement of its potential merger with ANI, the Company plans to reduce its workforce during the fourth quarter of 2012. In connection with the announced reduction, the Company will pay approximately \$300,000 in aggregate severance costs during the remainder of 2012. The termination of employment of these employees will result in the cessation of any further vesting in



**BIOSANTE PHARMACEUTICALS, INC.**

**SEPTEMBER 30, 2012**

**NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED) (Continued)**

**10. SUBSEQUENT EVENTS (Continued)**

certain stock options held by these employees and a reversal of previously recognized non-cash stock-based compensation expense related to such options in a similar amount, thereby offsetting the employee reduction severance costs.

*Third Amendment To License Agreement with Teva*

In October 2012, the Company entered into an amendment to its development and license agreement with Teva pursuant to which Teva made a \$1.0 million payment to the Company upon the signing of the amendment and agreed to make the following milestone-based payments to the Company: (1) \$500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an "AB-rated" equivalent to AndroGel®; (2) \$750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva's submission to the FDA of a final report regarding a "washing" clinical study required by the FDA; and (3) \$500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva's commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay the Company \$4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to the Company under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

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ANI FINANCIAL STATEMENTS

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders of  
ANIP Acquisition Company:

We have audited the accompanying balance sheets of ANIP Acquisition Company (d/b/a ANI Pharmaceuticals, Inc.) ("the Company") as of December 31, 2011 and 2010, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2011. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the 2011 and 2010 financial statements have been restated to correct a misstatement.

/s/ Stout, Causey & Horning, P.A.

Sparks, Maryland  
November 20, 2012

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Balance Sheets**

<u>As of December 31,</u>	<u>2011</u>	<u>2010</u>
Assets	<u>As Restated</u>	<u>As Restated</u>
	<u>(Note 2)</u>	<u>(Note 2)</u>
Current Assets		
Accounts receivable, net	\$ 5,104,568	\$ 1,689,203
Inventories, net	2,107,463	2,361,990
Prepaid expenses	224,618	978,408
Total Current Assets	<u>7,436,649</u>	<u>5,029,601</u>
Property and Equipment		
Land	86,949	86,949
Buildings	3,682,006	3,682,006
Machinery, furniture and equipment	3,445,284	3,354,854
Construction in progress	35,660	—
	<u>7,249,899</u>	<u>7,123,809</u>
Less: accumulated depreciation and amortization	2,145,630	1,639,862
Total Property and Equipment, net	<u>5,104,269</u>	<u>5,483,947</u>
Other Assets		
Intangible assets, net	135,000	—
Total Other Assets	<u>135,000</u>	<u>—</u>
Total Assets	<u>\$ 12,675,918</u>	<u>\$ 10,513,548</u>

The accompanying notes are an integral part of these financial statements.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Balance Sheets (Continued)**

<u>As of December 31,</u>	2011 As Restated (Note 2)	2010 As Restated (Note 2)
<b>Liabilities and Stockholders' Deficit</b>		
Current Liabilities		
Accounts payable	\$ 1,208,323	\$ 1,638,226
Accrued expenses	824,011	338,422
Returned goods reserve	252,045	80,067
Borrowings under line of credit	3,064,414	1,722,678
Current maturities of long-term debt	—	400,000
Notes payable	300,000	275,000
Current liabilities of discontinued operation	512,275	1,500,693
Total Current Liabilities	<u>6,161,068</u>	<u>5,955,086</u>
Long-term debt, net of current maturities	—	233,333
Convertible debt	16,581,933	11,968,603
Total Liabilities	<u>22,743,001</u>	<u>18,157,022</u>
Commitments and Contingencies (Note 14)		
Redeemable Convertible Preferred Stock		
10% Convertible Preferred Stock, Series A, \$0.10 par value, stated value of \$100 per share; 108,494 shares authorized, 102,774 and 108,494 issued and outstanding, respectively, including cumulative dividends of \$995,557 and \$6,802,664, respectively	10,388,357	16,252,664
10% Convertible Preferred Stock, Series B, \$0.10 par value, stated value of \$110 per share; 118,915 shares authorized, 78,491 and 80,773 shares issued and outstanding, respectively, including cumulative dividends of \$836,368 and \$5,386,525, respectively	9,559,716	14,134,975
12% Convertible Preferred Stock, Series C, \$0.10 par value, stated value of \$110 per share; 37,956 shares authorized, 34,810 and 35,333 shares issued and outstanding, respectively, including cumulative dividends of \$448,148 and \$1,594,659, respectively	4,268,412	5,420,676
Total Redeemable Convertible Preferred Stock	<u>24,216,485</u>	<u>35,808,315</u>
Stockholders' Deficit		
Common stock, \$0.10 par value, 3,700,000 shares authorized; 1,129 and 7,879 shares issued and outstanding, respectively	113	788
Additional paid-in capital	1,086,461	1,081,911
Loan receivable from stockholder	—	(90,215)
Accumulated deficit	(35,370,142)	(44,444,273)
Total Stockholders' Deficit	<u>(34,283,568)</u>	<u>(43,451,789)</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 12,675,918</u>	<u>\$ 10,513,548</u>

The accompanying notes are an integral part of these financial statements.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Statements of Operations**

<u>For the Years Ended December 31,</u>	2011 As Restated (Note 2)	2010 As Restated (Note 2)
Net Revenues	\$ 16,514,579	\$ 8,974,818
Operating Expenses		
Cost of Sales (exclusive of depreciation and amortization)	6,860,551	3,456,999
Salaries and benefits	4,352,250	4,425,012
Freight	253,394	137,837
Research and development	799,302	84,762
Selling, general and administrative	3,711,669	3,214,706
Depreciation and amortization	532,768	486,315
Total Operating Expenses	<u>16,509,934</u>	<u>11,805,631</u>
Operating Income (Loss) from Continuing Operations	4,645	(2,830,813)
Other Expense		
Interest expense	(2,253,794)	(1,179,431)
Other expense	(384,555)	(138,061)
Total Other Expenses	<u>(2,638,349)</u>	<u>(1,317,492)</u>
Net Loss from Continuing Operations	<u>(2,633,704)</u>	<u>(4,148,305)</u>
Discontinued Operation		
Gain (Loss) on Discontinued Operation	205,545	(5,124,805)
Net Loss	<u>\$ (2,428,159)</u>	<u>\$ (9,273,110)</u>
<b>Computation of Loss from Continuing Operations</b>		
<b>Attributable to Common Stockholders:</b>		
Net Loss from Continuing Operations	\$ (2,633,704)	\$ (4,148,305)
Preferred Stock Dividends	(2,280,073)	(3,661,254)
Loss from Continuing Operations Attributable to Common Stockholders, basic and diluted	<u>\$ (4,913,777)</u>	<u>\$ (7,809,559)</u>
<b>Basic and diluted income (loss) per share:</b>		
Continuing operations	\$ (723.89)	\$ (1,010.68)
Discontinued operation	30.28	(663.23)
Basic and diluted loss per share	<u>\$ (693.61)</u>	<u>\$ (1,673.92)</u>
Basic and diluted weighted-average shares outstanding	<u>6,788</u>	<u>7,727</u>

The accompanying notes are an integral part of these financial statements.

**ANIP ACQUISITION COMPANY**  
d/b/a ANI Pharmaceuticals, Inc.

**Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit**

**For the Years Ended December 31, 2011 and 2010**

	Redeemable Convertible Preferred Stock			Stockholders' Deficit				
	10% Convertible Preferred Stock, Series A	10% Convertible Preferred Stock, Series B	12% Convertible Preferred Stock, Series C	Common Stock	Additional Paid-in Capital	Loan Receivable from Stockholder	Accumulated Deficit	Total
Balance, January 1, 2010 As Previously Reported	\$ 14,570,583	\$ 12,775,024	\$ 4,801,454	\$ 750	\$ 1,151,556	\$ (86,723)	\$ (31,466,475)	\$ (30,400,892)
Prior Period Adjustment (Note 2)	—	—	—	—	(76,050)	—	(43,434)	(119,484)
Balance, January 1, 2010 As Restated (Note 2)	14,570,583	12,775,024	4,801,454	750	1,075,506	(86,723)	(31,509,909)	(30,520,376)
Issuance of common stock	—	—	—	38	—	—	—	38
Preferred stock dividends	1,682,081	1,359,951	619,222	—	—	—	(3,661,254)	(3,661,254)
Interest income on loan receivable from stockholder	—	—	—	—	—	(3,492)	—	(3,492)
Non-cash compensation related to stock options	—	—	—	—	6,405	—	—	6,405
Net loss	—	—	—	—	—	—	(9,273,110)	(9,273,110)
Balance, December 31, 2010 As Restated (Note 2)	16,252,664	14,134,975	5,420,676	788	1,081,911	(90,215)	(44,444,273)	(43,451,789)
Preferred stock dividends forgiven through January 28, 2011	(6,802,664)	(5,386,525)	(1,594,659)	—	—	—	13,783,848	13,783,848
Preferred stock dividends	995,557	836,368	448,148	—	—	—	(2,280,073)	(2,280,073)
Redemption of stock in exchange for forgiveness of loan receivable from stockholder	(57,200)	(25,102)	(5,753)	(675)	—	90,215	(1,485)	88,055
Non-cash compensation related to stock options	—	—	—	—	4,550	—	—	4,550
Net loss	—	—	—	—	—	—	(2,428,159)	(2,428,159)
Balance, December 31, 2011 As Restated (Note 2)	\$ 10,388,357	\$ 9,559,716	\$ 4,268,412	\$ 113	\$ 1,086,461	\$ —	\$ (35,370,142)	\$ (34,283,568)

The accompanying notes are an integral part of these financial statements.

**ANIP ACQUISITION COMPANY**  
d/b/a ANI Pharmaceuticals, Inc.

**Statements of Cash Flows**

<u>For the Years Ended December 31,</u>	<u>2011</u> <u>As Restated</u> <u>(Note 2)</u>	<u>2010</u> <u>As Restated</u> <u>(Note 2)</u>
<b>Cash Flows From Operating Activities</b>		
Net loss from continuing operations	\$ (2,633,704)	\$ (4,148,305)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	532,768	486,315
Non-cash interest relating to convertible debt	1,919,036	937,705
Non-cash compensation expense related to stock option grants	4,550	6,405
Interest income on loan receivable from stockholder	—	(3,492)
Changes in operating assets and liabilities:		
Accounts receivable	(3,415,365)	1,740,750
Inventories	254,527	205,179
Prepaid expenses	753,790	(873,730)
Accounts payable	(429,903)	(3,256,517)
Accrued expenses	657,567	(383,660)
Net Cash and Cash Equivalents Used in Continuing Operations	(2,356,734)	(5,289,350)
Net Cash (Used in) Provided by Discontinued Operation	(782,873)	2,343,195
Net Cash and Cash Equivalents Used in Operating Activities	(3,139,607)	(2,946,155)
<b>Cash Flows From Investing Activities</b>		
Acquisition of property and equipment	(128,090)	(434,323)
Acquisition of intangible assets	(160,000)	—
Net Cash and Cash Equivalents Used in Investing Activities	(288,090)	(434,323)
<b>Cash Flows From Financing Activities</b>		
Issuance of common stock	—	38
Borrowings (repayments) under line of credit, net	1,341,736	(2,351,625)
Repayments on long-term debt	(633,333)	(3,017,886)
Repayments of notes payable, net	25,000	275,000
Proceeds from convertible debt	2,694,294	8,474,951
Net Cash and Cash Equivalents Provided by Financing Activities	3,427,697	3,380,478
Change in Cash and Cash Equivalents	—	—
Cash and cash equivalents, beginning of year	—	—
Cash and cash equivalents, end of year	\$ —	\$ —
<b>Supplemental disclosure for cash flow information:</b>		
Cash paid for interest	\$ 279,432	\$ 326,938
<b>Supplemental non-cash investing and financing activities:</b>		
Preferred stock dividends	\$ 2,280,073	\$ 3,661,254
Forgiveness of preferred stock dividends	\$ 13,783,848	\$ —
Redemption of stock in exchange for forgiveness of loan receivable from stockholder	\$ 90,215	\$ —

The accompanying notes are an integral part of these financial statements.



**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

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**Financial Statements**  
**Together with Report of Independent Registered Public Accounting Firm**

**For the Years Ended December 31, 2011 and 2010**

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Financial Statements**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Overview**

ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc. ("the Company") is a specialty pharmaceutical company, developing and marketing generic and branded prescription products. In two facilities located in Baudette, Minnesota, with combined manufacturing, packaging and laboratory capacity totaling 173,000 sq. ft., the Company manufactures oral solid dose products, as well as liquids and topicals, including those that must be manufactured in a fully contained environment due to their potency and/or toxicity. The Company also performs contract manufacturing for other pharmaceutical companies.

The Company also previously owned an operation in Gulfport, Mississippi that manufactured over-the-counter pharmaceuticals products, which were sold under private-label contracts to retail pharmacy chains. The Gulfport operation was sold in September 2010 and accounted for as a discontinued operation as of December 31, 2011 and 2010 (Note 7). The Company recognized a loss for the difference between the consideration received from the sale of the Gulfport operation and the carrying value of the operation's net assets on the date of sale. This loss is reported as a gain/loss on discontinued operation on the accompanying statements of operations.

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. Since inception, the Company has incurred a cumulative loss from operations and has had operating cash flow deficits. Management believes that as a result of the sale of the Gulfport operation, the Company can focus on prescription pharmaceuticals and increase its revenues while controlling operating costs in order to improve operating performance in the future. To date, the Company has funded its cash flow requirements using debt, equity, and equity-linked financings. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations and the ability to generate sufficient cash from operations and potential other funding sources to meet the Company's obligations as they become due. Management believes the going-concern basis is appropriate for the accompanying financial statements based on its current operating plan through December 31, 2013. In addition, management has the intent and ability to take additional actions as necessary to continue as a going concern, including by drawing on available funding sources and/or reducing discretionary operating costs.

**Basis of Accounting**

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP).

**Use of Estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, returns and other allowances, allowance for inventory obsolescence, derivative liabilities, and the depreciable lives of fixed assets. Actual results could differ from those estimates.

**Credit Concentration**

The Company's customers are primarily pharmaceutical companies, wholesale distributors, chain drug stores, and group purchasing organizations.

During the year ended December 31, 2011, three customers represented approximately 21%, 16%, and 16% of net revenues, respectively. As of December 31, 2011, accounts receivable from these customers totaled \$3,212,359. During the year ended December 31, 2010, three customers represented approximately 42%, 17% and 7% of net revenues, respectively. As of December 31, 2010, accounts receivable from these customers totaled \$883,017.

**Vendor Concentration**

During the year ended December 31, 2011, the Company purchased approximately 27% of total costs of goods sold from two suppliers. As of December 31, 2011, amounts payable to these suppliers totaled \$205,838. During the year ended December 31, 2010, the Company purchased approximately 21% of total costs of goods sold from two suppliers. There were no amounts payable to these suppliers as of December 31, 2010.

**Cash and Cash Equivalents**

Effective January 1, 2011 through December 31, 2012, all non-interest bearing transaction accounts are fully guaranteed by the Federal Deposit Insurance Corporation (FDIC). Such accounts are guaranteed by the FDIC up to \$250,000 thereafter. Interest bearing accounts are guaranteed by the FDIC up to \$250,000. The Company may maintain cash balances in excess of FDIC coverage. Management considers this to be a normal business risk.

**Revenue Recognition**

Revenue is recognized for product sales upon shipment, when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and the Company has no further performance obligations. These estimates reduce gross revenues to net revenues in the accompanying statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying balance sheets.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Accounts Receivable**

The Company extends credit to customers on an unsecured basis. The Company utilizes the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable. The Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. The Company's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. The Company determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. The Company determined that no allowance for doubtful accounts was necessary as of December 31, 2011 and 2010.

**Accruals for Chargebacks, Returns and Other Allowances**

The Company's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these gross-to-net accruals exceed 65% of generic and branded gross product sales and reduce gross revenues to net revenues in the accompanying statements of operations, or are presented as current liabilities or reductions in accounts receivable in the accompanying balance sheets. The Company continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. The Company makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances.

*Chargebacks*

Chargebacks, primarily from wholesalers, are the most significant of the Company's accruals. Chargebacks result from arrangements the Company has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost (WAC).

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price (ASP) for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- A change in customer mix
- A change in negotiated terms with customers
- A change in product sales mix

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

- A change in the volume of off-contract purchases
- Changes in WAC

As necessary, the Company adjusts ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded, at the same time the Company recognizes revenue from the product sale, as a reduction in both gross revenues and accounts receivable.

To evaluate the adequacy of its chargeback accruals, the Company obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. The Company continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

*Returns*

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The Company's product returns are settled through the issuance of a credit to the customer. The Company's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. The Company continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

*Administrative Fees and Other Rebates*

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers, consistent with pharmaceutical industry practice. The Company accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, the Company obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. The Company continually monitors administrative fee activity and adjusts its accruals when it believes that actual administrative fees will differ from the accruals.

*Prompt Payment Discounts*

Sales discounts are granted for prompt payment. The reserve for sales discounts is based on invoices outstanding. The Company assumes based on past experience that 100% of available discounts will be taken.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The following table summarizes activity in the balance sheet for accruals and allowances for the years ended December 31, 2011 and 2010:

	Accruals for Chargebacks, Returns and Other Allowances			
	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at January 1, 2010	\$ 439,176	\$ —	\$ —	\$ —
Accruals/Adjustments	1,975,853	80,067	114,727	25,000
Credits Taken Against Reserve	(1,664,571)	—	(55,125)	—
Balance at December 31, 2010	750,458	80,067	59,602	25,000
Accruals/Adjustments	13,005,579	356,364	672,882	446,187
Credits Taken Against Reserve	(10,075,199)	(184,386)	(494,289)	(304,748)
Balance at December 31, 2011	<u>\$ 3,680,838</u>	<u>\$ 252,045</u>	<u>\$ 238,195</u>	<u>\$ 166,439</u>

**Inventories**

Inventories are stated at the lower of cost or net realizable value. The Company values inventory at standard cost. The Company reviews and adjusts standard costs periodically and believes its inventory, as valued, approximates weighted average cost.

**Property and Equipment**

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation is recorded on a straight-line basis over estimated useful lives as follows:

Buildings and improvements	20 - 40 years
Machinery, furniture and equipment	3 - 10 years

Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest, if any. Depreciation is not recorded on construction in progress until such time as the assets are placed in service. During the years ended December 31, 2011 and 2010, there was no material interest capitalized into construction in progress.

Depreciation expense for the years ended December 31, 2011 and 2010 totaled \$507,768 and \$486,315, respectively.

The Company accounts for the valuation of long-lived assets in accordance with Accounting Standards Codification (ASC) 360, *Property, Plant, and Equipment*. ASC 360 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be

**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed are reportable at the lower of the carrying amount or fair value, less costs to sell. Management determined that no assets were impaired and no assets were held for disposal as of December 31, 2011 and 2010.

**Research and Development Expenses**

Research and development costs are expensed as incurred and primarily consist of expenses relating to product development. Research and development costs totaled \$799,302 and \$84,762 for the years ended December 31, 2011 and 2010, respectively, and are included in the accompanying statements of operations.

**Stock-Based Compensation**

The Company expenses the estimated fair value of stock-based awards made in exchange for employee services over the requisite employee service period. Stock-based compensation cost for stock options is determined at the grant date using an option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

**Income Taxes**

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company evaluates and accounts for uncertain income tax positions in accordance with ASC 740, *Income Taxes*. ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. In accordance with ASC 740, the Company began accounting for uncertain income tax positions during the year ended December 31, 2009. The Company did not identify any uncertain income tax positions that could have a material impact to the financial statements. The Company is subject to taxation in various jurisdictions and remains subject to examination by taxing jurisdictions for the years 2004 and all subsequent periods due to the availability of net operating loss carryforwards.

The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. The Company did not have any amounts accrued relating to interest and penalties as of December 31, 2011 and 2010.

**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The Company considers potential tax effects resulting from discontinued operations and records intra-period tax allocations, when those effects are deemed material.

**Income (Loss) per Share**

Basic income (loss) per share is calculated by dividing net income (loss) less preferred stock dividends by the weighted-average number of shares of common stock outstanding during the period. For periods of net income, and when the effects are dilutive, diluted earnings per share is computed by dividing net income (as adjusted for interest expense on convertible debt, if outstanding) by the weighted-average number of shares of common stock outstanding plus the number of shares that would be outstanding if warrants were exercised for common shares or preferred stock convertible into common shares, using the treasury method, or if convertible debt and convertible preferred stock had been converted into common shares, using the if-converted method. Diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share.

The number of anti-dilutive shares, consisting of common stock options, warrants exercisable for common stock, warrants exercisable for preferred stock, convertible debt, and convertible preferred stock which have been excluded from the computation of diluted loss per share for the years ended December 31, 2011 and 2010, were 2,109,869 and 687,377, respectively.

Basic and diluted loss per share has been adjusted for a 10:1 reverse stock split effected on January 28, 2011.

**Redeemable Preferred Stock**

The carrying value of the Company's redeemable convertible preferred stock is increased by the accretion of any related discounts and accrued but unpaid dividends so that the carrying amount will equal the redemption amount at the dates the stock becomes redeemable. The Company's Series A, B, and C preferred stock is redeemable at the option of the holders, subject to certain additional requirements (Note 11).

**Stock Splits and Other Reclassifications**

In January 2011 the Company's Board of Directors approved a resolution to effect a one-for-ten reverse stock split of the Company's common and preferred stock with a corresponding change to the par values. The par values, and all common and preferred share numbers for all periods presented, have been adjusted retrospectively to reflect the change in par value and the one-for-ten reverse stock split.

The Company historically classified its redeemable convertible preferred stock as "permanent equity" according to accepted practices for private companies. As of December 31, 2011, and for all periods presented, the Company has classified its redeemable convertible preferred stock as "temporary equity" as required by the rules and regulations of the Securities and Exchange Commission.



**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Financial Instruments**

The Company's balance sheets include various financial instruments (primarily cash and cash equivalents, prepaid expenses, accounts receivable, accounts payable, accrued expenses, borrowings under line of credit, notes payable and other current liabilities) that approximate fair value. Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. US GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.

Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

See Note 15 for additional information regarding fair value.

**Recent Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05, *Presentation of Comprehensive Income*. ASU 2011-05 revises the manner in which entities present comprehensive income in their financial statements. The new guidance removes the presentation options in ASC 220 and requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. ASU 2011-05 did not change the items that must be reported in other comprehensive income. The Company adopted the provisions of ASU 2011-05 in the first quarter of 2012. As the Company's net loss is the same as comprehensive loss, the Company did not present a statement of comprehensive loss.

**Subsequent Events**

The Company performed an evaluation of subsequent events through November 20, 2012, the date the accompanying financial statements were available to be issued, and did not identify any material events that warrant disclosure, except as disclosed in Note 16.

**2. RESTATEMENT OF 2011 AND 2010 FINANCIAL STATEMENTS**

In connection with certain convertible debt financings in 2010 and 2009, the Company issued stock purchase warrants to the lenders to purchase the Company's preferred stock. The Company allocated fair value to the stock purchase warrants issued in 2010 (\$667,021) and 2009 (\$76,050) based on management's estimate of fair value. In 2012, in connection with the review of certain equity

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**2. RESTATEMENT OF 2011 AND 2010 FINANCIAL STATEMENTS (Continued)**

transactions, the Company obtained independent third-party valuations of its equity securities and determined that the fair value of the stock purchase warrants issued in 2010 and 2009 (and for all subsequent periods) was *de minimis* and that the prior allocation should be revised. As a result, the Company has restated its 2011 and 2010 annual financial statements to correctly value the warrants. This correction resulted in changes to the following financial statement line items as of and for the periods indicated:

	<u>As Previously Reported</u>	<u>Increase (Decrease)</u>	<u>As Restated</u>
<b>Year ended December 31, 2011</b>			
<i>Statement of Operations</i>			
Interest expense	\$ (2,592,613)	\$ (338,819)	\$ (2,253,794)
Total other expense	(2,977,168)	(338,819)	(2,638,349)
Net loss from continuing operations	(2,972,523)	(338,819)	(2,633,704)
Net loss	(2,766,978)	(338,819)	(2,428,159)
<i>Statement of Cash Flows</i>			
Net loss	\$ (2,766,978)	\$ (338,819)	\$ (2,428,159)
Non-cash interest relating to convertible debt	2,257,855	(338,819)	1,919,036
<b>As of December 31, 2011</b>			
Additional paid-in capital	\$ 1,829,532	\$ (743,071)	\$ 1,086,461
Accumulated deficit	(36,113,213)	(743,071)	(35,370,142)

**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**2. RESTATEMENT OF 2011 AND 2010 FINANCIAL STATEMENTS (Continued)**

	As Previously Reported	Increase (Decrease)	As Restated
<b>Year ended December 31, 2010</b>			
<i>Statement of Operations</i>			
Interest expense	\$ (1,627,117)	\$ (447,686)	\$ (1,179,431)
Total other expense	(1,765,178)	(447,686)	(1,317,492)
Net loss from continuing operations	(4,595,991)	(447,686)	(4,148,305)
Net loss	(9,720,796)	(447,686)	(9,273,110)
<i>Statement of Cash Flows</i>			
Net loss	\$ (9,720,796)	\$ (447,686)	\$ (9,273,110)
Non-cash interest relating to convertible debt	1,385,391	(447,686)	937,705
Fair market value of stock purchase warrants issued in connection with convertible debt	667,021	(667,021)	—
<b>As of December 31, 2010</b>			
Convertible debt	\$ 11,629,784	\$ 338,819	\$ 11,968,603
Total liabilities	17,818,203	338,819	18,157,022
Additional paid-in capital	1,824,982	(743,071)	1,081,911
Accumulated deficit	(44,848,525)	(404,252)	(44,444,273)

The effect of the restatement as of January 1, 2010 (the earliest period presented) was a decrease of \$76,050 in additional paid-in capital and an increase of \$43,434 in accumulated deficit.

**3. ACCOUNTS RECEIVABLE**

Accounts receivable consist of the following as of December 31:

	2011	2010
Accounts receivable, gross	\$ 8,991,124	\$ 2,439,751
Adjustments for chargebacks and other allowances	(3,886,556)	(750,548)
Accounts receivable, net	<u>\$ 5,104,568</u>	<u>\$ 1,689,203</u>

**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

#### 4. INVENTORIES

Inventories consist of the following as of December 31:

	<u>2011</u>	<u>2010</u>
Raw materials	\$ 836,724	\$ 987,169
Packaging materials	687,185	290,858
Work-in-progress	95,762	40,996
Finished goods	501,230	1,067,592
	<u>2,120,901</u>	<u>2,386,615</u>
Reserve for excess/obsolete inventories	(13,438)	(24,625)
Inventories, net	<u>\$ 2,107,463</u>	<u>\$ 2,361,990</u>

#### 5. INTANGIBLE ASSETS

Intangible assets consist of the exclusive rights, including all of the applicable technical data and other relevant information, to produce certain pharmaceutical products which the Company has acquired from various companies during the year ended December 31, 2011. The purchase prices totaled \$160,000 and are being amortized, upon product commercialization, on a straight-line basis over the estimated useful life of the products of three years. Amortization expense for the year ended December 31, 2011 totaled \$25,000.

#### 6. NOTES PAYABLE

Notes payable consist of amounts previously owed to suppliers as accounts payable that were subsequently converted to notes payable, as agreed upon by the Company and their respective suppliers. During the year ended December 31, 2009, the Company reached an agreement with a supplier to convert \$938,276 of accounts payable to a note payable. Under the terms of the agreement, the Company was required make monthly payments of principal amounts plus interest of 6% per annum. In May 2011, the Company reached an agreement with the supplier to settle all amounts due by the Company in full and final for \$175,000. The resulting gain is included as a gain on the discontinued operation in the accompanying statements of operations. Amounts due under this agreement as of December 31, 2011 and 2010 totaled \$0 and \$275,000, respectively.

During October 2011, the Company reached a settlement agreement with another supplier in the amount of \$450,000. Under the terms of the agreement, the Company is required make monthly payments of \$50,000. Amounts due under this agreement totaled \$300,000 as of December 31, 2011 and mature on July 1, 2012.

#### 7. DISCONTINUED OPERATION

On September 17, 2010, the Company sold its operation in Gulfport, Mississippi to a third-party for \$2,300,000. This operation manufactured over-the-counter pharmaceuticals products, which were sold under private-label contracts to retail pharmacy chains. The net assets of the Gulfport operation had a carrying value of \$5,819,473 on the date of the sale, resulting in a loss of \$3,669,245 on disposal

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**7. DISCONTINUED OPERATION (Continued)**

of the discontinued operation. The decision to sell the Gulfport operation was based on its historical underperformance and recurring losses and the anticipated need for continued financing from outside sources to maintain ongoing operations.

The following liabilities relate to the Gulfport operation's discontinued operation and have been segregated from continuing operations in the accompanying balance sheets as of December 31:

	<u>2011</u>	<u>2010</u>
Liabilities:		
Accounts payable	\$ 512,275	\$ 1,488,211
Accrued expenses	—	12,482
Net Current Liabilities from Discontinued Operation	<u>\$ 512,275</u>	<u>\$ 1,500,693</u>

As of December 31, 2011, accounts payable consisted of balances due to various vendors of the discontinued operation.

The following revenues and expenses relate to the Gulfport facility's discontinued operation and have been segregated from continuing operations in the accompanying statements of operations for the years ended December 31,:

	<u>2011</u>	<u>2010</u>
Net Revenues	\$ —	\$ 6,286,353
Operating Expenses		
Cost of Sales (exclusive of depreciation and amortization)	—	4,607,036
Salaries and benefits	—	1,196,134
Freight	—	367,598
Selling, general and administrative	—	930,658
Depreciation and amortization	—	615,113
Total Operating Expenses	<u>—</u>	<u>7,716,539</u>
Operating Income (Loss) from Discontinued Operation	<u>—</u>	<u>(1,430,186)</u>
Other Income (Expense)		
Interest expense	—	(166,927)
Other income	205,545	141,553
Total Other Income (Expense)	<u>205,545</u>	<u>(25,374)</u>
Income (Loss) from Discontinued Operation	<u>205,545</u>	<u>(1,455,560)</u>
Loss on Disposal of Discontinued Operation	<u>—</u>	<u>(3,669,245)</u>
Gain (Loss) on Discontinued Operation	<u>\$ 205,545</u>	<u>\$ (5,124,805)</u>

During the year ended December 31, 2011, the majority of the gain on discontinued operation consisted of a recovery of a previously written-off accounts receivable balance totaling \$150,000 and

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**7. DISCONTINUED OPERATION (Continued)**

various other vendor settlements. During the year ended December 31, 2010, interest expense was allocated to the discontinued operation in proportion to the assets of the discontinued operation against which the Company borrowed under the line of credit as well as certain capital leases for equipment specifically used for the discontinued operation.

**8. LINE OF CREDIT**

During the years ended December 31, 2011 and 2010, the Company had borrowings under a line of credit agreement with a commercial lender. Due to covenant defaults, the Company entered into a forbearance agreement in May 2010, which was last amended in October 2011. Under the terms of the amended forbearance agreement, the Company could borrow an amount equal to the lesser of the borrowing base, as defined, or \$3.5 million. Interest accrued at an annual rate of the Base Rate, as defined, plus 6.0%. The Base Rate as of December 31, 2011 and 2010 was 3.25%. The effective rate as of December 31, 2011 and 2010 was 9.25%. In addition, a usage fee equal to 0.75% per annum of the unused facility and a management fee equal to \$9,000 per annum were assessed monthly. The line of credit was secured by substantially all of the Company's assets. The amended forbearance agreement expired in June 2012, however, the Company entered into a new revolver loan agreement with a different commercial bank in June 2012 (Note 16).

Borrowings under the line of credit plus outstanding checks as of December 31, 2011 and 2010 totaled \$3,064,414 and \$1,722,678, respectively. The Company was required to meet certain financial covenants under the amended forbearance agreement. The Company was in compliance with all covenants as of December 31, 2011 and 2010.

**9. LONG-TERM DEBT**

Long-term debt consisted of the following as of December 31:

	<u>2011</u>	<u>2010</u>
Term note payable to a financial institution, due in monthly installments of \$33,333, with interest at a maximum rate of Base Rate, as defined, plus 8% (effective rate was 11.25% at December 31, 2010)	\$ —	\$ 633,333
	<u>—</u>	<u>633,333</u>
Less: current maturities	—	(400,000)
Long-term debt, net of current maturities	<u>\$ —</u>	<u>\$ 233,333</u>

The long term debt was secured by substantially all of the Company's assets and included financial covenants and limitations on the Company's ability to enter into certain transactions during the term of the agreements. Due to covenant defaults, the Company entered into a forbearance agreement in May 2010, which was most recently amended in October 2011. The Company was in compliance with all covenants as of December 31, 2010. As of December 31, 2011, the note had been paid in full.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**10. CONVERTIBLE DEBT**

In 2009, the Company issued \$2,502,814 of Secured Subordinated Convertible Notes ("the 2009 Convertible Notes"). The 2009 Convertible Notes, which bore interest at 10% per annum, were due on September 3, 2011. Interest on the 2009 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 Convertible Notes were secured by a second lien on substantially all of the Company's assets and included financial covenants and limitations on the Company's ability to enter into certain transactions while the 2009 Convertible Notes were outstanding.

In connection with the issuance of the 2009 Convertible Notes, the Company also issued warrants to acquire shares of the Company's common and preferred stock ("the 2009 Warrants"). The 2009 Warrants, accounted for as derivative liabilities, expired on the earlier of the repayment of the 2009 Convertible Notes or a Qualified Public Offering, as defined, and had an exercise price of \$0.10 per share. The estimated fair value of the 2009 Warrants upon issuance, based on an independent third-party valuation of the Company's equity securities, was deemed immaterial.

In 2010, the Company issued \$8,474,951 of Secured Subordinated Convertible Notes ("the 2010 Convertible Notes"). The 2010 Convertible Notes, which bore interest at 14% per annum, were due on September 3, 2011. Interest on the 2010 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 Convertible Notes were secured by a second lien on substantially all of the Company's assets and included financial covenants and limitations on the Company's ability to enter into certain transactions while the 2010 Convertible Notes were outstanding.

In connection with the issuance of the 2010 Convertible Notes, the Company also issued warrants to acquire shares of the Company's Series D Preferred stock ("the 2010 Warrants"). The 2010 Warrants, accounted for as derivative liabilities, expired on the earlier of the repayment of the 2010 Convertible Notes or a Qualified Public Offering, as defined, and had an exercise price of \$0.10 per share. The estimated fair value of the 2010 Warrants upon issuance, based on an independent third-party valuation of the Company's equity securities, was deemed immaterial.

Interest expense relating to the 2009 and 2010 Convertible Notes totaled \$937,705 during the year ended December 31, 2010. The change in fair value of the derivative liabilities relating to the 2009 Warrants and 2010 Warrants during the year ended December 31, 2010 was not material.

In 2011, the Company issued \$2,694,294 of Secured Subordinated Convertible Notes ("the 2011 Convertible Notes") and consolidated all of the outstanding 2009 and 2010 Convertible Notes into the 2011 Convertible Notes (collectively "the Consolidated 2011 Convertible Notes"). The consolidation of the 2009 and 2010 Convertible Notes was accounted for as a debt modification. The Consolidated 2011 Convertible Notes, which bore interest at 14% per annum, were due on the earliest to occur of: (i) the date of the closing of a merger, consolidation or reorganization of the Company with or into any other entity or a sale of all or substantially all of the assets of the Company, resulting in a change of control, (ii) the date of any dissolution, liquidation or winding up of the Company, or (iii) December 31, 2012. Interest on the Consolidated 2011 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**10. CONVERTIBLE DEBT (Continued)**

The Consolidated 2011 Convertible Notes were convertible into equity securities issued in a Qualified Financing, as defined, ("Qualified Financing Securities") or Series D Convertible Preferred Stock of the Company. In the event of the consummation of a Qualified Financing, or upon the election of the holders of at least 65% of the Consolidated 2011 Convertible Notes, or in the event that the Company refinanced its senior credit facility in a manner satisfactory to the holders of at least 65% of the Consolidated 2011 Convertible Notes, then all outstanding principal and accrued but unpaid interest was convertible into such number of shares of the Qualified Financing Securities or Series D Preferred as was obtained by dividing the Conversion Value of the notes by \$30.00, subject to adjustment. The Conversion Value was equal to four times (4x) the sum of all outstanding principal and accrued but unpaid interest under the Consolidated 2011 Convertible Notes.

The Consolidated 2011 Convertible Notes were secured by a second lien on substantially all of the Company's assets and included covenants and limitations on the Company's ability to enter into certain transactions while the Consolidated 2011 Convertible Notes were outstanding.

Interest expense relating to the Consolidated 2011 Convertible Notes totaled \$1,919,036 during the year ended December 31, 2011. The change in fair value of the derivative liabilities relating to the 2009 Warrants and 2010 Warrants during the year ended December 31, 2011 was not material.

The Company was in compliance with all covenants as of December 31, 2011 and 2010.

As part of the agreements relating to the Convertible Notes, the Company is required to pay monitoring and advisory fees to two investors totaling \$200,000 per annum, which are included in other expense in the accompanying statement of operations for the year ended December 31, 2011. These fees commenced on January 1, 2011 and are paid quarterly in advance on the first business day of each calendar quarter.

In June 2012, the holders of the Consolidated 2011 Convertible Notes converted all outstanding convertible debt and accrued interest into shares of Series D Preferred (Note 16).

**11. CAPITALIZATION**

**Authorized shares**

The Company is authorized to issue up to 7,300,000 shares of stock of which 3,700,000 are designated as common stock with a \$0.10 per share par value and 3,600,000 are designated as preferred stock with a \$0.10 par value.



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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

**Series A 10% Convertible Preferred Stock**

The Company has designated 108,494 shares of its authorized preferred stock as Series A 10% Convertible Preferred Stock ("the Series A Preferred"). The Series A Preferred has a stated value of \$100 per share. Among the terms and conditions of the Series A Preferred are the following:

*Ranking*

The Series A Preferred is senior to the common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series A Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 10% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series A Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$995,557 and \$6,802,664 as of December 31, 2011 and 2010, respectively, and are included in Series A Preferred Stock in the accompanying balance sheets.

*Conversion*

Each share of Series A Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least 60% of the then issued and outstanding shares of the Series A Preferred, or the date all of the outstanding shares of Series D Preferred Stock are mandatorily converted to shares of common stock, each share of Series A Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series A Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series A Preferred shall have the right to the number of votes it would have obtained had the Series A Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 54,246.7 shares of the Series A Preferred remain outstanding, the vote of a majority of the outstanding shares of Series A Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series A Preferred.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series A Preferred shall have the right to receive, prior to any payment to holders of common stock, the greater of (i) the stated value of the Series A Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the common stock if the Series A Preferred was converted to common stock immediately prior to the event.

**Series B 10% Convertible Preferred Stock**

The Company has designated 118,915 shares of its authorized preferred stock as Series B 10% Convertible Preferred Stock ("the Series B Preferred"). The Series B Preferred has a stated value of \$110 per share. Among the terms and conditions of the Series B Preferred are the following:

*Ranking*

The Series B Preferred is senior to the Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series B Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 10% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series B Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$836,368 and \$5,386,525 as of December 31, 2011 and 2010, respectively, and are included in Series B Preferred Stock in the accompanying balance sheets.

*Conversion*

Each share of Series B Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least the majority of the then issued and outstanding shares of the Series B Preferred, or the date all of the outstanding shares of Series D Preferred Stock are mandatorily converted to shares of common stock, each share of Series B Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series B Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series B Preferred shall have the right to the number of votes

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

it would have obtained had the Series B Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 40,381.3 of the shares of the Series B Preferred remain outstanding, the vote of a majority of the outstanding shares of Series B Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series B Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series B Preferred shall have the right to receive, prior to any payment to holders of Series A Preferred and common stock, the greater of (i) the stated value of the Series B Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series A Preferred and common stock if the Series B Preferred was converted to common stock immediately prior to the event.

**Series C 12% Convertible Preferred Stock**

The Company has designated 37,956 shares of its authorized preferred stock as Series C 12% Convertible Preferred Stock ("the Series C Preferred"). The Series C Preferred has a stated value of \$110 per share. Among the terms and conditions of the Series C Preferred are the following:

*Ranking*

The Series C Preferred is senior to the Series B Preferred, Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series C Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 12% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series C Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$448,148 and \$1,594,659 as of December 31, 2011 and 2010, respectively, and are included in Series C Preferred Stock in the accompanying balance sheets.

*Conversion*

Each share of Series C Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least the majority of the then issued and outstanding shares of the Series C preferred, or the date all of the outstanding shares of Series D Preferred Stock are mandatorily converted to shares of common stock, each share of Series C Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series C Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series C Preferred shall have the right to the number of votes it would have obtained had the Series C Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 18,977.5 shares of the Series C Preferred remain outstanding, the vote of a majority of the outstanding shares of Series C Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series C Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series C Preferred shall have the right to receive, prior to any payment to holders of Series B Preferred, Series A Preferred and common stock, the greater of (i) the stated value of the Series C Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series B Preferred, Series A Preferred and common stock if the Series C Preferred was converted to common stock immediately prior to the event.

**Series D 10% Convertible Preferred Stock**

The Company has designated 3,400,000 shares of its authorized preferred stock as Series D 10% Convertible Preferred Stock ("the Series D Preferred"). The Series D Preferred has a stated value of \$30 per share. As of December 31, 2011, the Company had not issued any Series D Preferred (Note 16). Among the terms and conditions of the Series D Preferred are the following:

*Ranking*

The Series D Preferred is senior to the Series C Preferred, Series B Preferred, Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series D Preferred accrue from the date of issuance, whether or not earned or declared, at the rate of 10% per annum.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

*Conversion*

Each share of Series D Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least 65% of the then issued and outstanding shares of the Series D preferred, each share of Series D Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series D Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series D Preferred shall have the right to the number of votes it would have obtained had the Series D Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, in the event that 1,000,000 shares of the Series D Preferred are outstanding, the vote of 65% of the outstanding shares of Series D Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series D Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series D Preferred shall have the right to receive, prior to any payment to holders of Series C Preferred, Series B Preferred, Series A Preferred and common stock, an amount equal to the sum of all accrued but unpaid dividends plus the greater of (i) the Preferred D stated value and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series C Preferred, Series B Preferred, Series A Preferred and common stock if the Series D Preferred was converted to common stock immediately prior to the event.

**Warrants**

In connection with the issuance of the Company's Convertible Debt (Note 10), the Company issued warrants for common stock at an exercise price of \$0.10 per share and warrants for preferred stock at an exercise price of \$0.10 per share. The number of common shares issuable upon exercise of the common warrants was based on accrued interest on the 2009 Convertible Notes. The number of preferred shares issuable upon exercise of the preferred warrants was based on the principal amount of certain of the 2009 Convertible Notes and on 12% of the Conversion Value of certain of the 2010 Convertible Notes. The warrants expired on the earlier of the repayment or conversion of the

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

respective convertible debt or a Qualified Public Offering, as defined by the agreement. For the years ended December 31, 2011 and 2010, the common warrants were exercisable for 17,536 and 10,196 common shares, respectively. For the years ended December 31, 2011 and 2010, the preferred warrants were exercisable for 25,910 and 20,659 preferred shares, respectively.

In June 2012, in conjunction with the conversion of the Consolidated 2011 Convertible Notes, 27,359 Series D Preferred shares were issued from the exercise of the preferred warrants, and 22,484 shares of common stock were issued from the exercise of the common warrants (Note 16).

**Stockholders' Agreement**

The Company and its stockholders have entered into an agreement ("the Stockholders' Agreement"). Under the terms of the agreement, the parties have agreed to elect certain individuals, as designated by holders of the Series A Preferred, Series B Preferred, and Series C Preferred and, upon issuance, Series D Preferred, as members of the Company's Board of Directors ("the Board"). In addition, the Stockholders' Agreement requires the approval of the majority of the holders of the Series A Preferred, Series B Preferred, Series C Preferred and Series D Preferred and, in some cases, the approval of 65% of the holders of the Series D Preferred prior to making certain changes to the Company's Charter, By-laws or Board configuration and entering into certain transactions.

Under the terms of the Stockholders' Agreement, at any time after December 31, 2012, the holders of a majority of Series D Preferred have the right to require the Company to redeem all of the holders' shares of Series D Preferred at a price which is the sum of all accrued but unpaid dividends plus the greater of (i) the fair market value of the Series D Preferred being redeemed or (ii) the holders' pro-rata share, based on the Series D Preferred being redeemed, of the equity value of the Company as determined by a nationally recognized investment bank or a valuation formula as defined in the Stockholders' Agreement. At any time after the holders of a majority of Series D Preferred require the Company to redeem all of the holders' shares of Series D Preferred, the holders of a majority of Series A Preferred and Series B Preferred, and the holders of 55% of the Series C Preferred shall have the right to require the Company to redeem the holders' shares at a price which is the sum of all accrued but unpaid dividends plus the greater of (i) the fair market value of the Series A, Series B, and Series C Preferred being redeemed or (ii) the holders' pro-rata share, based on the Series A, Series B, and Series C Preferred being redeemed, of the equity value of the Company as determined by a nationally recognized investment bank or a valuation formula as defined in the Stockholders' Agreement.

The Stockholders' Agreement also contains provisions that govern the process a stockholder must follow concerning disposition of shares, the requirements for a stockholder to sell shares in the event of certain approved transactions (drag along rights), the rights of a stockholder to sell shares in the event other stockholders propose to sell their shares (tag along rights) and the rights of the stockholder in the event the Company proposes to sell additional shares (preemptive rights).

**ANIP ACQUISITION COMPANY**  
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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**11. CAPITALIZATION (Continued)**

**Loan Receivable from Stockholder**

In connection with the issuance of the Series B Preferred in 2006, a stockholder purchased 18,812 shares of Series B Preferred from the Company at an aggregate purchase price of \$200,000. Concurrent with the purchase, the Company loaned the stockholder \$200,000 to finance the purchase of the Series B Preferred. In connection with the issuance of the Series C Preferred during the year ended December 31, 2010, the stockholder purchased 5,231 shares of Series C Preferred from the Company at an aggregate purchase price of \$57,535. Concurrent with the purchase, the Company loaned the stockholder \$57,535 to finance the purchase of the Series C Preferred. The loans bore interest at 5% and were secured by the respective Preferred Stock purchased by the stockholder. The outstanding balance totaled \$90,215 as of December 31, 2010 and was recorded as loan receivable from stockholder in the accompanying balance sheet. During the year ended December 31, 2011, the Company canceled the indebtedness from the stockholder in exchange for the surrender of all the stockholder's shares of common and preferred stock in the Company. Accordingly, there was no outstanding balance on the loan receivable from stockholder as of December 31, 2011.

**12. STOCK-BASED COMPENSATION**

The Company has adopted the ANIP Acquisition Company 2005 Stock Option Plan ("the Plan"). The maximum number of shares which may be subject to option and sold under the Plan was originally 108,750. During the year ended December 31, 2007, the Board of Directors of the Company amended the Plan and increased the maximum number of shares to issue by an additional 204,000 shares.

As of December 31, 2011, the Company has granted 17,500 options and has 295,250 shares available for future grants. Under the terms of the Stock Option Plan, stock options are granted at exercise prices not less than the fair value of the stock at the date of grant. The Board establishes the exercise price at the time each option is granted. Unless terminated at an earlier date, options expire on the tenth anniversary of the date of grant. Generally, share options vest over 5 years. The Board determines the effect on an option grant as of the disability, death, or other change in the employment of a participant, and the extent to which the participant, the participant's legal representative, conservator, guardian, or designated beneficiary may exercise rights under the option grant. The Company intends to issue new shares to satisfy share options upon exercise.

The Company has adopted ASC 718, *Compensation—Stock Compensation*, which requires that the cost of equity-based service awards be measured based on the grant-date fair value of the award. The cost will be recognized over the period during which an employee is required to provide service in exchange for the award or the requisite service period. The Company recognizes stock-based compensation expense ratably over the vesting periods of options, adjusted for estimated forfeitures. For the years ending December 31, 2011 and 2010, the Company recognized non-cash compensation expense related to stock options of \$4,550 and \$6,405, respectively.

The Company values options using the Black-Scholes option-pricing model which was developed for use in estimating the fair value of traded options that are fully transferable and have no vesting restrictions. Black-Scholes and other option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's stock-based awards

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**12. STOCK-BASED COMPENSATION (Continued)**

have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock-based awards.

The following is a summary of option activity for the year ending December 31, 2011:

	<u>Number</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding at December 31, 2010	17,500	\$ 11.00	6.2	—
Granted	—	—		
Exercised	—	—		
Forfeited	—	—		
Expired	—	—		
Options outstanding at December 31, 2011	<u>17,500</u>	<u>\$ 11.00</u>	<u>5.2</u>	<u>—</u>
Options exercisable at December 31, 2011	<u>16,680</u>	<u>\$ 11.00</u>	<u>4.2</u>	<u>—</u>

The following is a summary of non-vested options for the year ending December 31, 2011:

	<u>Number</u>	<u>Weighted Average Grant Date Fair Value</u>
Nonvested options outstanding at December 31, 2010	4,102	\$ 1.30
Granted	—	—
Vested	(3,282)	1.30
Forfeited	—	—
Nonvested options outstanding at December 31, 2011	<u>820</u>	<u>\$ 1.32</u>

The total compensation cost related to non-vested awards not yet recognized as of December 31, 2011 totaled \$455 and will be recognized over a weighted average period of 0.25 years.



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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**12. STOCK-BASED COMPENSATION (Continued)**

The following is a summary of option activity for the year ending December 31, 2010:

	Number	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2009	33,625	\$ 10.83	6.7	—
Granted	—	—		
Exercised	—	—		
Forfeited	(16,125)	10.65		
Expired	—	—		
Options outstanding at December 31, 2010	<u>17,500</u>	<u>\$ 11.00</u>	<u>6.2</u>	<u>—</u>
Options exercisable at December 31, 2010	<u>13,398</u>	<u>\$ 11.00</u>	<u>5.2</u>	<u>—</u>

The following is a summary of non-vested options for the year ending December 31, 2010:

	Number	Weighted Average Grant Date Fair Value
Nonvested options outstanding at December 31, 2009	11,813	\$ 1.30
Granted	—	—
Vested	(3,281)	1.30
Forfeited	(4,430)	0.85
Nonvested options outstanding at December 31, 2010	<u>4,102</u>	<u>\$ 1.30</u>

**13. INCOME TAXES**

The Company has no current tax provision due to its current and accumulated losses, which result in net operating loss carryforwards. At December 31, 2011, the Company had approximately \$32 million in net operating loss carryforwards, which begin to expire in 2025. The utilization of the net operating loss carryforwards may be limited in future years as prescribed by Section 382 of the United States Internal Revenue Code. The net operating loss carryforwards, as well as other items, have generated deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. In assessing the realizability of the deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Based upon the historical losses and uncertainty of future taxable income, management has established a 100% valuation allowance as of December 31, 2011 and 2010.

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**13. INCOME TAXES (Continued)**

The components of the deferred tax asset are as follows as of December 31:

	2011	2010
Net operating loss carryforwards	\$ 12,965,000	\$ 11,742,000
Allowance for doubtful accounts	—	275,000
Inventory	107,000	122,000
Prepaid expenses	(49,000)	(53,502)
Book vs. tax depreciation	(289,000)	(300,000)
Accrued expenses	287,000	202,000
Charitable contributions	16,000	16,000
Miscellaneous	43,000	107,502
Total deferred tax asset, net	13,080,000	12,111,000
Valuation allowance	(13,080,000)	(12,111,000)
Deferred tax asset, net	\$ —	\$ —

The difference between the Company's reported income tax benefit and the income tax benefit that would have resulted from applying Federal statutory tax rates to the pre-tax loss from operations relates primarily to the effect of state income taxes and changes in the valuation allowance.

**14. COMMITMENTS AND CONTINGENCIES**

**Operating Leases**

The Company leases equipment under operating leases that expire in September 2012. Future minimum lease payments due under these leases total \$6,284 as of December 31, 2011.

Rent expense for the years ended December 31, 2011 and 2010 totaled \$18,633 and \$49,893, respectively.

**Government Regulation**

The Company's products and facilities are subject to regulation by a number of Federal and State governmental agencies. The Food and Drug Administration (FDA), in particular, maintains oversight of the formulation, manufacture, distribution, packaging and labeling of all of the Company's products. The Drug Enforcement Administration (DEA) maintains oversight over the Company's products that are considered controlled substances.

**Unapproved Products**

Certain of the Company's generic products are marketed without approved New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA). During the years ended December 31, 2011 and 2010, combined net revenues for these products totaled \$3.5 million and \$95,000, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 compliance policy guide, *Marketed New Drugs without Approved NDAs or*

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**14. COMMITMENTS AND CONTINGENCIES (Continued)**

ANDAs. Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. The Company believes that so long as it complies with applicable manufacturing and labeling standards, it will be in compliance with the FDA's current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, the Company may be required to seek FDA approval for these products or withdraw such products from the market (Note 16).

In addition, one group of products that the Company manufactures on behalf of a contract customer is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2011 and 2010 was \$1.3 million and \$623,000, respectively.

The Company receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company's royalties on the net sales of these unapproved products for the years ended December 31, 2011 and 2010 were \$320,000 and \$118,000, respectively.

**Other Commitments and Contingencies**

All manufacturers of the drug Reglan® and its generic equivalent metoclopramide, including the Company, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan® prior to the FDA's February 2009 Black Box warning requirement. The Company has been named and served in 79 separate complaints, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, the Company was dismissed with prejudice from all New Jersey cases. Management considers the Company's exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by the Company prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) the Company's market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once the Company received a request for change of labeling from the FDA, it submitted its proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, the Company's management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. The Company cannot provide assurances that the outcome of these matters will not have an adverse effect on its business,

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**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**14. COMMITMENTS AND CONTINGENCIES (Continued)**

results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

**15. FAIR VALUE DISCLOSURES**

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. US GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of the Company's funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, notes payable, and other current liabilities) approximate their carrying values because of their short-term nature.

The Company's stock purchase warrants are classified as derivative liabilities and are measured at fair value using level 3 inputs. The fair value of stock purchase warrants is determined based on the Black-Scholes option pricing model or an equity allocation model. These models require the use of unobservable inputs such as fair value of the Company's common and preferred stock, expected term, anticipated volatility, future interest and interest rates, expected cash flows and the number of outstanding common and preferred shares as of a future date. The Company determined that the fair value of the derivative liabilities, and the changes in such fair value, was immaterial as of and for the years ended December 31, 2011 and 2010 (Note 2). The Company has no other financial assets and liabilities that are measured at fair value. The Company has no nonfinancial assets or liabilities that are measured at fair value.

**16. SUBSEQUENT EVENTS**

**Conversion of Convertible Debt**

In June 2012, the holders of the Consolidated 2011 Convertible Notes converted all outstanding convertible debt and accrued interest into 2,375,312 shares of Series D Preferred, of which 27,359 shares were issued from warrant exercise, and 22,484 shares of common stock, also from warrant exercise (Note 11). Accordingly, the Company has classified all of its outstanding convertible debt as of December 31, 2011 as long-term on the balance sheet as of December 31, 2011.

**New Line of Credit**

In June 2012, the Company entered into a new revolver loan agreement with a commercial bank in the amount of \$5,000,000. The revolver loan bears interest daily at LIBOR plus 5% and is secured by substantially all of the Company's assets. The revolver loan agreement expires in June 2015.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**16. SUBSEQUENT EVENTS (Continued)**

**Transaction Bonus Agreements**

In September 2012, the Company entered into Transaction Bonus Agreements ("Bonus Agreements") with certain management employees. Under the terms of the Bonus Agreements, the Company will make bonus payments, upon a change of control transaction resulting in Net Proceeds being available for distribution to the Company's shareholders, to certain executives. The bonus payments are based upon the amount of Net Proceeds, as defined in the Bonus Agreements, realized in a change of control transaction. The Company's obligation to make the bonus payments are subject to, among other things, a minimum level of Net Proceeds and continuous employment of the executive. Under the terms of the Bonus Agreements, the BioSante Pharmaceuticals, Inc. ("BioSante") transaction discussed below would be considered a change of control transaction.

**Merger Agreement with BioSante**

In October 2012, the Company entered into a definitive merger agreement with BioSante by which the companies will merge in an all-stock transaction. Under the terms of the agreement, upon completion of the merger, BioSante will issue to Company stockholders shares of BioSante common stock such that the former Company stockholders will own approximately 53 percent of the combined company's shares outstanding, and the former BioSante stockholders will own approximately 47 percent, subject to adjustment as provided in the merger agreement. In addition, immediately prior to the merger, BioSante plans to distribute to its then current stockholders contingent value rights (CVR) providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel® (female testosterone gel). Upon completion of the merger, the combined company will be renamed ANI Pharmaceuticals, Inc. and will operate under the leadership of the Company's management team. The board of directors of the combined company is expected to have two directors from BioSante and five Company directors. Consummation of the merger is subject to a number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible but not waived, the merger will not be consummated. The merger is expected to close during the first quarter of calendar 2013.

**Opium Tincture**

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is a non-NDA product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need

**ANIP ACQUISITION COMPANY  
d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Financial Statements (Continued)**

**For the Years Ended December 31, 2011 and 2010**

**16. SUBSEQUENT EVENTS (Continued)**

to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Unaudited Condensed Balance Sheets**

	September 30, 2012	December 31, 2011 As Restated (Note 2)
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 148,331	\$ —
Accounts receivable, net	5,622,997	5,104,568
Inventories, net	2,494,635	2,107,463
Prepaid expenses	402,335	224,618
<b>Total Current Assets</b>	<b>8,668,298</b>	<b>7,436,649</b>
<b>Property and Equipment</b>		
Land	86,949	86,949
Buildings	3,682,006	3,682,006
Machinery, furniture and equipment	3,553,732	3,445,284
Construction in progress	4,100	35,660
	<u>7,326,787</u>	<u>7,249,899</u>
Less: accumulated depreciation and amortization	2,533,368	2,145,630
<b>Total Property and Equipment, net</b>	<b>4,793,419</b>	<b>5,104,269</b>
<b>Other Assets</b>		
Intangible assets, net	97,500	135,000
<b>Total Other Assets</b>	<u>97,500</u>	<u>135,000</u>
<b>Total Assets</b>	<b><u>\$ 13,559,217</u></b>	<b><u>\$ 12,675,918</u></b>

The accompanying notes are an integral part of these condensed financial statements.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Unaudited Condensed Balance Sheets (Continued)**

	<u>September 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u> <u>As Restated</u> <u>(Note 2)</u>
<b>Liabilities and Stockholders' Deficit</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,296,220	\$ 1,208,323
Accrued expenses	876,712	824,011
Returned goods reserve	387,615	252,045
Borrowings under line of credit	3,428,776	3,064,414
Notes payable	—	300,000
Current liabilities of discontinued operation	378,565	512,275
<b>Total Current Liabilities</b>	<u>6,367,888</u>	<u>6,161,068</u>
<b>Convertible Debt</b>	—	16,581,933
<b>Total Liabilities</b>	<u>6,367,888</u>	<u>22,743,001</u>
<b>Commitments and Contingencies (Note 11)</b>		
<b>Redeemable Convertible Preferred Stock</b>		
10% Convertible Preferred Stock, Series A, \$0.10 par value, stated value of \$100 per share; 108,494 shares authorized, 102,774 shares issued and outstanding including cumulative dividends of \$1,875,665 and \$995,557 at September 30, 2012 and December 31, 2011, respectively	11,268,465	10,388,357
10% Convertible Preferred Stock, Series B, \$0.10 par value, stated value of \$110 per share; 118,915 shares authorized, 78,491 shares issued and outstanding including cumulative dividends of \$1,575,747 and \$836,368 at September 30, 2012 and December 31, 2011, respectively	10,299,095	9,559,716
12% Convertible Preferred Stock, Series C, \$0.10 par value, stated value of \$110 per share; 37,956 shares authorized, 34,810 shares issued and outstanding including cumulative dividends of \$850,905 and \$448,148 at September 30, 2012 and December 31, 2011, respectively	4,671,169	4,268,412
10% Convertible Preferred Stock, Series D, \$0.10 par value, stated value of \$30 per share; 3,400,000 shares authorized, 2,375,312 shares issued and outstanding including cumulative dividends of \$2,304,378 at September 30, 2012	19,916,760	—
<b>Total Redeemable Convertible Preferred Stock</b>	<u>46,155,489</u>	<u>24,216,485</u>
<b>Stockholders' Deficit</b>		
Common Stock, \$0.10 par value, 3,700,000 shares authorized; 23,613 and 1,129 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	2,361	113
Additional paid-in capital	1,081,477	1,086,461
Accumulated deficit	(40,047,998)	(35,370,142)
<b>Total Stockholders' Deficit</b>	<u>(38,964,160)</u>	<u>(34,283,568)</u>
<b>Total Liabilities and Stockholders' Deficit</b>	<u>\$ 13,559,217</u>	<u>\$ 12,675,918</u>

The accompanying notes are an integral part of these condensed financial statements.



**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Unaudited Condensed Statements of Operations**

<b>For the Nine-Month Periods Ended September 30,</b>	<b>2012</b>	<b>2011 As Restated (Note 2)</b>
Net Revenues	\$ 15,049,619	\$ 11,954,985
<b>Operating Expenses</b>		
Cost of Sales (excluding depreciation and amortization)	6,292,377	4,875,692
Salaries and benefits	3,516,427	3,245,637
Freight	242,814	178,499
Research and development	636,726	726,960
Selling, general and administrative	2,961,649	2,744,334
Depreciation and amortization	425,238	391,917
Total Operating Expenses	<u>14,075,231</u>	<u>12,163,039</u>
Operating Income (Loss) from Continuing Operations	974,388	(208,054)
<b>Other Expense</b>		
Interest expense	1,239,137	1,597,156
Other expense	190,605	254,006
Total Other Expenses	<u>1,429,742</u>	<u>1,851,162</u>
Net Loss from Continuing Operations	(455,354)	(2,059,216)
<b>Discontinued Operation</b>		
Gain on Discontinued Operation	104,120	291,096
Net Loss	<u>\$ (351,234)</u>	<u>\$ (1,768,120)</u>
<b>Computation of Loss from Continuing Operations Attributable to Common Stockholders:</b>		
Net Loss from Continuing Operations	\$ (455,354)	\$ (2,059,216)
Preferred Stock Dividends	(4,326,622)	(582,293)
Loss from Continuing Operations Attributable to Common Stockholders, basic and diluted	<u>\$ (4,781,976)</u>	<u>\$ (2,641,509)</u>
<b>Basic and diluted income (loss) per share:</b>		
Continuing operations	\$ (449.10)	\$ (335.26)
Discontinued operation	9.78	36.95
Basic and diluted loss per share	<u>\$ (439.32)</u>	<u>\$ (298.31)</u>
Basic and diluted weighted-average shares outstanding	<u>10,648</u>	<u>7,879</u>

The accompanying notes are an integral part of these condensed financial statements.

**ANIP ACQUISITION COMPANY**  
d/b/a ANI Pharmaceuticals, Inc.

**Unaudited Condensed Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit**

**For the Nine-Month Period Ended September 30, 2012**

	Redeemable Convertible Preferred Stock				Stockholders' Deficit			
	10% Convertible Preferred Stock, Series A	10% Convertible Preferred Stock, Series B	12% Convertible Preferred Stock, Series C	10% Convertible Preferred Stock, Series D	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total
Balance, January 1, 2012 As Restated (Note 2)	\$ 10,388,357	\$ 9,559,716	\$ 4,268,412	\$ —	\$ 113	\$ 1,086,461	\$ (35,370,142)	\$ (34,283,568)
Issuance of common stock upon warrant exercise	—	—	—	—	2,248	(2,248)	—	—
Issuance of preferred stock upon warrant exercise	—	—	—	2,736	—	(2,736)	—	(2,736)
Issuance of preferred stock upon convertible debt conversion	—	—	—	17,609,646	—	—	—	—
Preferred stock dividends	880,108	739,379	402,757	2,304,378	—	—	(4,326,622)	(4,326,622)
Net loss	—	—	—	—	—	—	(351,234)	(351,234)
Balance, September 30, 2012	<u>\$ 11,268,465</u>	<u>\$ 10,299,095</u>	<u>\$ 4,671,169</u>	<u>\$ 19,916,760</u>	<u>\$ 2,361</u>	<u>\$ 1,081,477</u>	<u>\$ (40,047,998)</u>	<u>\$ (38,964,160)</u>

The accompanying notes are an integral part of these condensed financial statements.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Unaudited Condensed Statements of Cash Flows**

<b>For the Nine-Month Periods Ended September 30,</b>	<b>2012</b>	<b>2011 As Restated (Note 2)</b>
<b>Cash Flows From Operating Activities</b>		
Net loss from continuing operations	\$ (351,234)	\$ (1,768,120)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Depreciation and amortization	425,238	391,917
Non-cash interest relating to convertible debt	1,027,713	1,396,641
Changes in operating assets and liabilities:		
Accounts receivable	(518,429)	(2,128,805)
Inventories	(387,172)	221,839
Prepaid expenses	83,031	668,718
Accounts payable	87,897	(726,547)
Accrued expenses	188,271	559,471
Net Cash and Cash Equivalents Provided By (Used in) Continuing Operations	555,315	(1,384,886)
Net Cash Used in Discontinued Operation	(133,710)	(519,611)
Net Cash and Cash Equivalents Provided By (Used in) Operating Activities	421,605	(1,904,497)
<b>Cash Flows From Investing Activities</b>		
Acquisition of property and equipment, net of disposals	(76,888)	(99,254)
Acquisition of intangible assets	—	(160,000)
Net Cash and Cash Equivalents Used in Investing Activities	(76,888)	(259,254)
<b>Cash Flows From Financing Activities</b>		
Borrowings under line of credit, net	364,362	949,503
Repayments on long-term debt	—	(299,999)
Repayments of notes payable, net	(300,000)	(275,000)
Proceeds from convertible debt	—	1,816,326
Payment of debt issuance costs	(260,748)	—
Net Cash and Cash Equivalents (Used in) Provided by Financing Activities	(196,386)	2,190,830
Change in Cash and Cash Equivalents	148,331	27,079
Cash and cash equivalents, beginning of period	—	—
Cash and cash equivalents, end of period	\$ 148,331	\$ 27,079
<b>Supplemental disclosure for cash flow information:</b>		
Cash paid for interest	\$ 211,424	\$ 200,515
<b>Supplemental non-cash investing and financing activities:</b>		
Preferred stock dividends	\$ 4,326,622	\$ 582,293
Issuance of common and preferred stock upon warrant exercise	\$ 4,984	\$ —
Forgiveness of preferred stock dividends	\$ —	\$ 13,783,848
Issuance of preferred stock upon convertible debt conversion	\$ 17,609,646	\$ —

The accompanying notes are an integral part of these condensed financial statements.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

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**Unaudited Condensed Financial Statements**  
**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**ANIP ACQUISITION COMPANY  
d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Overview**

ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc. ("the Company") is a specialty pharmaceutical company, developing and marketing generic and branded prescription products. In two facilities located in Baudette, Minnesota, with combined manufacturing, packaging and laboratory capacity totaling 173,000 sq. ft., the Company manufactures oral solid dose products, as well as liquids and topicals, including those that must be manufactured in a fully contained environment due to their potency and/or toxicity. The Company also performs contract manufacturing for other pharmaceutical companies.

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. Since inception, the Company has incurred a cumulative loss from operations and has had operating cash flow deficits. Management believes that as a result of the sale of the Gulfport operation (Note 6), the Company can focus on prescription pharmaceuticals and increase its revenues while controlling operating costs in order to improve operating performance in the future. To date, the Company has funded its cash flow requirements using debt, equity, and equity-linked financings. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations and the ability to generate sufficient cash from operations and potential other funding sources to meet the Company's obligations as they become due. Management believes the going-concern basis is appropriate for the accompanying financial statements based on its current operating plan through December 31, 2013. In addition, management has the intent and ability to take additional actions as necessary to continue as a going concern, including by drawing on available funding sources and/or reducing discretionary operating costs.

**Basis of Accounting**

The accompanying condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP). In the opinion of management, the accompanying condensed financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations and cash flows. The condensed balance sheet at December 31, 2011, has been derived from audited financial statements as of that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the Securities and Exchange Commission. The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these condensed financial statements are read in conjunction with the audited financial statements and notes previously distributed.

**ANIP ACQUISITION COMPANY  
d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Use of Estimates**

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying condensed financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, returns and other allowances, allowance for inventory obsolescence, derivative liabilities, and the depreciable lives of fixed assets. Actual results could differ from those estimates.

**Credit and Vendor Concentration**

The Company's customers are primarily pharmaceutical companies, wholesale distributors, chain drug stores, and group purchasing organizations. During the nine months ended September 30, 2012, three customers represented approximately 24%, 21%, and 12% of net revenues, respectively. As of September 30, 2012, accounts receivable from these customers totaled \$3,562,346. As of December 31, 2011, accounts receivable from these customers totaled \$3,212,359.

During the nine months ended September 30, 2012, the Company purchased approximately 43% of total costs of goods sold from two suppliers. As of September 30, 2012, amounts payable to these suppliers totaled \$159,705. As of December 31, 2011, amounts payable to these suppliers totaled \$205,838.

**Cash and Cash Equivalents**

Cash equivalents consist of investments in low risk, highly liquid securities with original maturities of three months or less at the time of purchase. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation (FDIC) limits.

**Revenue Recognition**

Revenue is recognized for product sales upon shipment, when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and the Company has no further performance obligations. These estimates reduce gross revenues to net revenues in the accompanying condensed statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying condensed balance sheets.

**Accounts Receivable**

The Company utilizes the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable. The Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. The Company's estimate is based on historical collection experience and a review of the current status of trade accounts

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

receivable. The Company determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. The Company determined that no allowance for doubtful accounts was necessary as of September 30, 2012 and December 31, 2011.

**Accruals for Chargebacks, Returns and Other Allowances**

The Company's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these gross-to-net accruals exceed 65% of generic and branded gross product sales and reduce gross revenues to net revenues in the accompanying condensed statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying condensed balance sheets. The Company continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. The Company makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances.

*Chargebacks*

Chargebacks, primarily from wholesalers, are the most significant of the Company's accruals. Chargebacks result from arrangements the Company has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost (WAC).

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price (ASP) for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- A change in customer mix
- A change in negotiated terms with customers
- A change in product sales mix
- A change in the volume of off-contract purchases
- Changes in WAC

As necessary, the Company adjusts ASPs based on anticipated changes in the factors above.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The difference between ASP and WAC is recorded, at the same time the Company recognizes revenue from the product sale, as a reduction in both gross revenues and accounts receivable.

To evaluate the adequacy of its chargeback accruals, the Company obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. The Company continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

*Returns*

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The Company's product returns are settled through the issuance of a credit to the customer. The Company's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. The Company continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

*Administrative Fees and Other Rebates*

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers, consistent with pharmaceutical industry practice. The Company accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, the Company obtains on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. The Company continually monitors administrative fee activity and adjusts its accruals when it believes that actual administrative fees will differ from the accruals.

*Prompt Payment Discounts*

Sales discounts are granted for prompt payment. The reserve for sales discounts is based on invoices outstanding. The Company assumes based on past experience that 100% of available discounts will be taken.



**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

The following table summarizes activity in the condensed balance sheets for accruals and allowances for the nine months ended September 30, 2012:

	<u>Accruals for Chargebacks, Returns and Other Allowances</u>			
	<u>Chargebacks</u>	<u>Returns</u>	<u>Administrative Fees and Other Rebates</u>	<u>Prompt Payment Discounts</u>
Balance at December 31, 2011	\$ 3,680,838	\$ 252,045	\$ 238,195	\$ 166,439
Accruals/Adjustments	15,996,550	486,844	925,488	522,812
Credits Taken Against Reserve	(15,348,165)	(351,274)	(892,370)	(481,435)
Balance at September 30, 2012	<u>\$ 4,329,223</u>	<u>\$ 387,615</u>	<u>\$ 271,313</u>	<u>\$ 207,816</u>

**Inventories**

Inventories are stated at the lower of cost or net realizable value. The Company values inventory at standard cost. The Company reviews and adjusts standard costs periodically and believes that its inventory, as valued, approximates weighted average cost.

**Property and Equipment**

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation is recorded on a straight-line basis over estimated useful lives as follows:

Buildings and improvements	20 - 40 years
Machinery, furniture and equipment	3 - 10 years

Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest if any. Depreciation is not recorded on construction in progress until such time as the assets are placed in service. During the nine months ended September 30, 2012 and the year ended December 31, 2011, there was no material interest capitalized into construction in progress.

Depreciation expense for the nine months ended September 30, 2012 and 2011 totaled \$387,738 and \$379,419, respectively. The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets to be disposed are reportable at the lower of the carrying amount or fair value, less costs to sell. Management determined that no assets were impaired and no assets were held for disposal as of September 30, 2012 and December 31, 2011.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Research and Development Expenses**

Research and development costs are expensed as incurred and primarily consist of expenses relating to product development. Research and development costs totaled \$636,726 and \$726,960 for the nine months ended September 30, 2012 and 2011, respectively.

**Stock-Based Compensation**

The Company expenses the estimated fair value of stock-based awards made in exchange for employee services over the requisite employee service period. Stock-based compensation cost for stock options is determined at the grant date using an option-pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

**Income Taxes**

Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company evaluates and accounts for uncertain income tax positions in accordance with Accounting Standards Codification (ASC) 740, *Income Taxes*. ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. In accordance with ASC 740, the Company began accounting for uncertain income tax positions during the year ended December 31, 2009. The Company did not identify any uncertain income tax positions that could have a material impact to the financial statements. The Company is subject to taxation in various jurisdictions and remains subject to examination by taxing jurisdictions for the years 2004 and all subsequent periods due to the availability of net operating loss carryforwards.

The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. The Company did not have any amounts accrued relating to interest and penalties as of September 30, 2012 and December 31, 2011.

The Company considers potential tax effects resulting from discontinued operations and records intra-period tax allocations, when those effects are deemed material.

**ANIP ACQUISITION COMPANY**  
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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Income (Loss) per Share**

Basic income (loss) per share is calculated by dividing net income (loss) less preferred stock dividends by the weighted-average number of shares of common stock outstanding during the period. For periods of net income, and when the effects are dilutive, diluted earnings per share is computed by dividing net income (as adjusted for interest expense on convertible debt, if outstanding) by the weighted-average number of shares of common stock outstanding plus the number of shares that would be outstanding if warrants were exercised for common shares or preferred stock convertible into common shares, using the treasury method, or if convertible debt and convertible preferred stock had been converted into common shares, using the if-converted method. Diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses; accordingly, diluted loss per share is the same as basic loss per share.

The number of anti-dilutive shares, consisting of common stock options, warrants exercisable for common stock, warrants exercisable for preferred stock, convertible debt, and convertible preferred stock which have been excluded from the computation of diluted loss per share for the nine months ended September 30, 2012 and 2011, were 2,500,134 and 2,067,330, respectively.

Basic and diluted loss per share has been adjusted for a 10:1 reverse stock split effected on January 28, 2011.

**Redeemable Preferred Stock**

The carrying value of the Company's redeemable convertible preferred stock is increased by the accretion of any related discounts and accrued but unpaid dividends so that the carrying amount will equal the redemption amount at the dates the stock becomes redeemable. The Company's Series A, B, C and D preferred stock is redeemable at the option of the holders, subject to certain additional requirements (Note 9).

**Stock Splits and Other Reclassifications**

In January 2011 the Company's Board of Directors approved a resolution to affect a one-for-ten reverse stock split of the Company's common and preferred stock with a corresponding change to the par values. The par values, and all common and preferred share numbers for all periods presented, have been adjusted retrospectively to reflect the change in par value and the one-for-ten reverse stock split.

The Company historically classified its redeemable convertible preferred stock as "permanent equity" according to accepted practices for private companies. As of December 31, 2011, and for all periods presented, the Company has classified its redeemable convertible preferred stock as "temporary equity" as required by the rules and regulations of the Securities and Exchange Commission.

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

**Financial Instruments**

The Company's balance sheets include various financial instruments (primarily cash and cash equivalents, prepaid expenses, accounts receivable, accounts payable, accrued expenses, borrowings under line of credit, notes payable and other current liabilities) that approximate fair value. Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.

Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

See Note 12 for additional information regarding fair value.

**Recent Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2011-05, *Presentation of Comprehensive Income*. ASU 2011-05 revises the manner in which entities present comprehensive income in their financial statements. The new guidance removes the presentation options in Accounting Standards Codification 220 and requires entities to report components of comprehensive income in either (1) a continuous statement of comprehensive income or (2) two separate but consecutive statements. ASU 2011-05 did not change the items that must be reported in other comprehensive income. The Company adopted the provisions of ASU 2011-05 in the first quarter of 2012. As the Company's net loss is the same as comprehensive loss, the Company did not present a statement of comprehensive loss.

**Subsequent Events**

The Company performed an evaluation of subsequent events through December 11, 2012, the date the accompanying condensed financial statements were issued, and did not identify any material events that warrant disclosure, except as disclosed in Note 13.

**2. RESTATEMENT OF 2011 FINANCIAL STATEMENTS**

In connection with certain convertible debt financings in 2010 and 2009, the Company issued stock purchase warrants to the lenders to purchase the Company's preferred stock. The Company allocated fair value to the stock purchase warrants issued in 2010 (\$667,021) and 2009 (\$76,050) based on management's estimate of fair value. In 2012, in connection with the review of certain equity

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**2. RESTATEMENT OF 2011 FINANCIAL STATEMENTS (Continued)**

transactions, the Company obtained independent third-party valuations of its equity securities and determined that the fair value of the stock purchase warrants issued in 2010 and 2009 (and for all subsequent periods) was *de minimis* and that the prior allocation should be revised. As a result, the Company has restated its 2011 and 2010 annual financial statements to correctly value the warrants. This correction resulted in changes to the following financial statement line items as of and for the periods indicated:

	As Previously Reported	Increase (Decrease)	As Restated
<b>Nine months ended September 30, 2011</b>			
<i>Statement of Operations</i>			
Interest expense	\$ (1,935,975)	\$ (338,819)	\$ (1,597,156)
Total other expense	(2,189,981)	(338,819)	(1,851,162)
Net loss from continuing operations	(2,398,035)	(338,819)	(2,059,216)
Net loss	(2,106,939)	(338,819)	(1,768,120)
<i>Statement of Cash Flows</i>			
Net loss	\$ (2,106,939)	\$ (338,819)	\$ (1,768,120)
Non-cash interest relating to convertible debt	1,735,460	(338,819)	1,396,641
<b>As of December 31, 2011</b>			
Additional paid-in capital	\$ 1,829,532	\$ (743,071)	\$ 1,086,461
Accumulated deficit	(36,113,213)	(743,071)	(35,370,142)

**3. ACCOUNTS RECEIVABLE**

Accounts receivable consist of the following as of:

	September 30, 2012	December 31, 2011
Accounts receivable, gross	\$ 10,196,336	\$ 8,991,124
Adjustments for chargebacks and other allowances	(4,573,339)	(3,886,556)
Accounts receivable, net	<u>\$ 5,622,997</u>	<u>\$ 5,104,568</u>

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**4. INVENTORIES**

Inventories consist of the following as of:

	September 30, 2012	December 31, 2011
Raw materials	\$ 489,079	\$ 836,724
Packaging materials	592,530	687,185
Work-in-progress	385,294	95,762
Finished goods	1,034,924	501,230
	<u>2,510,827</u>	<u>2,120,901</u>
Reserve for excess/obsolete inventories	(16,192)	(13,438)
Inventories, net	<u>\$ 2,494,635</u>	<u>\$ 2,107,463</u>

**5. NOTES PAYABLE**

Notes payable consist of amounts previously owed to suppliers as accounts payable that were subsequently converted to notes payable, as agreed upon by the Company and the respective suppliers. During the year ended December 31, 2009, the Company reached an agreement with a supplier to convert \$938,276 of accounts payable to a note payable. Under the terms of the agreement, the Company was required make monthly payments of principal amounts plus interest of 6% per annum. In May 2011, the Company reached an agreement with the supplier to settle all amounts due by the Company in full and final for \$175,000. The resulting gain is included as a gain on the discontinued operation in the accompanying statements of operations. The balance was paid in full in May 2011.

During October 2011, the Company reached a settlement agreement with another supplier in the amount of \$450,000. Under the terms of the agreement, the Company was required to make monthly payments of \$50,000. Amounts due under this agreement totaled \$300,000 at December 31, 2011. The balance was paid in full in July 2012.

**6. DISCONTINUED OPERATION**

On September 17, 2010, the Company sold its operation in Gulfport, Mississippi to a third-party for \$2,300,000. This operation manufactured over-the-counter pharmaceutical products, which were sold under private-label contracts to retail pharmacy chains. The net assets of the Gulfport operation had a carrying value of \$5,819,473 on the date of the sale, resulting in a loss of \$3,669,245 on disposal of the discontinued operation. The decision to sell the Gulfport operation was based on the historical underperformance and recurring losses and the anticipated need for continued financing from outside sources to maintain ongoing operations.

As of September 30, 2012 and December 31, 2011, total net liabilities associated with discontinued operations were \$378,565 and \$512,275, respectively, and consisted of balances due to various vendors of the discontinued operation.

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**7. LINES OF CREDIT**

Prior to June 2012, the Company had borrowings under a line of credit agreement with a commercial lender. Due to covenant defaults, the Company entered into a forbearance agreement in May 2010, which was most recently amended in October 2011. Under the terms of the amended forbearance agreement, the Company could borrow an amount equal to the lesser of the borrowing base, as defined, or \$3.5 million. Interest accrued at an annual rate of the Base Rate, as defined, plus 6.0%. In addition, a usage fee equal to 0.75% per annum of the unused facility and a management fee equal to \$9,000 per annum were assessed monthly. The line of credit was secured by substantially all of the Company's assets. Borrowings under the line of credit plus outstanding checks as of December 31, 2011 totaled \$3,064,414; the line of credit and amended forbearance agreement expired in June 2012 and all amounts borrowed were repaid in full at that time.

In June 2012, the Company entered into a new revolver loan agreement with a commercial bank in the amount of \$5,000,000. The revolver loan agreement bears interest daily at the greater of (i) LIBOR or 1% plus (ii) 5%, and is secured by substantially all of the Company's assets. In addition, a usage fee equal to 0.375% per annum of the unused facility and a management fee equal to \$18,000 per annum are assessed monthly. Under the agreement, the Company must maintain a minimum fixed charge coverage ratio of 1.1 to 1.0, calculated by dividing (a) (i) earnings before interest, taxes, depreciation and amortization (EBITDA) less (ii) unfinanced capital expenditures, by the sum of cash paid for (b) (i) interest and (ii) monitoring and advisory fees (Note 8). Also, the Company must generate at least \$800,000 in EBITDA measured on a trailing four-quarter basis. Restrictive covenants apply to, among other things, research and development expenditures, additional liens, mergers or consolidations, and sales of assets. The revolver loan agreement expires in June 2015. As of September 30, 2012, \$3,428,776 was outstanding on the revolver, at an effective interest rate of 6.0%.

**8. CONVERTIBLE DEBT**

In 2009, the Company issued \$2,502,814 of Secured Subordinated Convertible Notes ("the 2009 Convertible Notes"). The 2009 Convertible Notes, which bore interest at 10% per annum, were due on September 3, 2011. Interest on the 2009 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2009 Convertible Notes were secured by a second lien on substantially all of the Company's assets and included financial covenants and limitations on the Company's ability to enter into certain transactions while the 2009 Convertible Notes were outstanding.

In connection with the issuance of the 2009 Convertible Notes, the Company also issued warrants to acquire shares of the Company's common and preferred stock ("the 2009 Warrants"). The 2009 Warrants, accounted for as derivative liabilities, expired on the earlier of the repayment of the 2009 Convertible Notes or a Qualified Public Offering, as defined, and had an exercise price of \$0.10 per share. The estimated fair value of the 2009 Warrants upon issuance, based on an independent third-party valuation of the Company's equity securities, was deemed immaterial.

In 2010, the Company issued \$8,474,951 of Secured Subordinated Convertible Notes ("the 2010 Convertible Notes"). The 2010 Convertible Notes, which bore interest at 14% per annum, were due on September 3, 2011. Interest on the 2010 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock. The 2010 Convertible Notes were

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**8. CONVERTIBLE DEBT (Continued)**

secured by a second lien on substantially all of the Company's assets and included financial covenants and limitations on the Company's ability to enter into certain transactions while the 2010 Convertible Notes were outstanding.

In connection with the issuance of the 2010 Convertible Notes, the Company also issued warrants to acquire shares of the Company's Series D Preferred stock ("the 2010 Warrants"). The 2010 Warrants, accounted for as derivative liabilities, expired on the earlier of the repayment of the 2010 Convertible Notes or a Qualified Public Offering, as defined, and had an exercise price of \$0.10 per share. The estimated fair value of the 2010 Warrants upon issuance, based on an independent third-party valuation of the Company's equity securities, was deemed immaterial.

In 2011, the Company issued \$2,694,294 of Secured Subordinated Convertible Notes ("the 2011 Convertible Notes") and consolidated all of the outstanding 2009 and 2010 Convertible Notes into the 2011 Convertible Notes (collectively "the Consolidated 2011 Convertible Notes"). The consolidation of the 2009 and 2010 Convertible Notes was accounted for as a debt modification. The Consolidated 2011 Convertible Notes, which bore interest at 14% per annum, were due on the earliest to occur of: (i) the date of the closing of a merger, consolidation or reorganization of the Company with or into any other entity or a sale of all or substantially all of the assets of the Company, resulting in a change of control, (ii) the date of any dissolution, liquidation or winding up of the Company, or (iii) December 31, 2012. Interest on the Consolidated 2011 Convertible Notes accrued until the outstanding principal and interest was either paid in full or converted into preferred stock.

The Consolidated 2011 Convertible Notes were convertible into equity securities issued in a Qualified Financing, as defined, ("Qualified Financing Securities") or Series D Convertible Preferred Stock of the Company. In the event of the consummation of a Qualified Financing, or upon the election of the holders of at least 65% of the Consolidated 2011 Convertible Notes, or in the event that the Company refinanced its senior credit facility in a manner satisfactory to the holders of at least 65% of the Consolidated 2011 Convertible Notes, then all outstanding principal and accrued but unpaid interest was convertible into such number of shares of the Qualified Financing Securities or Series D Preferred as was obtained by dividing the Conversion Value of the notes by \$30.00, subject to adjustment. The Conversion Value was equal to four times (4x) the sum of all outstanding principal and accrued but unpaid interest under the Consolidated 2011 Convertible Notes.

The Consolidated 2011 Convertible Notes were secured by a second lien on substantially all of the Company's assets and included covenants and limitations on the Company's ability to enter into certain transactions while the Consolidated 2011 Convertible Notes were outstanding.

Interest expense relating to the 2009, 2010 and 2011 Convertible Notes totaled \$1,027,712 and \$1,396,641 for the nine-month periods ended September 30, 2012 and 2011, respectively. The change in fair value of the derivative liabilities relating to the 2009 Warrants and 2010 Warrants during the nine months ended September 30, 2012 and 2011 was not material.

As part of the agreements relating to the Convertible Notes, the Company is required to pay monitoring and advisory fees to two investors totaling \$200,000 per annum. A total of \$150,000 is included in other expense in the accompanying condensed statements of operations for the nine months



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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**8. CONVERTIBLE DEBT (Continued)**

ended September 30, 2012 and 2011, respectively. These fees commenced on January 1, 2011 and are paid quarterly in advance on the first business day of each calendar quarter.

In June 2012, the holders of the Consolidated 2011 Convertible Notes converted all outstanding convertible debt and accrued interest into 2,375,312 shares of Series D Preferred, of which 27,359 shares were issued from warrant exercise, and 22,484 shares of common stock, also from warrant exercise (Note 9).

**9. CAPITALIZATION**

**Authorized Shares**

The Company is authorized to issue up to 7,300,000 shares of stock of which 3,700,000 are designated as common stock with a \$0.10 per share par value and 3,600,000 are designated as preferred stock with a \$0.10 par value.

**Series A 10% Convertible Preferred Stock**

The Company has designated 108,494 shares of its authorized preferred stock as Series A 10% Convertible Preferred Stock ("the Series A Preferred"). The Series A Preferred has a stated value of \$100 per share. Among the terms and conditions of the Series A Preferred are the following:

*Ranking*

The Series A Preferred is senior to the common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series A Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 10% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series A Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$1,875,665 and \$995,557 as of September 30, 2012 and December 31, 2011, respectively, and are included in Series A Preferred Stock in the accompanying condensed balance sheets.

*Conversion*

Each share of Series A Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least 60% of the then issued and outstanding shares of the Series A Preferred, or the date all of the outstanding shares of Series D Preferred Stock are

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

mandatorily converted to shares of common stock, each share of Series A Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series A Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series A Preferred shall have the right to the number of votes it would have obtained had the Series A Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 54,246.7 shares of the Series A Preferred remain outstanding, the vote of a majority of the outstanding shares of Series A Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series A Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series A Preferred shall have the right to receive, prior to any payment to holders of common stock, the greater of (i) the stated value of the Series A Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the common stock if the Series A Preferred was converted to common stock immediately prior to the event.

**Series B 10% Convertible Preferred Stock**

The Company has designated 118,915 shares of its authorized preferred stock as Series B 10% Convertible Preferred Stock ("the Series B Preferred"). The Series B Preferred has a stated value of \$110 per share. Among the terms and conditions of the Series B Preferred are the following:

*Ranking*

The Series B Preferred is senior to the Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series B Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 10% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series B Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$1,575,747 and \$836,368 as of September 30, 2012 and December 31, 2011, respectively, and are included in Series B Preferred Stock in the accompanying condensed balance sheets.

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

*Conversion*

Each share of Series B Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least the majority of the then issued and outstanding shares of the Series B Preferred, or the date all of the outstanding shares of Series D Preferred Stock are mandatorily converted to shares of common stock, each share of Series B Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series B Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series B Preferred shall have the right to the number of votes it would have obtained had the Series B Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 40,381.3 of the shares of the Series B Preferred remain outstanding, the vote of a majority of the outstanding shares of Series B Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series B Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series B Preferred shall have the right to receive, prior to any payment to holders of Series A Preferred and common stock, the greater of (i) the stated value of the Series B Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series A Preferred and common stock if the Series B Preferred was converted to common stock immediately prior to the event.

**ANIP ACQUISITION COMPANY**  
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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

**Series C 12% Convertible Preferred Stock**

The Company has designated 37,956 shares of its authorized preferred stock as Series C 12% Convertible Preferred Stock ("the Series C Preferred"). The Series C Preferred has a stated value of \$110 per share. Among the terms and conditions of the Series C Preferred are the following:

*Ranking*

The Series C Preferred is senior to the Series B Preferred, Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series C Preferred accrue from January 28, 2011, whether or not earned or declared, at the rate of 12% per annum. All dividends accrued prior to January 28, 2011 were waived by the Series C Preferred holders. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$850,905 and \$448,148 as of September 30, 2012 and December 31, 2011, respectively, and are included in Series C Preferred Stock in the accompanying condensed balance sheets.

*Conversion*

Each share of Series C Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least the majority of the then issued and outstanding shares of the Series C preferred, or the date all of the outstanding shares of Series D Preferred Stock are mandatorily converted to shares of common stock, each share of Series C Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series C Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series C Preferred shall have the right to the number of votes it would have obtained had the Series C Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

In addition to the rights to vote on all matters submitted to the Company's shareholders, for as long as 18,977.5 shares of the Series C Preferred remain outstanding, the vote of a majority of the outstanding shares of Series C Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series C Preferred.

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**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series C Preferred shall have the right to receive, prior to any payment to holders of Series B Preferred, Series A Preferred and common stock, the greater of (i) the stated value of the Series C Preferred and all accrued but unpaid dividends and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series B Preferred, Series A Preferred and common stock if the Series C Preferred was converted to common stock immediately prior to the event.

**Series D 10% Convertible Preferred Stock**

The Company has designated 3,400,000 shares of its authorized preferred stock as Series D 10% Convertible Preferred Stock ("the Series D Preferred"). The Series D Preferred has a stated value of \$30 per share. Among the terms and conditions of the Series D Preferred are the following:

*Ranking*

The Series D Preferred is senior to the Series C Preferred, Series B Preferred, Series A Preferred and common stock as to the payment of dividends and the distributions of assets and rights upon liquidation, dissolution or winding up of the Company.

*Dividends and Distributions*

Dividends on the Series D Preferred accrue from the date of issuance, whether or not earned or declared, at the rate of 10% per annum. The accrued dividends compound quarterly and are payable in cash. Accrued dividends totaled \$2,304,378 as of September 30, 2012 and are included in Series D Preferred Stock in the accompanying condensed balance sheets. No Series D Preferred Stock was outstanding as of December 31, 2011.

*Conversion*

Each share of Series D Preferred is initially convertible into one share of common stock of the Company at the option of the holder. The conversion rate is subject to adjustment upon the occurrence of certain events including the issuance of dividends payable in the form of common stock, a recapitalization, reorganization or other similar change in the outstanding common stock, or upon the occurrence of certain dilutive financings, as defined.

In the event of the consummation of a Qualified Public Offering, as defined, or a date specified by vote or written consent of the holders of at least 65% of the then issued and outstanding shares of the Series D preferred, each share of Series D Preferred shall be mandatorily converted into common stock.

*Voting Rights*

Holders of Series D Preferred are entitled to vote on all matters submitted to a vote of the Company's shareholders. Each share of Series D Preferred shall have the right to the number of votes it would have obtained had the Series D Preferred been converted to common stock in accordance with the conversion rate in effect at the time of the vote.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

In addition to the rights to vote on all matters submitted to the Company's shareholders, in the event that 1,000,000 shares of the Series D Preferred are outstanding, the vote of 65% of the outstanding shares of Series D Preferred is required to approve of certain events including, but not limited to, the sale of the Company or substantially all of its assets, a change in control, the repurchase of any of the Company's outstanding securities or the issuance of equity securities having certain rights equal with or senior to the Series D Preferred.

*Liquidation Preference*

Upon the liquidation, dissolution or winding up of the Company, holders of the Series D Preferred shall have the right to receive, prior to any payment to holders of Series C Preferred, Series B Preferred, Series A Preferred and common stock, an amount equal to the sum of all accrued but unpaid dividends plus the greater of (i) the Preferred D stated value and (ii) the distribution amount such holders would be entitled to receive pro rata with the holders of the Series C Preferred, Series B Preferred, Series A Preferred and common stock if the Series D Preferred was converted to common stock immediately prior to the event.

**Warrants**

In connection with the issuance of the Company's Convertible Debt (Note 8), the Company issued warrants for common stock at an exercise price of \$0.10 per share and warrants for preferred stock at an exercise price of \$0.10 per share. The number of common shares issuable upon exercise of the common warrants was based on accrued interest on the 2009 Convertible Notes. The number of preferred shares issuable upon exercise of the preferred warrants was based on the principal amount of certain of the 2009 Convertible Notes and on 12% of the Conversion Value of certain of the 2010 Convertible Notes. The warrants expired on the earlier of the repayment or conversion of the respective convertible debt or a Qualified Public Offering, as defined by the agreement. As of September 30, 2011, the common warrants were exercisable for 15,011 common shares. As of September 30, 2011, the preferred warrants were exercisable for 25,171 preferred shares.

In June 2012, in conjunction with the conversion of the Consolidated 2011 Convertible Notes, 27,359 Series D Preferred shares were issued from the exercise of the preferred warrants, and 22,484 shares of common stock were issued from the exercise of the common warrants.

**Stockholders' Agreement**

The Company and its stockholders have entered into an agreement ("the Stockholders' Agreement"). Under the terms of the agreement, the parties have agreed to elect certain individuals, as designated by holders of the Series A Preferred, Series B Preferred, and Series C Preferred and, upon issuance, Series D Preferred, as members of the Company's Board of Directors ("the Board"). In addition, the Stockholders' Agreement requires the approval of the majority of the holders of the Series A Preferred, Series B Preferred, Series C Preferred and Series D Preferred and, in some cases, the approval of 65% of the holders of the Series D Preferred prior to making certain changes to the Company's Charter, By-laws or Board configuration and entering into certain transactions.

Under the terms of the Stockholders' Agreement, at any time after December 31, 2012, the holders of a majority of Series D Preferred have the right to require the Company to redeem all of the

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**9. CAPITALIZATION (Continued)**

holders' shares of Series D Preferred at a price which is the sum of all accrued but unpaid dividends plus the greater of (i) the fair market value of the Series D Preferred being redeemed or (ii) the holders' pro-rata share, based on the Series D Preferred being redeemed, of the equity value of the Company as determined by a nationally recognized investment bank or a valuation formula as defined in the Stockholders' Agreement. At any time after the holders of a majority of Series D Preferred require the Company to redeem all of the holders' shares of Series D Preferred, the holders of a majority of Series A Preferred and Series B Preferred, and the holders of 55% of the Series C Preferred shall have the right to require the Company to redeem the holders' shares at a price which is the sum of all accrued but unpaid dividends plus the greater of (i) the fair market value of the Series A, Series B, and Series C Preferred being redeemed or (ii) the holders' pro-rata share, based on the Series A, Series B, and Series C Preferred being redeemed, of the equity value of the Company as determined by a nationally recognized investment bank or a valuation formula as defined in the Stockholders' Agreement.

The Stockholders' Agreement also contains provisions that govern the process a stockholder must follow concerning disposition of shares, the requirements for a stockholder to sell shares in the event of certain approved transactions (drag along rights), the rights of a stockholder to sell shares in the event other stockholders propose to sell their shares (tag along rights) and the rights of the stockholder in the event the Company proposes to sell additional shares (preemptive rights).

**10. STOCK-BASED COMPENSATION**

In 2005, the Company adopted the ANIP Acquisition Company 2005 Stock Option Plan (the "Plan"). In 2007, the Board of Directors of the Company amended the Plan and increased the maximum number of shares issuable to 312,750. As of December 31, 2011, the Company had granted 17,500 options and had 295,250 shares available for future grants. In September 2012, the Company entered into Transaction Bonus Agreements with certain management employees (Note 11). In connection with the Transaction Bonus Agreements, all prior option awards were forfeited and the Plan was terminated.

**11. COMMITMENTS AND CONTINGENCIES**

**Operating Leases**

The Company leases equipment under operating leases that expire in May 2017. Future minimum lease payments due under these leases total \$43,982 as of September 30, 2012. Rent expense for the nine-months ended September 30, 2012 and 2011 totaled \$6,987 and \$6,716, respectively.

**Transaction Bonus Agreements**

In September 2012, the Company entered into Transaction Bonus Agreements ("Bonus Agreements") with certain management employees. Under the terms of the Bonus Agreements, the Company will make bonus payments, upon a change of control transaction resulting in Net Proceeds being available for distribution to the Company's shareholders, to certain executives. The bonus payments are based upon the amount of Net Proceeds, as defined in the Bonus Agreements, realized in a change of control transaction. The Company's obligation to make the bonus payments are subject to, among other things, a minimum level of Net Proceeds and continuous employment of the executive.

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**11. COMMITMENTS AND CONTINGENCIES (Continued)**

Under the terms of the Bonus Agreements, the BioSante Pharmaceuticals, Inc. ("BioSante") transaction discussed below would be considered a change of control transaction (Note 13).

**Government Regulation**

The Company's products and facilities are subject to regulation by a number of Federal and State governmental agencies. The Food and Drug Administration (FDA), in particular, maintains oversight of the formulation, manufacture, distribution, packaging and labeling of all of the Company's products. The Drug Enforcement Administration (DEA) maintains oversight over the Company's products that are considered controlled substances.

**Unapproved Products**

Certain of the Company's generic products are marketed without approved New Drug Applications (NDA) or Abbreviated New Drug Applications (ANDA). During the nine months ended September 30, 2012 and 2011, combined net revenues for these products totaled \$3.6 million and \$2.2 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 compliance policy guide, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. The Company believes that so long as it complies with applicable manufacturing and labeling standards, it will be in compliance with the FDA's current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, the Company may be required to seek FDA approval for these products or withdraw such products from the market (Note 13).

In addition, one group of products that the Company manufactures on behalf of a contract customer is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company's contract manufacturing revenue for the group of unapproved products for the nine months ended September 30, 2012 and 2011 was \$775,000 and \$1.1 million, respectively.

The Company receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company's royalties on the net sales of these unapproved products for the nine months ended September 30, 2012 and 2011 were \$220,000 and \$249,000, respectively.



**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**11. COMMITMENTS AND CONTINGENCIES (Continued)**

**Other Commitments and Contingencies**

All manufacturers of the drug Reglan® and its generic equivalent metoclopramide, including the Company, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan® prior to the FDA's February 2009 Black Box warning requirement. The Company has been named and served in 79 separate complaints, including three in Pennsylvania, nine in New Jersey, and 67 in California, covering 2,921 plaintiffs in total. In August 2012, the Company was dismissed with prejudice from all New Jersey cases. Management considers the Company's exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by the Company prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) the Company's market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once the Company received a request for change of labeling from the FDA, it submitted its proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, the Company's management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. The Company cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

**12. FAIR VALUE DISCLOSURES**

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. US GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of the Company's funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, notes payable, and other current liabilities) approximate their carrying values because of their short-term nature.

The Company's stock purchase warrants are classified as derivative liabilities and are measured at fair value using level 3 inputs. The fair value of stock purchase warrants is determined based on the Black-Scholes option pricing model or an equity allocation model. These models require the use of unobservable inputs such as fair value of the Company's common and preferred stock, expected term, anticipated volatility, future interest and interest rates, expected cash flows and the number of outstanding common and preferred shares as of a future date. The Company determined that the fair value of the derivative liabilities, and the changes in such fair value, was immaterial as of and for the nine months ended September 30, 2012 and 2011 (Note 2). The Company has no other financial assets

**ANIP ACQUISITION COMPANY**  
**d/b/a ANI Pharmaceuticals, Inc.**

**Notes to Unaudited Condensed Financial Statements (Continued)**

**For the Nine-Month Periods Ended September 30, 2012 and 2011**

**12. FAIR VALUE DISLCOSURES (Continued)**

and liabilities that are measured at fair value. The Company has no nonfinancial assets or liabilities that are measured at fair value.

**13. SUBSEQUENT EVENTS**

**Merger Agreement with BioSante**

In October 2012, the Company entered into a definitive merger agreement with BioSante by which the companies will merge in an all-stock transaction. Under the terms of the agreement, upon completion of the merger, BioSante will issue to Company stockholders shares of BioSante common stock such that the former Company stockholders will own approximately 53 percent of the combined company's shares outstanding, and the former BioSante stockholders will own approximately 47 percent, subject to adjustment as provided in the merger agreement. In addition, immediately prior to the merger, BioSante plans to distribute to its then current stockholders contingent value rights (CVR) providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel® (female testosterone gel). Upon completion of the merger, the combined company will be renamed ANI Pharmaceuticals, Inc. and will operate under the leadership of the Company's management team. The board of directors of the combined company is expected to have two directors from BioSante and five Company directors. Consummation of the merger is subject to a number of customary conditions, including, but not limited to, the approval of the merger agreement by the BioSante and ANI stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible but not waived, the merger will not be consummated. The merger is expected to close during the first quarter of calendar 2013.

**Opium Tincture**

In October 2012, ANI received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is a non-NDA product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research (CDER). Discussions with CDER are continuing. If, as a result of such discussions or otherwise, the FDA were to make a determination that ANI could not continue to sell Opium Tincture as an unapproved product, ANI would be required to seek FDA approval for such product or withdraw such product from the market. If ANI determined to withdraw the product from the market, ANI's net revenues for generic pharmaceutical products would decline materially, and if ANI decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that ANI would receive such approval.

**AGREEMENT AND PLAN OF MERGER**

**by and between**

**BIOSANTE PHARMACEUTICALS, INC.**

**and**

**ANIP ACQUISITION COMPANY**

**Dated as of October 3, 2012**

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## AGREEMENT AND PLAN OF MERGER

This AGREEMENT AND PLAN OF MERGER, dated as of October 3, 2012 (this "**Agreement**"), is by and between BioSante Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and ANIP Acquisition Company (d/b/a ANI Pharmaceuticals), a Delaware corporation ("**ANI**"). The Company and ANI are sometimes referred to in this Agreement as the "**Parties**".

A. The Company and ANI intend to effect a merger of ANI with and into the Company (the "**Merger**") in accordance with this Agreement and the General Corporation Law of the State of Delaware (the "**DGCL**").

B. Immediately before the Effective Time of the Merger, and subject to stockholder approval, the Company intends to effect a Reverse Stock Split.

C. The board of directors of the Company has approved unanimously and declared advisable the Merger, upon the terms and subject to the conditions set forth herein, has determined that the Merger and the other transactions contemplated by this Agreement are fair to, and in the best interests of, the Company and its stockholders, and has determined to recommend that the Company stockholders adopt this Agreement and approve the Company Charter Amendments, the Merger and the issuance of Company Common Stock as contemplated by this Agreement.

D. The board of directors of ANI has approved unanimously and declared advisable the Merger, upon the terms and subject to the conditions set forth herein, has determined that the Merger and the other transactions contemplated by this Agreement are fair to, and in the best interests of, ANI and its stockholders, and has determined to recommend that ANI stockholders adopt this Agreement and approve the Merger as contemplated by this Agreement.

E. It is intended that the Merger qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "**Code**").

F. In order to induce the Company to enter into this Agreement and to cause the Merger to be consummated, the Company and the stockholders of ANI listed on *Schedule I* hereto are executing voting agreements and irrevocable proxies in favor of the Company concurrently with the execution and delivery of this Agreement in the forms substantially attached hereto as *Exhibit A-1* and *Exhibit A-2* (the "**Voting Agreements**").

G. In order to induce ANI to enter into this Agreement and to cause the Merger to be consummated, ANI and the stockholders of the Company listed on *Schedule II* hereto are executing Voting Agreements in favor of ANI concurrently with the execution and delivery of this Agreement.

Accordingly, and in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein and intending to be legally bound, the Parties agree as follows:

### ARTICLE I. The Transactions

1.1 **The Merger.** At the Effective Time, and subject to and upon the terms and conditions of this Agreement and the applicable provisions of the DGCL, ANI will be merged with and into the Company, with the Company being the surviving entity. The Company, as the surviving entity of the Merger, is hereinafter sometimes referred to as the "Surviving Corporation". At the Effective Time, and as a result of the approval of the Company Charter Amendments, the name of the Surviving Corporation will be changed to "ANI Pharmaceuticals, Inc."

1.2 **Effects of the Merger.** The effects of the Merger will be as provided in this Agreement, the Certificate of Merger and the applicable provisions of the DGCL. Without limiting the foregoing, at

the Effective Time, by virtue of the Merger and in accordance with the DGCL, all of the property, rights, privileges, powers and franchises of ANI will vest in the Surviving Corporation, and all debts, liabilities and duties of ANI will become the debts, liabilities and duties of the Surviving Corporation.

**1.3 Closing; Effective Time.** Unless this Agreement is terminated pursuant to *Article VII* hereof, the closing of the Merger and the other transactions contemplated hereby (the "Closing") will take place through the remote exchange of electronic copies of executed documents on the second (2<sup>nd</sup>) Business Day after satisfaction or waiver of the conditions set forth in *Article VI* (other than those conditions that by their terms are to be satisfied at the Closing), or at such other place or on such other date as is mutually agreeable to the parties hereto. The date of the Closing is herein referred to as the "Closing Date". At the Closing, the parties hereto will cause the Merger to be consummated by filing a certificate of merger (the "Certificate of Merger") with the Secretary of State of the State of Delaware (the "Delaware Secretary"), in accordance with the relevant provisions of the DGCL (the time of such filing, or such later time as may be agreed to in writing by the parties hereto and specified in the Certificate of Merger, being referred to herein as the "Effective Time"). For the purposes of this Agreement, "Business Day" means each day other than a Saturday, Sunday or any other day when commercial banks in New York, New York are authorized or required by law to close.

**1.4 Recapitalization of Company Common Stock.**

(a) Effective as of the close of business on the Business Day immediately prior to the Effective Time, and subject to receipt of the requisite stockholder approval at the Company Special Meeting of amendments to the certificate of incorporation of the Company (the "**Company Charter Amendments**"), in the forms attached hereto as *Exhibit B*, the Company will cause to be filed a Certificate of Amendment to its Certificate of Incorporation (the "**Company Certificate of Amendment**"), whereby without any further action on the part of the Company, ANI or any stockholder of the Company:

(i) each share of common stock, \$0.0001 per share, of the Company ("**Company Common Stock**") issued and outstanding immediately prior to the filing of the Company Certificate of Amendment will be converted into and become a fractional number of fully paid and nonassessable shares of Company Common Stock to be determined by the Company and ANI, but which in any event will be between the range of one-for-two and one-for-five (the "**Reverse Stock Split**"); and

(ii) any shares of Company Common Stock held as treasury stock or held or owned by the Company immediately prior to the filing of the Company Certificate of Amendment will each be converted into and become an identical fractional number of shares of Company Common Stock, as determined by the Company and ANI in connection with *Section 1.4(a)(i)* above.

(b) No fractional shares of Company Common Stock will be issued in connection with the Reverse Stock Split, and no certificates or scrip for any such fractional shares will be issued. Any holder of Company Common Stock who otherwise would be entitled to receive a fraction of a share of Company Common Stock (after aggregating all fractional shares of Company Common Stock issuable to such holder) will, in lieu of such fraction of a share and upon surrender of such holder's certificate representing such fractional shares of Company Common Stock, be paid in cash the dollar amount (provided to the nearest whole cent), without interest, determined by multiplying such fraction by the closing price of a share of Company Common Stock on The NASDAQ Global Market on the date immediately preceding the effective date of the Reverse Stock Split.

(c) The Exchange Ratio determined in accordance with *Section 2.2* will be appropriately adjusted at the Effective Time to account for the effect of the Reverse Stock Split without

enlarging or diluting the relative rights and ownership of the stockholders of ANI and stockholders of the Company resulting from such Exchange Ratio.

1.5 **Lock-Up Agreements.** Concurrently with the execution hereof, the chief executive officer and chief financial officer of ANI and each holder of ANI Shares set forth on *Schedule I* is entering into a Lock-up Agreement in the form attached hereto as *Exhibit C*.

## ARTICLE II.

### Conversion and Cancellation of Securities

2.1 **Cancellation and Conversion of ANI Securities.** As of the Effective Time, by virtue of the Merger, and without any action on the part of the holders of any of the shares of capital stock of ANI ("**ANI Shares**"):

(a) Except as otherwise provided in *Section 2.1(d)* or *Section 2.4*, each share of series D convertible preferred stock, par value \$0.10 per share, of ANI ("**ANI Series D Preferred Stock**") outstanding immediately prior to the Effective Time will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series D Exchange Ratio (as determined pursuant to *Section 2.2* (all such shares of Company Common Stock to be issued pursuant to this *Section 2.1(a)* or *2.1(f)*, together with cash in lieu of any fractional shares of Company Common Stock paid pursuant to *Section 2.3(d)*, are collectively referred to herein as the "**Merger Consideration**").

(b) Each share of ANI's series C convertible preferred stock, par value \$0.10 per share (the "**ANI Series C Preferred Stock**"), ANI's series B convertible preferred stock, par value \$0.10 per share (the "**ANI Series B Preferred Stock**"), ANI's series A convertible preferred stock (the "**ANI Series A Preferred Stock**"), par value \$0.10 per share, and ANI Common Stock, in each case outstanding immediately prior to the Effective Time, will be canceled without consideration therefor, except as may be provided in *Section 2.1(f)* for the ANI Series C Preferred Stock, the ANI Series B Preferred Stock and the ANI Series A Preferred Stock.

(c) Each option, warrant or other right to purchase shares of ANI capital stock outstanding immediately prior to the Effective Time will be canceled without consideration therefor other than the ANI Warrants which, at and after the Effective Time, will not represent the right to acquire any equity or other interest in the Surviving Corporation.

(d) As of the Effective Time, subject to *Section 2.4*, all such canceled and/or converted ANI Shares will no longer be outstanding and will automatically be canceled and will cease to exist, and each certificate which immediately prior to the Effective Time represented any such ANI Shares (each, a "**Certificate**") will thereafter represent only the right (and, except as provided in *Section 2.1(f)*, only in the case of the shares of ANI Series D Preferred Stock) to receive the applicable portion of the Merger Consideration in exchange therefor in accordance with *Section 2.3*.

(e) Each ANI Share held by ANI or any of the ANI Subsidiaries or owned by the Company or any of the Company Subsidiaries immediately prior to the Effective Time will be canceled, and no payment will be made with respect thereto.

(f) In the event the product of (x) the Merger Shares and (y) the volume weighted average price (rounded to the nearest cent) of the Company Common Stock on The NASDAQ Global Market (as reported by Bloomberg L.P. or, if not reported thereby, by another authoritative source mutually agreed by the Company and ANI) for the five (5) consecutive trading days immediately

preceding the second trading day prior to the Closing Date, as adjusted for the Reverse Stock Split (the "**Share Value**");

(i) exceeds the Series D Preference Amount, but does not exceed an amount equal to the Series D Preference Amount *plus* the Series C Preference Amount, then that number of Merger Shares with a Share Value in excess of the Series D Preference Amount will be allocated to the ANI Series C Preferred Stock and each share of (A) ANI Series D Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series D Exchange Ratio and (B) Series C Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series C Exchange Ratio (each as determined pursuant to *Section 2.2*); or

(ii) exceeds the Series D Preference Amount *plus* the Series C Preference Amount, but does not exceed an amount equal to the Series D Preference Amount *plus* the Series C Preference Amount *plus* the Series B Preference Amount, then that number of Merger Shares with a Share Value in excess of the Series D Preference Amount *plus* the Series C Preference Amount will be allocated to the ANI Series Stock B Preferred Stock and each share of (A) ANI Series D Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series D Exchange Ratio, (B) Series C Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series C Exchange Ratio and (C) Series B Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series B Exchange Ratio (each as determined pursuant to *Section 2.2*); or

(iii) exceeds the Series D Preference Amount *plus* the Series C Preference Amount *plus* the Series B Preference Amount, then that number of Merger Shares with a Share Value in excess of the Series D Preference Amount *plus* the Series C Preference Amount *plus* the Series B Preference Amount will be allocated to the ANI Series Stock A Preferred Stock and each share of (A) ANI Series D Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series D Exchange Ratio, (B) Series C Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series C Exchange Ratio, (C) Series B Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series B Exchange Ratio and (D) Series A Preferred Stock will be automatically converted into the right to receive that number of shares of Company Common Stock equal to the Series A Exchange Ratio (each as determined pursuant to *Section 2.2*).

For purpose hereof: (x) the "**Series D Preference Amount**" means the amount the holders of the ANI Series D Preferred Stock are entitled to receive in respect of the liquidation preference of the ANI Series D Preferred Stock described in Article VII, Section 1(a) of the ANI's Certificate of Incorporation; (y) the "**Series C Preference Amount**" means the amount the holders of the ANI Series C Preferred Stock are entitled to receive in respect of the liquidation preference of the ANI Series C Preferred Stock described in Article VII, Section 1(b) of ANI's Certificate of Incorporation and (z) the "**Series B Preference Amount**" means the amount the holders of the ANI Series B Preferred Stock are entitled to receive in respect of the liquidation preference of the ANI Series B Preferred Stock described in Article VII, Section 1(c) of ANI's Certificate of Incorporation, the amount of which in each case will be as set forth in a certificate executed by the chief financial officer of ANI immediately prior to the Closing Date.

In the event any shares of Company Common Stock are issued to holders of ANI Series C Preferred Stock, Series B Preferred Stock or Series A Preferred Stock in accordance with this *clause (f)* then it is acknowledged and agreed that all references to ANI Series D Preferred Stock in *Sections 2.1(d), 2.2 and 2.3* shall be deemed to also include ANI Series C Preferred Stock and/or ANI Series B Preferred Stock and/or ANI Series A Preferred Stock, as applicable.

## 2.2 Determination of Exchange Ratio.

### (a) Definitions.

(i) "**Adjusted Outstanding Company Shares**" means a number equal to the sum of (A) the total number of shares of Company Common Stock outstanding immediately prior to the Effective Time and (B) the Company Warrant Amount immediately prior to the Effective Time.

(ii) "**ANI Percentage**" means fifty-three percent (53%); *provided, however*, that if the Company has more or less than \$18.0 million of Net Cash as of the Determination Date, then the ANI Percentage will be increased by 0.006% for each \$10,000 shortfall in Net Cash on the Determination Date or decreased by 0.006% for each \$10,000 excess in Net Cash on the Determination Date, *provided, further*, that in no event will the ANI Percentage be decreased to less than 50.1%.

(iii) "**Company Percentage**" means one hundred percent (100%), minus the ANI Percentage.

(iv) "**Company Warrant Amount**" means the product of .32 and the number of remaining shares of Company Common Stock that are issuable upon exercise of the August Warrants, as of immediately prior to the Effective Time.

(v) "**Determination Date**" will be either (A) the date that is fourteen (14) calendar days prior to the date of the Company Special Meeting set forth in the Joint Proxy Statement/Prospectus, (B) if the date of the Company Special Meeting is adjourned to a date with the consent of ANI, to the date that is fourteen (14) calendar days prior to the consented-to date of the Company Special Meeting or (C) if the date of the Company Special Meeting is adjourned to a date without the consent of ANI, to the date which is fourteen (14) calendar days prior to either the original date of the Company Special Meeting set forth in the Joint Proxy Statement/Prospectus, or the rescheduled date of the Company Special Meeting, as determined by ANI in its sole and absolute discretion.

(vi) "**Merger Shares**" means the total number of shares of Company Common Stock to be issued in the Merger pursuant to *Section 2.1(a)*, determined as follows:

$$(\text{ANI Percentage}) \times \frac{\text{Adjusted Outstanding Company Shares}}{\text{Company Percentage}}$$

(vii) "**Net Cash**" means, as of any particular time, (x) the Company's cash (including cash permitted to be included under *Section 5.22* and *Section 5.23* of the Agreement) and cash equivalents *minus* (y) the aggregate of the following obligations and liabilities of the Company, calculated without duplication (the "**Liabilities**"):

(A) All accounts payable, accrued compensation (including accrued paid time off, vacation time, bonuses and payments in respect of benefit plans) and other accrued expenses of the Company (but in each case, excluding any item taken into account pursuant to clauses (B)-(F) below), including amounts payable to any or all persons who were employees of or contractors to the Company or any of its subsidiaries at anytime up until immediately prior to the Effective Time (including former employees) as a result of

(1) their termination, whether prior to or after the date hereof until thirty (30) days following the Closing (provided such amount will be calculated for purposes hereof assuming remaining employees as of the Determination Date are terminated at the Closing and which calculation will include an estimate of the maximum compensation and benefits payable to such person through the expected Closing Date, except for employees who have the right to receive prior notice of termination, in which case such amount shall be calculated as of the first date such termination can be effective assuming notice is given at the Closing, but shall include any compensation and benefits payable to such employee during such period from Closing to the effective date of termination) and/or (2) the Merger constituting a change of control under their employment agreements or any other documents as in effect during the period beginning on the date hereof and ending immediately prior to the Effective Time (including associated severance costs such as accrued bonuses, excise and other Taxes and payments associated with such amounts and required to be paid by statute or contract), and including health, dental, life, disability and outplacement benefits owed to employees, including the Company Executives (as defined in *Section 5.17*) that are paid, incurred or expected to be incurred, payable or subject to reimbursement by the Company; *provided, however*, that (x) only such costs in excess of \$100,000 will be deducted under this *clause (A)* in the calculation of Net Cash; and (y) in the case of estimated maximum COBRA costs and costs referred to in *Sections 5.17(b)(i)-(iv)*, only the aggregate amount in excess of \$100,000 (in addition to the \$100,000 amount set forth above) will be deducted under this *clause (A)* in the calculation of Net Cash;

(B) All indebtedness of the Company for borrowed money or in respect of capitalized leases or the purchase of assets of the Company (including all principal, accrued interest thereon (and if such indebtedness is not prepayable, all remaining interest to be paid or accrued through maturity thereof)), and any other amounts payable to the holders of such indebtedness as a result of or in connection with, the consummation of the transactions contemplated by this Agreement);

(C) All amounts remaining to be paid by the Company under the lease for its offices in Lincolnshire, Illinois through the expiration thereof (including any amounts payable on any surrender of the premises) less the amount of any deposit;

(D) All out-of-pocket closing or transactional costs in connection with the transactions contemplated by this Agreement, including amounts payable to (1) financial advisors (including investment banks), attorneys or accountants (including 50% of the cost of the Independent Accountant, if any) that are paid, incurred or expected to be incurred, payable or subject to reimbursement by the Company, (2) all amounts payable in connection with the preparation, filing and mailing of the Registration Statement and Joint Proxy Statement/Prospectus, the Charter Amendments and the solicitation of proxies and the holding of the Company Special Meeting and 50% of any filing fee required to be paid pursuant to *Section 5.24*, (3) all amounts payable in respect of the Company Tail Policies for Company Executives and (4) all amounts payable in connection with the drafting and execution of the agreement described in *Section 5.2(c)*;

(E) All remaining costs associated with the Company's LibiGel® program (including the completion and/or conclusion of any clinical trials, safety studies or other research studies) and the cost of keeping in effect any related product liability and/or similar insurance policies providing coverage for personal injury claims arising out of such trials for the remaining statute of limitations thereof, including those of the type described in *Section 4.4* of the Company Disclosure Schedule hereto;



(F) Any cash received by the Company in respect of that Company Contract identified in *Section 5.22* of the Company Disclosure Schedule with the Amending Party which represents (1) an advance of or prepayment against or payment in lieu of any royalties otherwise payable to the Company under an existing license agreement with the other party to such contract or (2) a payment made in consideration of any change or amendment to an existing license agreement with such other party to such contract which is adverse to the Company ("**Ineligible Payments**"), and ANI agrees that the amounts payable by the Amending Party pursuant to the agreement of the Company with the Amending Party referred to in *Section 5.22* of the Company Disclosure Schedule, if executed in the form provided to ANI, will not contain any Ineligible Payments;

(G) A reserve to be mutually agreed upon in good faith by the Parties prior to November 15, 2012, to be sufficient to provide for any out-of-pocket costs associated with any then outstanding litigation of the Company, including in respect of defense costs, deductible payments and a provision for costs associated with an adverse determination not otherwise covered by the Company's existing Policies, which reserve amount is tentatively set as of the date hereof at \$50,000 (and which, if agreement between the Parties is not reached prior to November 15, 2012, will be determined as set forth in *Section 8.13*); and

(H) One-half ( $\frac{1}{2}$ ) of any settlement payments of the type identified in *Section 2.2(a)(vii)(H)* of the Company Disclosure Schedule; it being understood and agreed that the aggregate amount of all costs associated with the defense of any matter described in such section of the Company Disclosure Schedule not covered by the Company's existing Policies will be included as a Liability under *clause (D)(1)* above.

(b) **Exchange Ratio.** The Exchange Ratio for purposes of the Merger Agreement (the "**Exchange Ratio**") will equal the applicable ratio set forth below and each Exchange Ratio will be calculated to the nearest  $\frac{1}{10,000}$  of a share:

(i) The "**Series D Exchange Ratio**" will equal the quotient obtained by dividing (A) the total number of Merger Shares having an aggregate Share Value equal to or less than the Series D Preference Amount, by (B) the number of outstanding shares of ANI Series D Preferred Stock immediately prior to the Effective Time.

(ii) The "**Series C Exchange Ratio**" will equal the quotient obtained by dividing (A) the total number of Merger Shares not issued to the holders of ANI Series D Preferred Stock under *clause (i)* above having an aggregate Share Value equal to the Series C Preference Amount (or, if less, the remaining Merger Shares), by (B) the number of outstanding ANI Series C Preferred Stock immediately prior to the Effective Time.

(iii) The "**Series B Exchange Ratio**" will equal the quotient obtained by dividing (A) the total number of Merger Shares not issued to the holders of ANI Series D Preferred Stock under *clause (i)* above or ANI Series C Preferred Stock under *clause (ii)* above having an aggregate Share Value equal to or less than the Series B Preference Amount (or, if less, the remaining Merger Shares), by (B) the number of outstanding ANI Series B Preferred Stock immediately prior to the Effective Time.

(iv) The "**Series A Exchange Ratio**" will equal the quotient obtained by dividing (A) the total number of Merger Shares not issued to the holders of ANI Series D Preferred Stock under *clause (i)* above, ANI Series C Preferred Stock under *clause (ii)* above or ANI Series B Preferred Stock under *clause (iii)* above, by (B) the number of outstanding ANI Series A Preferred Stock immediately prior to the Effective Time.

(c) **Determination of Net Cash.**

(i) Within two (2) calendar days following the Determination Date, the Company will deliver to ANI a schedule (the "**Net Cash Schedule**") setting forth, in reasonable detail, the Company's calculation of Net Cash (as determined in accordance with the definition of Net Cash set forth above) (the "**Net Cash Calculation**") as of such Determination Date prepared by the Company's Chief Financial Officer, together with the work papers and back-up materials used in preparing the applicable Net Cash Schedule and as part of such documentation, the Company shall include letters that are duly executed by the following Persons to which such payment of Liabilities are to be made, in forms reasonably satisfactory to ANI (including a fixed capped amount to be paid by the Company): the Company's investment bankers, attorneys and accountants.

(ii) Within three (3) Business Days after the Company delivers the Net Cash Schedule to ANI (the "**Response Date**"), ANI will have the right to dispute any part of such Net Cash Schedule by delivering a written notice to that effect to the Company (a "**Dispute Notice**"). Any Dispute Notice will identify in reasonable detail the nature of any proposed revisions to the Net Cash Calculation and will be accompanied by reasonably detailed materials supporting the basis for such proposed revisions.

(iii) If on or prior to the Response Date, (i) ANI notifies the Company in writing that it has no objections to the Net Cash Calculation set forth in the Net Cash Schedule or (ii) ANI fails to deliver a Dispute Notice as set forth above, then the Net Cash Calculation as set forth in the Net Cash Schedule will be deemed to have been finally determined for purposes of this Agreement and to represent the Net Cash at the Determination Date for purposes of this Agreement, except in the case of intentional or willful misrepresentation.

(iv) If ANI delivers a Dispute Notice on or prior to the Response Date as provided above, then representatives of the Company and ANI will promptly meet and attempt in good faith to promptly resolve the disputed item(s) and negotiate an agreed-upon determination of Net Cash within two (2) calendar days after the Response Date, which agreed upon Net Cash amount will be deemed to have been finally determined for purposes of this Agreement and to represent the Net Cash at the Determination Date for purposes of this Agreement.

(v) In the event no agreement is reached within four (4) calendar days after the Response Date and the disagreements would result in at least a Two Million Dollar (\$2,000,000) adjustment to Net Cash or ANI reasonably believes the amount of Net Cash is less than the Minimum Net Cash amount, then the Parties agree to postpone the Company Special Meeting to a date mutually agreed upon so that such disagreement can be resolved in accordance with the terms of clause (vi) below.

(vi) If the Company and ANI are unable to resolve any disagreement between them concerning the Net Cash Calculation or any component thereof (the "**Dispute**") within three (3) calendar days, then the Dispute may be referred by the Company or ANI for determination to RSM McGladrey Inc. If RSM McGladrey Inc. is unwilling to serve in such capacity then ANI and the Company will refer the Dispute to the Chicago, Illinois office of a regionally or nationally recognized accounting firm that is mutually selected by the Company and ANI. If the Parties are unable to select a regionally or nationally recognized accounting firm within five (5) calendar days, then either the Company or ANI may thereafter request that the Chicago, Illinois office of the American Arbitration Association make such selection (as applicable, the "**Independent Accountant**"). Each of the Company and ANI will provide the Independent Accountant and the other Party with a statement of its position as to the amount for each Dispute within ten (10) calendar days from the date of the referral. The Independent Accountant will make a written determination as promptly as practicable, but in any event within fifteen (15) calendar days after the date on which the Dispute is referred to the Independent Accountant, by determining the

actual Net Cash and the applicable Exchange Ratio. If at any time the Company and ANI resolve their dispute, then notwithstanding the preceding provisions of this clause (vi), the Independent Accountant's involvement promptly will be discontinued and the Net Cash Calculation will be revised, if necessary, to reflect such resolution and thereupon will be final and binding for all purposes under this Agreement, except in the case of intentional or willful misrepresentation or manifest error. The Parties will make readily available to the Independent Accountant all relevant books and records relating to the Net Cash Calculation and the calculation set forth in the Net Cash Schedule and all other items reasonably requested by the Independent Accountant in connection with resolving the Dispute. The costs and expenses of the Independent Accountant will be borne by the Company (however, only 50% of such amount will be included in the calculation of Net Cash).

(vii) Once the Net Cash at the Determination Date has been finally determined, the Company will issue a news release publicly announcing (i) the Company's Net Cash at the Determination Date and (ii) any adjustment to the Exchange Ratio based on the Company's Net Cash at the Determination Date.

### 2.3 Payment of Consideration.

(a) At least ten (10) days prior to the Effective Time, the Company will send to each holder of record of shares of ANI Series D Preferred Stock a letter of transmittal setting forth instructions on the process for effecting the exchange of the ANI Series D Preferred for Company Common Stock. Such letter of transmittal will, among other things, (i) specify that the delivery will be effected, and risk of loss and title will pass, only upon proper delivery of the Certificates to the Company, (ii) provide for a release of any claims such holder might have against the Company, ANI or otherwise in connection with the Merger and (iii) otherwise be in customary form and contain such provisions as the Company may reasonably specify. At the Effective Time, each holder of record of shares of ANI Series D Preferred Stock will deliver the Certificates to the Company, together with a properly completed letter of transmittal and all other documents reasonably required by the Company, and the Company will issue the Merger Consideration to such holders of ANI Series D Preferred Stock by delivery of certificates or book entry notations and, if applicable, cash for fractional shares as provided in *Section 2.3(d)*. Until so surrendered or transferred, as the case may be, each such Certificate will represent after the Effective Time for all purposes only the right to receive such applicable portion of the Merger Consideration. In addition, no dividends or other distributions declared or made with respect to Company Common Stock with a record date after the Effective Time will be paid or otherwise delivered to any holder of ANI Series D Preferred Stock until such holder surrenders or transfers the applicable Certificate(s).

(b) The transfer books of ANI will be closed immediately upon the Effective Time and there will be no further registration of transfers of ANI Shares outstanding immediately prior to the Effective Time thereafter on the records of ANI. If, after the Effective Time, Certificates are presented to the Company or its transfer agent for any reason, they will be canceled and exchanged for the applicable portion of the Merger Consideration to the extent provided for, and in accordance with the procedures set forth, in this *Article II*.

(c) Notwithstanding anything to the contrary in this Agreement, neither the Company nor any Party will be liable to any holder of ANI Series D Preferred Stock as of immediately prior to the Effective Time for any amounts delivered to a public official pursuant to any applicable abandoned property, escheat or similar law. Immediately prior to such time when the amounts otherwise would escheat to or become property of any Government Authority, any amounts remaining unclaimed by holders of ANI Series D Preferred Stock immediately prior to the Effective Time will become, to the extent permitted by Applicable Law, the property of the

Company free and clear of any claims or interest of any Person previously entitled thereto. For purposes of this Agreement, "**Person**" means an individual, a corporation, a limited liability company, a partnership, an association, a trust or any other entity or organization, including a government or political subdivision or any agency or instrumentality thereof.

(d) No fractional shares of Company Common Stock will be issued in connection with the Merger, and no certificates or scrip for any such fractional shares will be issued. Any holder of ANI Series D Preferred Stock who otherwise would be entitled to receive a fraction of a share of Company Common Stock (after aggregating all fractional shares of Company Common Stock issuable to such holder) will, in lieu of such fraction of a share and upon satisfaction of the conditions set forth in *Section 2.3(a)*, be paid in cash the dollar amount (rounded to the nearest whole cent), without interest, determined by multiplying such fraction by the closing price of a share of Company Common Stock on The NASDAQ Global Market on the Closing Date.

**2.4 Dissenting Shares.** Notwithstanding any provision in this Agreement to the contrary, ANI Shares outstanding as of immediately prior to the Effective Time and held by a holder who has not voted in favor of the Merger or consented thereto in writing and who has properly demanded appraisal for such shares in accordance with Section 262 of the DGCL ("**Dissenting Shares**") will not be converted into the right to receive the applicable portion of Merger Consideration. Holders of such Dissenting Shares will instead be entitled to receive payment for the fair value of such Dissenting Shares as determined in accordance with Section 262 of the DGCL; *provided, however*, that if, after the Effective Time, such holder fails to perfect, withdraws or loses the right to appraisal, such Dissenting Shares will be treated as if they had been converted as of the Effective Time into the right to receive the applicable portion of the Merger Consideration. ANI will give the Company prompt notice of any demands received by ANI for appraisal of shares and withdrawals of any such demand, and any other communications delivered to ANI pursuant to or in connection with Section 262 of the DGCL, and the Company and ANI will jointly have the right to direct all negotiations and proceedings with respect to such demands (including settlement offers). Except with the prior written consent of the other Party, neither Party will not offer to settle or settle or (unless required pursuant to a valid and final Order) make any payment with respect to, any such demands.

**2.5 Required Withholdings.** The Company will be entitled to deduct and withhold from the Merger Consideration such amounts, if any, as may be required to be deducted or withheld therefrom under the Code or any other Applicable Law. To the extent such amounts are so deducted or withheld, such amounts will be treated for all purposes under this Agreement as having been delivered or otherwise paid to the Person to whom such amounts would otherwise have been delivered or otherwise paid pursuant to the Merger and this Agreement.

**2.6 Lost Certificates.** If any Certificate has been lost, stolen or destroyed, upon the making of an affidavit (in form and substance reasonably acceptable to the Company) of that fact by the Person claiming such Certificate to be lost, stolen or destroyed the Company will cause to be issued, in exchange for such lost, stolen or destroyed Certificate, the applicable portion of the Merger Consideration as contemplated by this *Article II*.

**2.7 Adjustments.** If, during the period between the date of this Agreement and the Effective Time, any change in the outstanding shares of capital stock of ANI or the Company occurs, as a result of any reclassification, recapitalization, stock split (including any reverse stock split), merger, combination, exchange or readjustment of shares, subdivision or other similar transaction, or any stock dividend thereon with a record date during such period, the Exchange Ratio will be appropriately adjusted to eliminate the effect of such event on the Exchange Ratio or any such other amounts payable pursuant to this Agreement.

2.8 **Tax Consequences.** For U.S. federal income tax purposes, the Merger is intended to constitute a reorganization within the meaning of Section 368(a) of the Code. The parties to this Agreement adopt this Agreement as a "plan of reorganization" within the meaning of Section 1.368-2(g) of the United States Treasury Regulations.

### ARTICLE III. Representations and Warranties of ANI

Except with respect to any subsection of this *Article III*, as set forth in the correspondingly identified subsection of the disclosure schedule delivered by ANI to the Company concurrently with this Agreement (the "**ANI Disclosure Schedule**") (it being understood by the Parties that the information disclosed in one subsection of the ANI Disclosure Schedule will be deemed to be included in each other subsection of the ANI Disclosure Schedule in which the relevance of such information thereto would be readily apparent on the face thereof), ANI represents and warrants to the Company as follows:

3.1 **Organization, Standing and Power.** ANI is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, and is duly qualified and in good standing to do business in each jurisdiction in which the nature of its business or the ownership or leasing of its properties makes such qualification necessary, other than in such other jurisdictions where the failure so to qualify and be in such standing would not, either individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on ANI. The Certificate of Incorporation and By-laws of ANI, copies of which were previously provided to the Company, are true, complete and correct copies of such documents as in effect on the date of this Agreement. The stock records, minute books and other records of ANI are accurate, up to date and complete in all materials respects.

As used in this Agreement:

(a) the word "**Subsidiary**" when used with respect to any Party, means any corporation or other organization, whether incorporated or unincorporated, (x) of which such Party or any other Subsidiary of such Party is a general partner (excluding partnerships, the general partnership interests of which held by such Party or any Subsidiary of such Party do not have a majority of the voting interests in such partnership), or (y) at least a majority of the securities or other interests of which, that have by their terms ordinary voting power to elect a majority of the board of directors or others performing similar functions with respect to such corporation or other organization, is directly or indirectly owned or controlled by such Party or by any one or more of its Subsidiaries, or by such Party and one or more of its Subsidiaries;

(b) any reference to any event, change or effect being "**material**" with respect to any entity means an event, change or effect which is material in relation to the financial condition, properties, assets, liabilities, businesses or results of operations of such entity and its Subsidiaries taken as a whole; and

(c) the term "**Material Adverse Effect**" means, with respect to any Person, any occurrence, condition, change, event or development, or series of any of the foregoing that, individually or in the aggregate, is or is reasonably likely to (i) be materially adverse to the business, properties, assets (including intangible assets), capitalization, liabilities, financial condition or results of operations of such entity taken as a whole with its Subsidiaries or (ii) materially impair, prevent or delay the ability of such Person to consummate the transactions contemplated by this Agreement or to perform its obligations hereunder; *provided* that, for purposes of paragraph (b) above and clause (i) of this paragraph (c), the following will not be deemed "material" or to have a "Material Adverse Effect": any change or event caused by or resulting from (1) changes in prevailing

economic or financial market conditions in the United States or any other jurisdiction in which such entity has substantial business operations (except to the extent that those changes have a materially disproportionate effect on such Person and its Subsidiaries relative to the other Party and its Subsidiaries), (2) changes, after the date hereof, in GAAP or requirements applicable to such Person and its Subsidiaries (except to the extent those changes have a materially disproportionate effect on such Person and its Subsidiaries relative to the other Party and its Subsidiaries), (3) changes, after the date hereof, in laws, rules or regulations of general applicability or interpretations thereof by any Government Authority (except to the extent those changes have a materially disproportionate effect on such Person and its Subsidiaries relative to the other Party and its Subsidiaries), (4) the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby or thereby or the announcement or pendency thereof, or (5) any outbreak of major hostilities in which the United States is involved or any act of terrorism within the United States or directed against its facilities or citizens wherever located; and *provided, further*, that in no event will a change in the trading prices of a Party's capital stock, by itself, be considered material or constitute a Material Adverse Effect.

### 3.2 Capital Structure.

(a) The authorized capital stock of ANI consists of 3,700,000 shares of ANI common stock, par value \$.10 per share ("**ANI Common Stock**"), of which 11,294 shares are issued and outstanding on the date hereof, 108,494 shares of ANI Series A Preferred Stock, par value \$.10 per share, of which 102,774 shares are issued and outstanding on the date hereof, 118,915 shares of ANI Series B Preferred Stock, par value \$.10 per share, of which 78,491 shares are issued and outstanding on the date hereof, 37,956 shares of ANI Series C Preferred Stock, par value \$.10 per share, of which 34,810 shares are issued and outstanding on the date hereof, and 3,400,000 shares of ANI Series D Preferred Stock (together with all other classes of preferred stock set forth above, the "**ANI Preferred Stock**"), of which 2,375,312 shares are issued and outstanding on the date hereof. As of the date hereof there are issued and unexercised warrants to purchase 17,526 shares of ANI Common Stock with a weighted average exercise price of \$0.10 per share (the "**ANI Warrants**"). As of the date hereof, no shares of ANI Common Stock were held by ANI's Subsidiaries. As of the date hereof, no shares of ANI Common Stock or ANI Preferred Stock are held by ANI in its treasury. All outstanding shares of ANI Common Stock and ANI Preferred Stock have been duly authorized and validly issued and are fully paid and, except as set forth in the DGCL, non-assessable and are not subject to preemptive rights.

(b) Other than the ANI Warrants, no outstanding warrants to purchase any ANI Shares are issued or outstanding.

(c) No bonds, debentures, notes or other indebtedness having the right to vote (or convertible into, or exchangeable for, securities having the right to vote) on any matters on which stockholders may vote ("**Voting Debt**") of ANI are issued or outstanding.

(d) Except for (i) this Agreement, (ii) the ANI Warrants, (iii) certain transaction bonus agreements described in *Section 3.8* of the ANI Disclosure Schedule and (iv) agreements entered into and securities and other instruments issued after the date of this Agreement as permitted by *Section 5.1*, there are no options, warrants, calls, rights, commitments or agreements of any character to which ANI or any Subsidiary of ANI is a party or by which it or any such Subsidiary is bound obligating ANI or any Subsidiary of ANI to issue, deliver or sell, or cause to be issued, delivered or sold, additional shares of capital stock or any Voting Debt or stock appreciation rights of ANI or of any Subsidiary of ANI or obligating ANI or any Subsidiary of ANI to grant, extend or enter into any such option, warrant, call, right, commitment or agreement. Except as set forth in *Section 3.2(c)* of the ANI Disclosure Schedule, there are no outstanding contractual obligations of

ANI or any of its Subsidiaries (x) to repurchase, redeem or otherwise acquire any shares of capital stock of ANI or any of its Subsidiaries, or (y) pursuant to which ANI or any of its Subsidiaries is or could be required to register shares of ANI Common Stock or other securities under the Securities Act of 1933, as amended (the "**Securities Act**"), except any such contractual obligations entered into after the date hereof as permitted by *Section 5.1*. Except as set forth in *Section 3.2(c)* of the ANI Disclosure Schedule, there are no agreements, trust or proxies that relate to the voting or control of any issued and outstanding capital stock of ANI or any Subsidiary of ANI.

(e) Except as set forth in *Section 3.2(e)* of the ANI Disclosure Schedule, since January 1, 2012, except as permitted by *Section 5.1* after the date hereof, ANI has not (i) issued or permitted to be issued any shares of capital stock, stock appreciation rights or securities exercisable or exchangeable for or convertible into shares of capital stock of ANI; (ii) repurchased, redeemed or otherwise acquired, directly or indirectly, any shares of capital stock of ANI; or (iii) declared, set aside, made or paid to the stockholders of ANI dividends or other distributions on the outstanding shares of capital stock of ANI.

(f) Pursuant to the terms of the Certificate of Incorporation of ANI: (i) the ANI Series D Preferred Stock is the only class or series of ANI Shares entitled to receive any consideration in connection with the Merger unless the Share Value exceeds the Series D Preference Amount; (ii) the ANI Series D Preferred Stock and the ANI Series C Preferred Stock are the only classes or series of ANI Shares entitled to receive any consideration in connection with the Merger unless the Share Value exceeds the sum of the Series D Preference Amount and the Series C Preference Amount, (iii) the ANI Series D Preferred Stock, ANI Series C Preferred Stock and ANI Series B Preferred Stock are the only classes or series of ANI Shares entitled to receive any consideration in connection with the Merger unless the Share Value exceeds the sum of the Series D Preference Amount, the Series C Preference Amount and the Series B Preference Amount, (iv) the ANI Series D Preferred Stock, ANI Series C Preferred Stock, ANI Series B Preferred Stock and ANI Series A Preferred Stock are the only classes or series of ANI Shares entitled to receive any consideration in connection with the Merger if the Share Value exceeds the sum of the Series D Preference Amount, the Series C Preference Amount and the Series B Preference Amount and (v) all other classes and series of ANI Shares, including the ANI Common Stock are to be cancelled at the Effective Time and no payment must be made with respect to any such other ANI Shares. Any ANI Warrants that remain outstanding after the Effective Time, will not, pursuant to their terms, entitle the holder thereof to receive upon exercise any equity or other interest in the Surviving Corporation or any other consideration.

(g) Each of the stockholders of ANI listed on *Schedule I* hereto who are executing Voting Agreements concurrently with the execution and delivery of this Agreement is an executive officer, director, affiliate, founder or holder of 5% or more of the voting equity securities of ANI and all of such stockholders of ANI that are executing Voting Agreements collectively own 90% of the voting equity of ANI.

### 3.3 Authority; Non-Contravention; Consents and Approvals.

(a) ANI has all requisite corporate power and authority to enter into this Agreement, subject in the case of the consummation of the Merger to the adoption of this Agreement by the holders of a majority of the outstanding shares of ANI Common Stock, calculated on an as-converted basis, and 65% of the issued and outstanding shares of ANI Series D Preferred Stock (the "**ANI Stockholder Approval**"), to consummate the transactions contemplated by this Agreement, including the Merger. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of ANI, subject in the case of the consummation of the Merger to obtaining the ANI Stockholder Approval, and no other corporate proceedings on the part of ANI (other than

obtaining the ANI Stockholder Approval and filing the Certificate of Merger with the Delaware Secretary) are necessary to authorize this Agreement or to consummate the transactions contemplated hereby, including the Merger. This Agreement has been duly executed and delivered by ANI and, assuming due authorization, execution and delivery by the Company, constitutes a valid and binding obligation of ANI, enforceable against ANI in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability relating to or affecting creditors' rights and to general equitable principles.

(b) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will, (i) conflict with, or result in any violation of, or constitute a default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation, modification or acceleration of any obligation or the loss of a material benefit under, or the creation of a lien, pledge, security interest, charge or other encumbrance on any assets (any such conflict, violation, default, right of termination, cancellation, modification or acceleration, loss or creation, a "**Violation**") pursuant to, any provision of the Certificate of Incorporation or By-laws of ANI or any Subsidiary of ANI, or (ii) subject to obtaining or making the consents, approvals, orders, authorizations, registrations, declarations and filings set forth in *Section 3.3(b)* of the ANI Disclosure Schedule, result in any Violation of any loan or credit agreement, note, mortgage, indenture, lease, ANI Benefit Plan (as defined in *Section 3.9*) or other agreement, obligation, instrument, permit, concession, franchise, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to ANI or any Subsidiary of ANI or their respective properties or assets, which Violation, in the case of clause (ii), individually or in the aggregate, would reasonably be expected to be material to ANI.

(c) No consent, approval, order or authorization of, or registration, declaration or filing with, any court, administrative agency or commission or other governmental authority or instrumentality, domestic or foreign (a "**Government Authority**") is required by or with respect to ANI or any Subsidiary of ANI in connection with the execution and delivery of this Agreement by ANI or the consummation by ANI of the transactions contemplated hereby, except for (i) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware, or (ii) actions required by or notices or filings required by applicable U.S. Food and Drug Administration (the "**FDA**"), Medicare/Medicaid, federal and state insurance and other federal and state Government Authorities with jurisdiction over or otherwise relating to the ANI Regulatory Filings, as disclosed in *Section 3.3(c)* of the ANI Disclosure Schedule.

#### 3.4 **Financial Statements; Undisclosed Liabilities.**

(a) ANI has previously delivered to the Company true, correct and complete copies of the following financial statements and notes (collectively, the "**ANI Financial Statements**"): (i) the audited balance sheets of ANI as of December 31, 2010 and 2011 (the December 31, 2011 balance sheet being referred to herein as the "**ANI Audited Balance Sheet**") and the related audited statements of operations, statements of stockholders' equity and statements of cash flows of ANI for the two years ended December 31, 2011, together with the notes thereto and the unqualified reports and opinions of Stout, Causey & Horning, P.A., relating thereto; and (ii) the unaudited balance sheet of ANI as of August 31, 2012 (the "**ANI Unaudited Interim Balance Sheet**") and the related unaudited statement of operations, statement of stockholders' equity and statement of cash flows of ANI for the eight (8) months then ended. The ANI Financial Statements are accurate and complete in all material respects and fairly present the financial position of ANI as of the respective dates thereof and the results of operations, changes in stockholders' equity and cash flows of ANI for the periods covered thereby. Except as may be indicated in the notes to the ANI Financial Statements, the ANI Financial Statements have been prepared in accordance with generally accepted accounting principles ("**GAAP**") applied on a consistent basis throughout the periods covered (except that the financial statements referred to in *Section 3.4(a)(ii)* do not



contain footnotes and are subject to normal and recurring year-end audit adjustments, which will not, individually or in the aggregate, be material).

(b) No financial statements of any Person other than ANI and the ANI Subsidiaries actually included in ANI Financial Statements are required by GAAP to be included in ANI Financial Statements.

(c) Except as required by GAAP, ANI has not, between the last day of its most recently ended fiscal year and the date of this Agreement, made or adopted any material change in its accounting methods, practices or policies in effect on such last day of its most recently ended fiscal year.

(d) ANI's external auditors have not identified to ANI any material weaknesses in ANI's internal controls impacting on the reliability of ANI Financial Statements.

(e) ANI has not had any material dispute with any of its auditors regarding accounting matters or policies during any of its past three (3) full fiscal years or during the current fiscal year and it has no reason to believe that there will be an adjustment to, or any restatement of, the ANI Financial Statements. No current or former independent auditor for ANI has resigned or been dismissed from such capacity as a result of or in connection with any disagreement with ANI on a matter of accounting practices. The ANI Financial Statements were prepared from, and are consistent with, the accounting records of ANI and its Subsidiaries. ANI has also delivered to the Company copies of all letters from ANI's auditors to the ANI Board or audit committee thereof since January 1, 2010, together with copies of all responses thereto.

(f) ANI keeps books, records and accounts that, in reasonable detail, accurately and fairly reflect the transactions and acquisitions and dispositions of assets of ANI. ANI has designed and maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

(g) Except for (i) those liabilities that are fully reflected or reserved for in the ANI Financial Statements, (ii) liabilities incurred since the date of the ANI Unaudited Interim Balance Sheet in the ordinary course of business consistent with past practice, (iii) liabilities (other than as a result of a breach of contract, breach of warranty, product liability, tort or intellectual property infringement or violation of Applicable Law or an Action) which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on ANI, (iv) liabilities incurred pursuant to the transactions contemplated by this Agreement, and (v) liabilities or obligations discharged or paid in full prior to the date of this Agreement in the ordinary course of business consistent with past practice, ANI and its Subsidiaries do not have, and since the date of the ANI Unaudited Interim Balance Sheet ANI and its Subsidiaries do not have outstanding and have not incurred (except as permitted by *Section 5.1*), any liabilities or obligations of any nature whatsoever (whether accrued, absolute, matured, determined, contingent or otherwise and whether or not required to be reflected in the ANI Financial Statements in accordance with GAAP).

**3.5 Compliance with Applicable Laws.** Neither ANI nor any ANI Subsidiary has violated or failed to comply with any Applicable Law material to the operation of ANI's business. For purposes of this Agreement, "**Applicable Law**" means, with respect to any Person, any U.S. federal, state or local or any foreign law (in each case, statutory, common or otherwise), constitution, treaty, convention, ordinance, code, rule, regulation, order, injunction, judgment, decree, ruling or other similar requirement enacted, adopted, promulgated or applied by a Government Authority that is binding upon or applicable to that Person. The businesses of ANI and its Subsidiaries are not being and have not

been conducted in violation of any law, ordinance or regulation of any Government Authority in any material respect.

**3.6 Legal Proceedings.** Except as set forth in *Section 3.6* of the ANI Disclosure Schedule, there is no claim, suit, action, litigation, arbitration, investigation or other demand or proceeding (whether judicial, arbitral, administrative or other) (each, an "**Action**") pending or, to the knowledge of ANI, threatened, against or affecting ANI or any Subsidiary of ANI as to which there is a significant possibility of an adverse outcome which would, individually or in the aggregate, be material to ANI, nor is there any judgment, decree, injunction, rule, award, settlement, stipulation or order of or subject to any Government Authority or arbitrator (an "**Order**") outstanding against ANI or any Subsidiary of ANI having or which would reasonably be expected, individually or in the aggregate, to be material to ANI. To the knowledge of ANI, no investigation by any Government Authority with respect to ANI or any of its Subsidiaries is pending or threatened.

**3.7 Taxes.**

(a) ANI and its Subsidiaries have timely filed all material Tax Returns required to be filed by them and all such Tax Returns are correct and complete in all material respects. ANI and its Subsidiaries have timely paid all material amounts of Taxes due and payable (whether or not shown on such Tax Returns) and the ANI Financial Statements reflect an adequate reserve, in accordance with GAAP, for all Taxes payable by ANI and its Subsidiaries accrued through the date of such financial statements.

(b) There is no Tax deficiency outstanding, proposed or assessed against ANI or any of its Subsidiaries. No audit or other examination of any Tax Return of ANI or any of its Subsidiaries by any Government Authority is presently in progress, nor has ANI or any of its Subsidiaries been notified in writing or, to the knowledge of ANI, otherwise been notified of any request for such an audit or other examination. There are no Liens for Taxes upon ANI or any of its Subsidiaries, or any assets of ANI or any of its Subsidiaries, except for Liens for Taxes not yet due and payable.

(c) Neither ANI nor any of its Subsidiaries has constituted either a "distributing corporation" or a "controlled corporation" within the meaning of Section 355(a)(1)(A) of the Code in a distribution of stock qualifying for tax-free treatment under Section 355 of the Code (i) in the two (2) years prior to the date of this Agreement or (ii) in a distribution which could otherwise constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) in conjunction with the transactions contemplated by this Agreement.

(d) No claim in writing has been made by a Government Authority in a jurisdiction where ANI or any of its Subsidiaries do not file Tax Returns that ANI or any of its Subsidiaries is or may be subject to Tax in that jurisdiction.

(e) Neither ANI nor any of its Subsidiaries is a party to any Tax sharing, allocation, indemnity or similar agreement or arrangement (whether or not written) pursuant to which it could have any obligation to make any payments after the Closing. Neither ANI nor any of its Subsidiaries have ever been a member of any consolidated, combined, affiliated or unitary group of corporations for any Tax purposes (other than a consolidated group of which ANI was the common parent), nor do any of them have any liability for Taxes of any other Person.

(f) ANI and its Subsidiaries have disclosed on their US federal income Tax Returns all positions taken therein that could give rise to substantial understatement of US federal income Tax within the meaning of Section 6662 of the Code. Neither ANI nor any of its Subsidiaries has entered into any transaction identified as a "reportable transaction" for purposes of Treasury Regulations Section 1.6011-4(b).

(g) There is no taxable income of ANI or any of its Subsidiaries that will be required under any Applicable Law to be reported in a Taxable period beginning after the Closing Date which Taxable income was realized (or reflects economic income) arising prior to the Closing Date as a result of any: (i) change in method of accounting for a taxable period ending on or prior to the Closing Date; (ii) "closing agreement" as described in Section 7121 of the Code executed on or prior to the Closing Date; (iii) installment sale or open transaction disposition made on or prior to the Closing Date; (iv) prepaid amount or deferred revenue received on or prior to the Closing Date or (v) election under Section 108(i) of the Code.

(h) Neither ANI nor any of its Subsidiaries has taken any action or know of any fact, agreement, plan or other circumstance that could reasonably be expected to prevent the Merger from qualifying as a reorganization within the meaning of Section 368(a) of the Code.

(i) As of December 31, 2011, ANI and its Subsidiaries had net operating loss carryovers of at least \$33,000,000 for federal income Tax purposes.

(j) For the purpose of this Agreement, the term "**Tax**" (including, with correlative meaning, the terms "**Taxes**" and "**Taxable**") means (i) all Federal, state, local and foreign income, alternative or add-on minimum, estimated, profits, windfall profits, franchise, business occupation, gross receipts, payroll, sales, value added, employment, unemployment, wage, workers compensation, social insurance, social security, disability, use, property, ad valorem, severance, environmental, transfer, stamp, occupation, withholding, excise, occupancy, lease, service, service use, license, capital stock, paid in capital, recording, registration, business license, customs duties, and other taxes, imposts, fees, duties or assessments of any nature whatsoever, together with all interest, penalties and additions imposed with respect to such amounts, (ii) liability for the payment of any amounts of the type described in clause (i) as a result of being party to any tax sharing agreement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (i) or (ii). For purposes of this Agreement, the term "**Tax Returns**" means all federal, state, local and foreign returns, estimates, information statements, declarations, claims for refund, and reports with respect to Taxes, including any schedule or attachment thereto, and including any amendment thereof.

### 3.8 Certain Agreements.

(a) Except as disclosed in *Section 3.8* of the ANI Disclosure Schedule, and except for this Agreement, neither ANI nor any of its Subsidiaries is bound by any contract, arrangement, commitment or understanding (a "**Contract**"):

(i) that constitutes a partnership, joint venture, technology sharing or similar agreement between ANI or any of its Subsidiaries and any other Person;

(ii) with respect to the service of any directors, officers, employees, or independent contractors or consultants that are natural persons, involving the payment of \$100,000 or more in any 12 month period, other than those that are terminable by ANI or any of its Subsidiaries on no more than 30 days' notice without penalty;

(iii) which limits the ability of ANI or any of its Subsidiaries to compete or enter into in any line of business, in any geographic area or with any person, or which requires referrals of business to a third party and, in each case, which limitation or requirement would reasonably be expected to be material to ANI and its Subsidiaries taken as a whole;

(iv) with or to a labor union, works council or guild (including any collective bargaining agreement or similar agreement);

- (v) relating to the use or right to use Intellectual Property, including any license or royalty agreements and an ANI IP Contract;
- (vi) that provides for indemnification by ANI to any Person, other than an agreement entered into in the ordinary course of business and that is not material to ANI;
- (vii) between ANI or any ANI Subsidiary and any current or former director or officer of ANI or an ANI Subsidiary, or any affiliate of any such Person (other than an ANI Benefit Plan);
- (viii) with respect to (A) indebtedness for borrowed money (including the issuance of any debt security) to any Person other than ANI or any of its Subsidiaries, (B) any obligations evidenced by notes, bonds, mortgages, debentures or similar agreements to any Person other than ANI or any of its Subsidiaries (any obligation described in this clause (B) or the foregoing clause (A) being referred to herein as "**Indebtedness**"), (C) any capital lease obligations to any Person other than ANI or any of its Subsidiaries, (D) any obligations to any Person other than ANI or any of its Subsidiaries in respect of letters of credit and bankers' acceptances, (E) any indebtedness to any Person other than ANI or any of its Subsidiaries under interest rate swap, hedging or similar agreements, (F) any obligations to pay to any Person other than ANI or any of its Subsidiaries the deferred purchase price of property or services, (G) indebtedness secured by any Lien on any property owned by ANI or any of its Subsidiaries even though the obligor has not assumed or otherwise become liable for the payment thereof, or (H) any guaranty of any such obligations described in clauses (A) through (G) of any Person other than ANI or any of its Subsidiaries, in each case, having an outstanding amount in excess of \$100,000 individually or \$250,000 in the aggregate;
- (ix) that is material to ANI or that contains any so called "most favored nation" provision or similar provisions requiring ANI to offer to a Person any terms or conditions that are at least as favorable as those offered to one or more other Persons;
- (x) pursuant to which any agent, sales representative, distributor or other third party markets or sells any ANI Product;
- (xi) pursuant to which ANI or any Subsidiary is a party granting rights of first refusal, rights of first offer or similar rights to acquire any business or assets of the ANI or any Subsidiary;
- (xii) relating to the purchase or sale of assets outside the ordinary course of business of ANI;
- (xiii) relating to the issuance of any securities of ANI or any Subsidiary;
- (xiv) pursuant to which any material asset of ANI or any of its Subsidiaries is leased;
- (xv) relates to the purchase of (A) any equipment entered into since December 31, 2011 and (B) any materials, supplies, or inventory since December 31, 2011, other than any agreement which, together with any other related agreement, involves the expenditure by the Company of less than Fifty Thousand Dollars (\$50,000);
- (xvi) that represents a purchase order with any supplier for the purchase of inventory items in an amount in excess of Fifty Thousand Dollars (\$50,000) of materials;
- (xvii) pursuant to which ANI or any Subsidiary is a party and having a remaining term of more than one (1) year after the Closing Date or involving a remaining amount payable thereunder (either to or from the Company) as of the Closing Date, of at least One Hundred Thousand Dollars (\$100,000),

(xviii) which involves the payment of \$200,000 or more in any 12 month period after the date hereof; or

(xix) which would prevent, delay or impede the consummation, or otherwise reduce the contemplated benefits, of any of the transactions contemplated by this Agreement.

ANI has previously made available to the Company or its representatives complete and accurate copies of each Contract of the type described in this Section 3.8(a) (collectively referred to herein as "**ANI Contracts**").

(b) All of the ANI Contracts were entered into at arms' length in the ordinary course of business and are valid and in full force and effect, except to the extent they have previously expired in accordance with their terms. Neither ANI nor any of its Subsidiaries has given or received a notice of cancellation or termination under any ANI Contract, or has, or is alleged to have, and to the knowledge of ANI, none of the other parties thereto have, violated any provision of, or committed or failed to perform any act, and no event or condition exists, which with or without notice, lapse of time or both would constitute a default under the provisions of, any ANI Contract.

### 3.9 Benefit Plans.

(a) Section 3.9 of the ANI Disclosure Schedule sets forth a true and complete list of each ANI Benefit Plan. An "**ANI Benefit Plan**" is any "employee benefit plan" within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), and whether or not subject to ERISA, any material employment, termination or severance agreement, and any material bonus, deferred compensation, incentive compensation, stock ownership, stock purchase, stock option, phantom stock, equity-based, vacation, severance, retention, change in control, profit sharing, retirement, welfare, disability, death benefit, hospitalization or insurance plan, and any other material plan, agreement, or program providing compensation or benefits to any current or former employee, director or independent contractor of ANI or any Subsidiary or ERISA Affiliate of ANI or maintained, contributed to, or required to be contributed to by ANI, any Subsidiary or other ERISA Affiliate or that ANI, any Subsidiary or other ERISA Affiliate has committed to establish, adopt or contribute to, or under which ANI, any Subsidiary or other ERISA Affiliate otherwise has or may have any liability. An "ERISA Affiliate" with respect to any Party means any entity required to be aggregated with such Party under Section 414 of the Code, or any trade or business, whether or not incorporated that together with such Party would be deemed a "single employer" within the meaning of Section 4001(b) of ERISA (an "**ERISA Affiliate**")

(b) No ANI Benefit Plan is a multiemployer plan within the meaning of ERISA Section 3(37).

(c) No ANI Benefit Plan is a "defined benefit pension plan" within the meaning of Code Section 414(j) or subject to Title IV of ERISA; no ANI Benefit Plan is subject to the minimum funding standards of Code Section 412 and/or ERISA Section 302; and neither ANI nor any Subsidiary has any liability to the Pension Benefit Guaranty Corporation ("**PBGC**") or any other person, arising directly or indirectly under Title IV of ERISA.

(d) Each ANI Benefit Plan has been maintained in material compliance with its terms and with all applicable laws, including, but not limited to ERISA and the Code and with respect to the ANI Benefit Plans, individually and in the aggregate, no event has occurred and, to the knowledge of ANI, there exists no condition or set of circumstances in connection with which ANI or any of its Subsidiaries or other ERISA Affiliates could be subject to any liability under ERISA, the Code or any other Applicable Law.

(e) There are no actions, suits or claims pending (other than routine claims for benefits) or, to the knowledge of ANI, threatened against, or with respect to, any ANI Benefit Plan.

(f) All required contributions to ANI Benefit Plans due on or before the Closing Date have been, or will have been, made or properly accrued on or before the Closing Date.

(g) Except as set forth in *Section 3.9(g)* of the ANI Disclosure Schedule, the execution and delivery by ANI of this Agreement does not, and the consummation of the Merger and compliance with the terms hereof (whether alone or in combination with any other event) will not, (A) entitle any current or former employee or director or independent contractor of ANI or any Subsidiary to severance pay, (B) except as expressly required by this Agreement, accelerate the time of payment or vesting or trigger any payment or funding (through a grantor trust or otherwise) of compensation or benefits under, increase the amount payable or trigger any other material obligation pursuant to, any ANI Benefit Plan, (C) result in any breach or violation of, or a default under, any ANI Benefit Plan, or (D) cause any amounts payable under any ANI Benefit Plan (whether in cash, in property or in the form of benefits) to fail to be deductible for federal income tax purposes by virtue of Sections 162(m) or 280G of the Code.

(h) None of ANI, any Subsidiary or other ERISA Affiliate, or ANI Benefit Plan has engaged in a transaction in connection with which ANI, any Subsidiary or other ERISA Affiliate, ANI Benefit Plan (or any such trust, or any trustee or administrator thereof), or any party dealing with any ANI Benefit Plan or any such trust could be subject to either a civil penalty assessed pursuant to Sections 409 or 502(i) of ERISA or a Tax imposed pursuant to Sections 4975 or 4976 of the Code.

(i) Each ANI Benefit Plan and related trust intended to qualify under Sections 401 and 501(a) of the Code is subject to a current favorable determination or opinion letter from the Internal Revenue Service ("IRS") and, to ANI's knowledge, nothing has occurred that is reasonably likely to result in the revocation of such letter. ANI and its Subsidiaries have not sponsored, maintained or contributed to or had any liability with respect to any qualified pension plan which, during the preceding two (2) years, has been terminated, including by way of merger with or into an ANI Benefit Plan or another plan.

(j) Except as set forth in *Section 3.9(j)* of the ANI Disclosure Schedule, ANI and its Subsidiaries do not contribute to, have or could have any liability with respect to retiree medical coverage or other medical, health, life or other welfare benefits for present or future terminated employees or their spouses or dependents other than as required by Part 6 of Subtitle B of Title I of ERISA ("COBRA") or any comparable state Applicable Law.

(k) No employer other than ANI, a Subsidiary or other ERISA Affiliate is permitted to participate in any ANI Benefit Plan and no leased employees (as defined in Code Section 414(n)) or independent contractors are eligible for, or participate in, any ANI Benefit Plan.

(l) Except as set forth on *Section 3.9* of the ANI Disclosure Schedule, no ANI Benefit Plan is a "nonqualified deferred compensation plan" subject to Section 409A of the Code and the regulations and other guidance promulgated thereunder (unless such ANI Benefit Plan complies with an exemption or exception to Code Section 409A). None of ANI, its Subsidiaries or its ERISA Affiliates is a party to any agreement, or otherwise obligated under any ANI Benefit Plan, to provide for a gross up of Taxes imposed by Section 409A of the Code. Each nonqualified deferred compensation plan (as defined in Section 409A(d)(1) of the Code) maintained or sponsored by ANI its Subsidiaries or its ERISA Affiliates has since (i) January 1, 2005, been maintained and operated in good faith compliance with Section 409A of the Code and Notice 2005-1, (ii) October 3, 2004, not been "materially modified" (within the meaning of Notice 2005 1) with respect to any amounts that are "grandfathered" from the application of Section 409A of the Code, and (iii) January 1, 2010, been in documentary and operational compliance with final regulations under Section 409A of the Code.

(m) No ANI Benefit Plan is not now, or in the past seven years has been, "top-heavy" pursuant to Code Section 416.

(n) ANI has delivered or made available to the Company true and complete copies of:

(i) all ANI Benefit Plan documents and related trust agreements or other agreements or contracts evidencing any funding vehicle with respect thereto;

(ii) the three most recent annual reports on Form 5500, including all schedules, attachments and/or audits thereto, with respect to any ANI Benefit Plan for which such a report (and/or audit) is required;

(iii) the summary plan description, including any summary of material modifications thereto or other modifications communicated to participants, currently in effect with respect to each ANI Benefit Plan;

(iv) the most recent determination letter or opinion letter issued by the IRS with respect to each ANI Benefit Plan intended to qualify under section 401(a) of the Code and with respect to any determination letter the full and complete application therefore submitted to the IRS; and

(v) material correspondence in the past seven years with regulatory authorities (such as a copy of all documents relating to any audit or investigation by any regulatory authority or any a voluntary correction submission with the Department of Labor or the IRS) with respect to any ANI Benefit Plan.

**3.10 Subsidiaries.** *Section 3.10* of the ANI Disclosure Schedule sets forth a true and complete list of all the Subsidiaries of ANI. Each Subsidiary of ANI is a corporation or other entity duly organized, validly existing and, in the case of corporations, in good standing under the laws of its jurisdiction of formation, has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, and is duly qualified and in good standing to do business in each jurisdiction in which the nature of its business or the ownership or leasing of its properties makes such qualification necessary and where the failure so to qualify would have a material effect on ANI. All of the shares of capital stock of each of the Subsidiaries held by ANI or by another ANI Subsidiary are fully paid and nonassessable and are owned by ANI or a Subsidiary of ANI free and clear of any material Lien, except for ANI Permitted Liens. Except for the Subsidiaries set forth in *Section 3.10* of the ANI Disclosure Schedule, ANI neither directly nor indirectly, (a) owns or otherwise controls, (b) has agreed to purchase or otherwise acquire or (c) holds any interest convertible into or exchangeable for, any capital stock or other equity interest of any other corporation, partnership, joint venture or other business association or entity.

**3.11 Absence of Certain Changes or Events.** (a) Since December 31, 2011, except as permitted by *Section 5.1* in the case of actions taken after the date hereof, there has not been any change, circumstance or event (including any event involving a prospective change) which, individually or in the aggregate, has had, or would reasonably be expected to have, a Material Adverse Effect on ANI, and (b) since December 31, 2011, except as contemplated by this Agreement ANI and its Subsidiaries have conducted their respective businesses in the ordinary course consistent with their past practices.

**3.12 Board Approval.** The board of directors of ANI (the "**ANI Board**"), by resolutions duly adopted at a meeting duly called and held has: (a) approved and adopted, and declared the advisability of, this Agreement and the transactions contemplated hereby, including the Merger; (b) determined that this Agreement and the transactions contemplated hereby, including the Merger, are fair to and in the best interests of ANI and ANI's stockholders; and (c) subject to *Section 5.3(d)*, resolved to make and maintain the ANI Board Recommendation.

3.13 **Takeover Statutes.** ANI has taken all action necessary to exempt or exclude this Agreement and the transactions contemplated hereby, including the Merger, from: (i) the restrictions on business combinations set forth in Section 203 of the DGCL; and (ii) any other similar antitakeover law, statute or regulation (each, a "**Takeover Statute**"). Accordingly, no Takeover Statute applies to this Agreement or the transactions contemplated hereby, including the Merger, with respect to ANI. ANI does not have any stockholder rights plan, "poison pill" or similar plan or arrangement in effect.

3.14 **Properties.** Except as set forth in *Section 3.14* of the ANI Disclosure Schedule, ANI or one of its Subsidiaries (a) has good and valid title to all of its properties and assets, including those reflected in the ANI Financial Statements as being owned by ANI or one of its Subsidiaries or acquired after the date thereof that are material to ANI's business (except properties sold or otherwise disposed of since the date thereof in the ordinary course of business and as permitted under *Section 5.1*), free and clear of all claims, liens (statutory or otherwise), charges, security interests, encumbrances or other adverse claims of any nature whatsoever, including mortgages, deeds of trust, pledges, options, conditional sales contracts, assessments, levies, easements, covenants, reservations, restrictions, rights-of-way or encumbrances of any nature whatsoever (each, a "**Lien**"), except (i) statutory liens securing payments not yet due or liens which are being properly contested by ANI or one of its Subsidiaries in good faith and by proper legal proceedings and for which adequate reserves related thereto are maintained on the ANI Financial Statements, (ii) such imperfections or irregularities of title, claims, liens, charges, security interests, easements, covenants and other restrictions or encumbrances as do not materially affect the use or value of the properties or assets subject thereto or affected thereby or otherwise adversely impair business operations at such properties, (iii) mortgages, or deeds of trust, security interests or other encumbrances on title related to indebtedness reflected in the ANI Financial Statements and which have been or will be satisfied and released at or prior to the Closing Date, and (iv) rights granted to any non-exclusive licensee of any ANI Intellectual Property in the ordinary course of business consistent with past practices (such liens, imperfections and irregularities in clauses (i), (ii), (iii) and (iv), "**ANI Permitted Liens**"), and (b) has a valid leasehold interest as a lessee of all leasehold estates reflected in the ANI Financial Statements or acquired after the date thereof which are material to its business on a consolidated basis (except for leases that have expired by their terms since the date thereof) and is in possession of the properties purported to be leased thereunder, and each such lease is valid without default thereunder by the lessee or, to ANI's knowledge, the lessor.

### 3.15 **Intellectual Property.**

(a) For purposes of this Agreement:

(i) "**Intellectual Property**" means and includes all algorithms, biological materials, cell lines, clinical data, chemical compositions or structures, databases and data collections, diagrams, formulae, inventions (whether or not patentable), know-how, logos, marks, methods, processes, proprietary information, protocols, schematics, specifications, software, techniques, URLs, web sites, works of authorship, and other forms of technology (whether or not embodied in any tangible form and including all tangible embodiments of the foregoing such as instruction manuals, laboratory notebooks, prototypes, samples, studies, and summaries).

(ii) "**Intellectual Property Rights**" means and includes all rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (i) rights associated with works of authorship, including exclusive exploitation rights, copyrights and moral rights; (ii) trademark and trade name rights and similar rights; (iii) trade secret rights; (iv) Patents rights; (v) other proprietary rights in Intellectual Property of every kind and nature; and (vi) all registrations, renewals, extensions, combinations, divisions, or reissues of, and applications for, any of the rights referred to in the foregoing clauses (i) through (v).



(iii) "**Patents**" means patents and patent applications (including provisional, continuation, divisional, continuation-in-part, reexamination, and reissue patent applications and any patents issuing therefrom and all corresponding foreign equivalents thereof) and utility models, industrial designs, and other government-issued rights protecting inventions and industrial designs, however denominated, registered with any Government Authority and all applications for any of the foregoing.

(iv) "**ANI Owned IP**" means all Intellectual Property Rights and Intellectual Property owned (solely or jointly) by ANI or any of the ANI Subsidiaries.

(v) "**ANI Licensed IP**" means all Intellectual Property Rights and Intellectual Property licensed to ANI or any of the ANI Subsidiaries.

(vi) "**Registered IP**" means all Intellectual Property Rights that are registered, filed, or issued under the authority of any Government Authority, including all Patents, registered copyrights and registered trademarks and all applications for any of the foregoing.

(b) *Section 3.15(b)* of the ANI Disclosure Schedule accurately identifies and describes each proprietary product or service currently developed, manufactured, marketed, performed or sold by or on behalf of ANI or any of the ANI Subsidiaries, including products or services currently designated as development candidates with a unique internal name by ANI or any of ANI Subsidiaries.

(c) *Section 3.15(c)* of the ANI Disclosure Schedule accurately identifies: (i) each item of ANI Owned IP in which ANI or any of ANI Subsidiaries has or purports to have an ownership interest of any nature (whether exclusively, jointly with another Person, or otherwise); (ii) in the case of Registered IP, the jurisdiction in which such item of Registered IP has been registered or filed and the applicable registration or serial number; and (iii) in the case of Registered IP, any other Person that has an ownership interest in such item of Registered IP and the nature of such ownership interest; and (iv) each ANI Owned IP that is a granted patent that in any way covers any product or service identified in *Section 3.15(b)* of the ANI Disclosure Schedule. ANI has provided to the Company reasonable access to accurate and complete copies of all applications and correspondence to and from the Government Authority related to each such item of ANI Owned IP. For the avoidance of doubt, for published applications and patents, ANI furnishing to the Company the relevant application, serial or patent number of the Registered IP will be considered reasonable access.

(d) *Section 3.15(d)* of the ANI Disclosure Schedule accurately identifies: (i) all Intellectual Property Rights or Intellectual Property licensed to ANI or any of ANI Subsidiaries (other than any non-customized software that (x) is so licensed solely in executable or object code form pursuant to a non-exclusive, internal use software license, (y) is not incorporated into, or used directly in the development, manufacturing or distribution of, any of ANI's or ANI Subsidiaries' products or services and (z) is generally available on standard terms for less than \$15,000); (ii) the corresponding Contract(s) pursuant to which such Intellectual Property Rights or Intellectual Property is licensed to ANI or the ANI Subsidiaries; and (iii) whether the license or licenses granted to ANI or the ANI Subsidiaries are exclusive or non-exclusive.

(e) No Person has been granted by ANI or any of ANI Subsidiaries any license under, or otherwise has received or acquired any right (whether or not currently exercisable) or interest in, any ANI Owned IP. Neither ANI nor any of ANI Subsidiaries are bound by, and no ANI Owned IP is subject to, any Contract containing any covenant or other provision that in any way limits or restricts the ability of ANI or any of ANI Subsidiaries to use, exploit, assert or enforce any ANI Owned IP anywhere in the world, except field and geographical restrictions in applicable licenses to ANI Owned IP granted to ANI.

(f) ANI has provided to the Company an accurate and complete copy of each standard form of any Contract to which ANI or any of the ANI Subsidiaries is a party or by which ANI or any of the ANI Subsidiaries is bound, if any, that contains any assignment or license of, covenant not to assert or enforce or granting of any other rights in, any Intellectual Property Right, including any ANI Owned IP or other Intellectual Property developed by, with, or for ANI or any of the ANI Subsidiaries (an "**ANI IP Contract**") that has been used by ANI or any of the ANI Subsidiaries at any time since January 1, 2010, including each standard form of: (i) employee agreement containing any intellectual property assignment or license of Intellectual Property or Intellectual Property Rights or any confidentiality provision; (ii) consulting or independent contractor agreement containing any intellectual property assignment or license of Intellectual Property or Intellectual Property Rights or any confidentiality provision; and (iii) confidentiality or nondisclosure agreement. *Section 3.15(f)* of the ANI Disclosure Schedule accurately identifies each ANI IP Contract that deviates in any material respect from the corresponding standard form agreement provided to the Company, if any.

(g) Except as set forth in *Section 3.15(g)* of the ANI Disclosure Schedule:

(i) the conduct of the business of ANI and the ANI Subsidiaries as currently conducted does not infringe upon, misappropriate or otherwise violate the Intellectual Property Rights of any third party in any material respect, and no claim has been asserted to ANI in writing that the conduct of the business of ANI and the ANI Subsidiaries as currently conducted infringes upon or misappropriates or otherwise violates the Intellectual Property rights of any third party in any material respect;

(ii) with respect to each item of ANI Owned IP, ANI or any ANI Subsidiary is the owner of the entire right, title and interest in and to such ANI Owned IP and neither ANI nor any ANI Subsidiary has granted to any third party exclusive rights to any ANI Owned IP under terms that would prevent ANI or an ANI Subsidiary from using such ANI Owned IP in the operation of its respective business as currently conducted;

(iii) with respect to each item of ANI Licensed IP, ANI or an ANI Subsidiary has the right to use such ANI Licensed IP in the operation of its respective business as currently conducted in accordance with the terms of the license agreement governing such ANI Licensed IP;

(iv) none of the ANI Owned IP has been adjudged invalid or unenforceable in whole or in part and the ANI Registered IP is valid, subsisting and enforceable (except for prospective challenges that may be received in the ordinary course of patent prosecution and maintenance);

(v) no person is engaging in any activity that infringes upon, misappropriates or otherwise violates the ANI Owned IP in any material respect;

(vi) each license of the ANI Licensed IP is binding on ANI and any of the ANI Subsidiaries party thereto and each of the other parties thereto, and is in full force and effect and no party to any license of the ANI Licensed IP (other than ANI or any ANI Subsidiary) is in material breach thereof or default thereunder; and

(vii) neither the execution of this Agreement nor the consummation of any transaction contemplated hereby will terminate, suspend or modify any of the ANI's rights with respect to any ANI Owned IP or material ANI Licensed IP.

(h) Except as set forth in *Section 3.15(h)* of the ANI Disclosure Schedules, each Person who is or was an employee or contractor of ANI or any of ANI Subsidiaries and who is or was involved in the creation or development of any ANI Owned IP has signed an agreement containing an

assignment of Intellectual Property Rights to ANI or one of ANI Subsidiaries. No current or former stockholder, officer, director, employee, consultant or contractor of ANI or any of ANI Subsidiaries has any claim, right (whether or not currently exercisable) or interest to or in any ANI Owned IP. To ANI's knowledge, no employee of ANI or any of ANI Subsidiaries is: (x) bound by or otherwise subject to any Contract restricting him or her from performing his or her duties for ANI or ANI Subsidiaries; or (y) in breach of any Contract with any former employer or other Person concerning Intellectual Property Rights or confidentiality obligations. Since January 1, 2010, neither ANI nor any of the ANI Subsidiaries have assigned or otherwise transferred ownership of, or agreed to assign or otherwise transfer ownership of, any Intellectual Property Right to any other Person.

(i) ANI and the ANI Subsidiaries have taken all commercially reasonable steps to maintain the confidentiality of and otherwise protect and enforce their rights in all material proprietary information that ANI or any of the ANI Subsidiaries holds, or purports to hold, as a trade secret.

(j) Neither ANI nor any of the ANI Subsidiaries are, and neither ANI nor any of the ANI Subsidiaries ever were, a contributor to any industry standards body or similar organization that could require or obligate ANI or any of ANI Subsidiaries to grant or offer to any other Person any license or right to any ANI Owned IP.

### 3.16 Regulatory Matters.

(a) Each of the products currently marketed by ANI or any of its Subsidiaries and each of the products under development by ANI or any of its Subsidiaries is identified in *Section 3.16(a)* of the ANI Disclosure Schedule (the "**ANI Products**"). Except as set forth in *Section 3.16(a)* of the ANI Disclosure Schedule, ANI and the ANI Subsidiaries hold all material licenses, permits, franchises, variances, registrations, exemptions, orders and other governmental authorizations, consents, approvals and clearances, and have submitted all material notices to, all Government Authorities, including all required authorizations under the Federal Food, Drug and Cosmetic Act of 1938, as amended (the "**FDCA**"), the Public Health Service Act of 1944, as amended (the "**PHSA**") and the regulations of the FDA promulgated thereunder, and any other Government Authority that regulates the quality, identity, strength, purity, safety, efficacy or manufacturing of the ANI Products (any such Government Authority, an "**ANI Regulatory Agency**") required for the lawful operation of the businesses of ANI and the ANI Subsidiaries (the "**ANI Permits**"), except, in each case, as would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect on ANI. Except as set forth in *Section 3.16(a)* of the ANI Disclosure Schedule all such ANI Permits are valid and in full force and effect. Except as set forth in *Section 3.16(a)* of the ANI Disclosure Schedule, none of such ANI Permits will be terminated or impaired or become terminable, in whole or in part, as a result of the transactions contemplated by this Agreement. ANI and the ANI Subsidiaries are the sole and exclusive owner of the ANI Permits and the associated filings and applications with the FDA, including any biologics license application, new drug application, abbreviated new drug application, drug master files, biologics master files, master files for devices, 510(k) submission, premarket approval, investigational new drug or investigational device exemption application, comparable regulatory application or filing made or held by or issued to ANI and the ANI Subsidiaries (collectively, the "**ANI Regulatory Filings**") and hold all right, title and interest in and to all ANI Regulatory Filings free and clear of any Lien. ANI and the ANI Subsidiaries have not granted any third party any right or license to use, access or reference any of the ANI Regulatory Filings, including any of the know-how contained in any of the ANI Regulatory Filings or rights (including any regulatory exclusivities) associated with each such ANI Regulatory Filing.

(b) Except as set forth in *Section 3.16(b)* of the ANI Disclosure Schedule, since January 1, 2010, there has not occurred any breach or violation of, default (with or without notice or lapse of time or both) under or event giving rise to any right of termination, amendment or cancellation of (with or without notice or lapse of time or both), any ANI Permit. Except as set forth in *Section 3.16(b)* of the ANI Disclosure Schedule, ANI and the ANI Subsidiaries are in compliance in all material respects with the terms of all ANI Permits, and no event has occurred and no facts or circumstances exist that, to the knowledge of ANI, would reasonably be expected to result in the revocation, cancellation, non-renewal or adverse modification of any material ANI Permit.

(c) Except as set forth in *Section 3.16(c)* of the ANI Disclosure Schedule, since January 1, 2010, all material applications, submissions, information and data used by ANI or the ANI Subsidiaries as the basis for, or submitted by or, to the knowledge of ANI, on behalf of ANI or the ANI Subsidiaries in connection with, any and all requests for ANI Permits when submitted to the FDA or other ANI Regulatory Agency, were, to ANI's knowledge, accurate and complete in all material respects as of the date of submission, and any updates, changes, corrections or modifications to such applications, submissions, information and data required under Applicable Law have been submitted to the FDA or other ANI Regulatory Agency.

(d) Since January 1, 2010, neither ANI nor any of the ANI Subsidiaries has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA or any other ANI Regulatory Agency to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" or similar policies under Applicable Law. Except as set forth in *Section 3.16(d)* of the ANI Disclosure Schedule, neither ANI nor any of its ANI Subsidiaries nor, to the knowledge of ANI, any agent, subcontractor, director, officer, employee or other Person associated with or acting on behalf of ANI has been convicted of any crime or engaged in any conduct which has resulted or could result in debarment or disqualification by the FDA or any other Government Authority, and there are no proceedings pending or threatened that reasonably might be expected to result in criminal or civil liability or debarment or disqualification by the FDA or any other Government Authority.

(e) Neither ANI nor any of the ANI Subsidiaries nor, to the knowledge of ANI, any director, officer, agent, employee or other Person associated with or acting on behalf of ANI or any of the ANI Subsidiaries has: (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), or any similar Applicable Law; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment. There are no pending or, to the knowledge of ANI, threatened filings against ANI or any ANI Subsidiary of an action relating to the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)).

(f) Since January 1, 2010, there has not been any voluntarily or involuntarily initiated, conducted, or issued recall, field notification, field correction, market withdrawal or replacement, safety alert, warning, "dear doctor" letter, market correction, or investigator notice relating to an alleged material lack of safety or efficacy of any ANI Product.

(g) Except as set forth in *Section 3.16(g)* of the ANI Disclosure Schedule, ANI and its Subsidiaries are in compliance in all material respects with all Applicable Laws and any other letters, notices or guidance issued by the FDA or any Government Authority which regulate the clinical investigation, manufacture, sale, promotion, sampling and distribution of pharmaceutical products or biological, or device products in any jurisdiction. ANI has at all times and is currently distributing, marketing, promoting, labeling and selling its products in accordance with the FDCA and Prescription Drug Marketing Act of 1987. There are no pending or, to the knowledge of ANI,

threatened regulatory Actions (other than non-material routine or periodic inspections or reviews) against ANI or its Subsidiaries. Since January 1, 2010 there have been no written notices, reports, FDA Form 483 observations that have not been disclosed by ANI, warning letters, or untitled letters alleging or asserting noncompliance in any material respect with any Applicable Law relating to ANI or any ANI Subsidiary or any ANI Product or any subpoenas or investigative demands or other written inquiries that would reasonably be interpreted as raising a compliance concern sent or delivered by any Government Authority with regard to any ANI Product.

(h) The manufacture of the ANI Products is being conducted in compliance in all material respects with current "good manufacturing practices," as defined by the FDA. ANI has been in material compliance with FDA's registration and listing requirements to the extent required by FDA.

(i) ANI and its Subsidiaries are and have been in compliance in all material respects with all Applicable Laws requiring the maintenance or submission of reports or records under requirements administered by the FDA or any other Government Authority, including Adverse Experiences, Serious Adverse Events, and Serious Injuries. Except as set forth in *Section 3.16(i)* of the ANI Disclosure Schedule, there have been no Serious Adverse Events or Serious Injuries associated with the use (including in clinical trials) of any ANI Products that have not been reported to the FDA in accordance with Applicable Law.

(j) To the knowledge of ANI, all studies, tests, and preclinical and clinical research being conducted by ANI and ANI Subsidiaries, and to the knowledge of ANI, on behalf of ANI and ANI Subsidiaries, are being, and at all times have been, conducted in compliance in all material respects with all Applicable Laws, including, as applicable, good laboratory practice regulations set forth in 21 C.F.R. Part 58, good clinical practices, as defined or recognized by the FDA, including the ICH Tripartite Guideline for Good Clinical Practice, other applicable provisions of the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812, and comparable laws of any other Government Authority. No clinical trial conducted by ANI or any ANI Subsidiary or, to the knowledge of ANI, on behalf of ANI or any ANI Subsidiary has been terminated or suspended prior to completion for safety or non-compliance reasons, and neither the FDA nor any other Government Authority, clinical investigator or institutional review board that has or had jurisdiction over or participated in any such clinical trial has initiated, or, to the knowledge of ANI, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, materially delay or suspend, any such ongoing clinical trial, or to disqualify, restrict or debar any clinical investigator or other Person or entity involved in any such clinical trial.

(k) Neither ANI nor any ANI Subsidiary nor any officer, director, managing employee (as those terms are defined in 42 C.F.R. § 1001.1001) of ANI or any ANI Subsidiary, nor, to the knowledge of ANI, any agent (as such term is defined in 42 C.F.R. § 1001.1001(a)(1)(ii)) of ANI or any ANI Subsidiary is a party to, or bound by, any order, individual integrity agreement, corporate integrity agreement, monitoring agreement, consent decree, settlement order, deferred prosecution agreement or other formal or informal agreement with any Government Authority concerning compliance with the laws governing any "**Federal Health Care Program**" (which means Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and any other state or federal health care program). ANI meets all the requirements of participation and payment of Medicare, Medicaid, and any other governmental health care programs and third party payment programs to the extent in which it participates (collectively, "**Programs**"). There is no action pending, received or, to ANI's knowledge, threatened against ANI which relates in any way to a violation of any health care laws or which could result in the imposition penalties against or the exclusion of ANI from participation in any Programs. Neither ANI nor any ANI Subsidiary nor officer, director, managing employee have engaged in any activities which are cause for civil penalties or mandatory or permissive exclusion from any Program. To ANI's knowledge, there is no pending,

proposed or final Medicare national or local coverage determination that, if finalized, would restrict coverage for ANI's Products. ANI has not established any reimbursement support program, such that payment for ANI product is contingent upon a purchaser's receipt of payment from a third party payer. ANI does not furnish any coverage, coding or billing advice to any health care professionals regarding off-label indications of ANI products.

(l) Neither ANI nor any ANI Subsidiary nor any officer, director, managing employee (as those terms are defined in 42 C.F.R. § 1001.1001) of ANI or any ANI Subsidiary, nor, to the knowledge of ANI, any agent (as such term is defined in 42 C.F.R. § 1001.1001(a)(1)(ii)) of ANI or any ANI Subsidiary: (i) has been debarred, excluded or suspended under 21 U.S.C. § 335a, or any similar law, from participation in any Federal Health Care Program; (ii) has had a civil monetary penalty assessed against it, him or her under Section 1128A of the Social Security Act of 1935, codified at Title 42, Chapter 7, of the United States Code (the "**Social Security Act**"); (iii) is currently listed on the General Services Administration published list of parties excluded from federal procurement programs and non-procurement programs; (iv) to the knowledge of ANI, is the target or subject of any current investigation by a Government Authority relating to any Federal Health Care Program related offense; (v) is currently charged with or convicted of any criminal offense relating to the delivery of an item or service under any Federal Health Care Program; or (vi) is the subject of any pending or threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto.

(m) There are no pending or, to the knowledge of ANI, threatened filings against ANI or any ANI Subsidiary of an action relating to ANI or any ANI Subsidiary under any federal or state whistleblower statute, including under the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)) or the Anti-Inducement Law (42 U.S.C. § 1320a-7a(5)).

(n) To the knowledge of ANI, neither ANI nor any ANI Subsidiary is under investigation by any Government Authority for a violation of the Health Insurance Portability and Accountability Act of 1995, as amended by the Health Information Technology for Economic and Clinical Health Act ("**HIPAA**"), or the regulations contained in 45 C.F.R. Parts 160 and 164, including receiving any notices from the United States Department of the Health and Human Services Office of Civil Rights relating to any such violations, or any comparable state or local laws. Neither ANI nor any ANI Subsidiaries are "covered entities" as that term is defined in HIPAA. ANI and the ANI Subsidiaries have been in compliance in all material respects with federal and state data breach laws.

(o) ANI and its Subsidiaries are and have been in compliance in all material respects with all Applicable Laws requiring state registration, reporting of applicable sales and marketing expenditures and transactions to health care professionals, and compliance program requirements, which may include (depending on the state) but is not limited to adoption of the OIG Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, the AdvaMed Code, and/or the PhRMA Code. See Cal. Health & Safety Code §§ 119400 - 119402; Connecticut, Subst. Senate Bill No. 270, File No. 468, Cal. No. 333; D.C., D.C. Code Ann. §§ 48-833.01-48-833.09; Maine, Maine Rev. Stat. Ann. tit. 22, § 2698-A; Massachusetts, Mass. Chapter 111N of the Massachusetts General Acts; Minnesota, Minn.Stat. § 151.47 (general); Minn.Stat. § 151.461 (gifts); Nevada, Nev. Rev. Stat. §639.570; Vermont, 18 V.S.A. Sec. 4631a; 18 V.S.A. Sec. 4632.; West Virginia, W. Va. Code § 5A-3C-13, W. Va. Code §16-29H-8.

**3.17 Environmental Matters.** Except as set forth in *Section 3.17* of the ANI Disclosure Schedule, (a) ANI and its Subsidiaries hold, and are currently, and at all prior times have been, in continuous compliance with all permits required by Environmental Laws for ANI to conduct its operations ("**Environmental Permits**"), and are currently, and at all prior times have been, otherwise in

continuous compliance with all Applicable Laws relating to: (i) protection, preservation or cleanup of the environment or natural resources; (ii) any Release or threatened Release, including control, investigation, study, assessment, testing, monitoring, containment, removal, remediation, cleanup or abatement of such Release or threatened Release; (iii) the management, manufacture, generation, formulation, processing, labeling, distribution, introduction into commerce, registration, use, treatment, handling, storage, disposal, transportation, re-use, recycling or reclamation of any Hazardous Material, or (iv) health and safety ("**Environmental Laws**") and, to the knowledge of ANI, there is no condition that would reasonably be expected to prevent or interfere with compliance with all applicable Environmental Laws and all applicable Environmental Permits in the future, (b) ANI and its Subsidiaries have not received any written notice, claim, demand, action, suit, complaint, proceeding or other communication by any person alleging any violation of, or any actual or potential liability under, any Environmental Laws (an "**Environmental Claim**"), and ANI has no knowledge of any pending or threatened Environmental Claim, (c) no hazardous, dangerous or toxic substance, including petroleum (including crude oil or any fraction thereof), asbestos and asbestos-containing materials, polychlorinated biphenyls, radon, fungus, mold, urea-formaldehyde insulation or any other material that is regulated or as to which liability or standards of conduct are imposed pursuant to any Environmental Laws or that could result in liability under any Environmental Laws ("**Hazardous Materials**") has been generated, transported, treated, stored, installed, disposed of, arranged to be disposed of, released or threatened to be released at, on, from or under any of the properties or facilities currently or formerly owned, leased or otherwise used by ANI or its Subsidiaries, in violation of, or in a manner or to a location that could give rise to liability to ANI or its Subsidiaries under Environmental Laws, and (d) ANI and its Subsidiaries have not assumed, contractually or by operation of law, any liabilities or obligations under or relating to any Environmental Laws. For purposes hereof, "Release" means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, generating, disposing or dumping of any Hazardous Material at, in, on, into or onto the environment, including the migration of any Hazardous Material through or in the environment.

**3.18 Labor and Employment Matters.** Except as set forth in *Section 3.18* of the ANI Disclosure Schedule, (a) there is no labor strike, dispute, slowdown, stoppage or lockout actually pending or, to the knowledge of ANI, threatened against ANI or any of its Subsidiaries, (b) no union, works council or other labor organization represents, or claims to represent, any group of employees with respect to their employment by ANI or any of its Subsidiaries and no union organizing campaign with respect to the employees of ANI or its Subsidiaries is threatened or underway, (c) there is no unfair labor practice charge or complaint against ANI or its Subsidiaries pending or, to the knowledge of ANI, threatened before the National Labor Relations Board or any similar state or foreign agency, (d) there is no grievance pending relating to any collective bargaining agreement or other grievance procedure, (e) no charges with respect to or relating to ANI or its Subsidiaries are pending before the Equal Employment Opportunity Commission or any other state or foreign agency responsible for the prevention of unlawful employment practices; and (f) no employee of ANI or its Subsidiaries is in violation of (and to the knowledge of ANI no written allegation has been made that any employee is in violation of) any term of any restrictive covenant, common law nondisclosure obligation, fiduciary duty, or other obligation to a former employer of any such employee relating (i) to the right of any such employee to be employed by ANI or its Subsidiaries or (ii) to the knowledge or use of trade secrets or proprietary information. Neither ANI nor any of its Subsidiaries is a party to a current conciliation agreement, consent decree, or other agreement or order with any Government Authority with respect to labor or employment practices.

**3.19 Insurance.**

(a) *Section 3.19(a)* of the ANI Disclosure Schedule sets forth, as of the date hereof, an accurate and complete list of the policies of insurance currently maintained by or for the benefit of the ANI or any of its Subsidiaries (including any policies of insurance maintained for purposes of

providing benefits such as workers' compensation and employers' liability coverage) (collectively, the "**ANI Policies**"). All such ANI Policies are in full force and effect and the limits of liability thereunder have not been exhausted by the payment of claims. There has not been any interruption in insurance coverage for the types of risks covered under such Policies since January 1, 2010. ANI and its Subsidiaries and, to the knowledge of the ANI, their counterparties are not in default under the Policies, and no event has occurred that, with the lapse of time or the giving of notice or both, would constitute a default under any Policy by the ANI or any of its Subsidiaries or, to the knowledge of the ANI, any other Person. No written notice of cancellation or termination has been received with respect to any such Policy (except Policies replaced in the ordinary course). To the knowledge of the ANI, no insurer on any such Policy has been declared insolvent or placed in receivership or liquidation.

(b) *Section 3.19(b)* of the ANI Disclosure Schedule sets forth a list of all pending claims (including with respect to insurance obtained but not currently maintained) and the claims history for the ANI and its Subsidiaries since January 1, 2010 (including with respect to insurance obtained but not currently maintained), in each case with respect to each claim (or series of related claims) involving amounts in excess of \$25,000. Neither the ANI nor any of its Subsidiaries has been refused any insurance coverage with respect to any aspect of its operations nor has its coverage been limited by any insurance carrier to which it has applied for insurance or with which it has carried insurance since January 1, 2010. There is no claim by the ANI or any of its Subsidiaries pending under any such Policies in excess of \$50,000 as to which coverage has been questioned, denied or disputed by the underwriters of such Policies.

**3.20 Registration Statement; Joint Proxy Statement/Prospectus.** The information regarding ANI and the ANI Subsidiaries supplied by ANI for inclusion in the Registration Statement (and any amendment or supplement thereto), at the time the Registration Statement (and any amendment or supplement thereto) is filed, at the time the Registration Statement (and any amendment or supplement thereto) is declared effective by the Securities and Exchange Commission (the "**SEC**") and at the Effective Time, will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The information regarding ANI and the ANI Subsidiaries supplied by ANI for inclusion in the joint proxy statement/prospectus to be sent to (a) the Company's stockholders in connection with the solicitation of proxies in favor of (i) the approval of the Company Charter Amendments and (ii) the approval of the issuance of shares of Company Common Stock pursuant to this Agreement (and any amendment or supplement thereto) and (b) ANI's stockholders in connection with the solicitation of proxies in favor of the adoption of this Agreement and the approval of the transactions contemplated by this Agreement, including the Merger (the "**Joint Proxy Statement/Prospectus**"), in each case, at the date the Joint Proxy Statement/Prospectus (and any amendment or supplement thereto) is first mailed to the Company and ANI stockholders and at the time of the Company Special Meeting and the ANI Special Meeting (or any adjournment or postponement thereof), will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The representations and warranties contained in this *Section 3.20* will not apply to statements or omissions included in the Joint Proxy Statement/Prospectus (and, in each case, any amendment or supplement thereto) based upon information regarding the Company or any the Company Subsidiary supplied by the Company for use therein. Subject to *Section 5.3(d)*, the Joint Proxy Statement/Prospectus will include the ANI Board Recommendation.



3.21 **Affiliate Transactions.** Except as set forth in *Section 3.21* of the ANI Disclosure Schedule, during the past three (3) years neither ANI nor any of the ANI Subsidiaries has, directly or indirectly, purchased, leased or otherwise acquired any property or obtained any services from, or sold, leased or otherwise disposed of any property or furnished any services to, or otherwise dealt with, in the ordinary course of business or otherwise, any director, officer, Affiliate or associate of any of ANI or any of the ANI Subsidiaries or any shareholder or member of any Affiliate or associate of any ANI or any of the ANI Subsidiaries (except with respect to compensation in the ordinary course of business for services rendered as a director, officer or employee of ANI or any of the ANI Subsidiaries). Except as set forth in *Section 3.21* of the ANI Disclosure Schedule, none of ANI or any of the ANI Subsidiaries owes any amount to, or has any agreement or contract with or commitment to, any of its shareholders, directors, officers, employees or consultants or any Affiliate or associate thereof (other than compensation for current services not yet due and payable and reimbursement of expenses arising in the ordinary course of business), and none of such Persons owes any amount to ANI or any of the ANI Subsidiaries. For purposes of this Agreement, "**Affiliate**" means (i) with respect to any person, any member of the immediate family of such person or any entity controlled, directly or indirectly, by such person and/or members of the immediate family of such person, and (ii) with respect to any entity, (a) any Person that, directly or indirectly, controls, is controlled by or is under common control with, such entity or (b) any director, officer, manager, stockholder, member, partner or other owner of such entity.

3.22 **Brokers or Finders.** No agent, broker, investment banker or financial advisor has been retained by or is authorized to act on behalf of ANI or any of its Subsidiaries and is or might be entitled to any broker's or finder's fee or any other similar commission or fee in connection with any of the transactions contemplated by this Agreement.

3.23 **Disclosure.** No representation or warranty or other statement made by the Company in this Agreement, the ANI Disclosure Schedule, the certificates delivered pursuant to *Section 6.3(d)(i)* or otherwise in connection with the transactions contemplated herein contains any untrue statement or omits to state a material fact necessary to make any of them, in light of the circumstances in which it was made, not misleading.

#### **ARTICLE IV. Representations and Warranties of the Company**

Except with respect to any subsection of this *Article IV*, as set forth in the correspondingly identified subsection of the disclosure schedule delivered by the Company to ANI concurrently with this Agreement (the "**Company Disclosure Schedule**") (it being understood by the Parties that the information disclosed in one subsection of the Company Disclosure Schedule will be deemed to be included in each other subsection of the Company Disclosure Schedule in which the relevance of such information thereto would be readily apparent on the face thereof), the Company represents and warrants to ANI as follows:

4.1 **Organization, Standing and Power.** The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, has all requisite power and authority to own, lease and operate its properties and to carry on its business as now being conducted, and is duly qualified and in good standing to do business in each jurisdiction in which the nature of its business or the ownership or leasing of its properties makes such qualification necessary, other than in such other jurisdictions where the failure so to qualify and be in such standing would not, either individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on the Company. The Certificate of Incorporation and By-laws of the Company, copies of which were previously provided to ANI, are true, complete and correct copies of such documents as in effect on the date of this Agreement. Except as set forth in *Section 4.1* of the Company Disclosure Schedule, the Company neither directly nor indirectly, (a) owns or otherwise controls, (b) has agreed to purchase or otherwise acquire or (c) holds any interest convertible into or exchangeable for, any capital stock or

other equity interest of any other corporation, partnership, joint venture or other business association or entity. Except as set forth in *Section 4.1* of the Company Disclosure Schedule, the Company has not at any time during the preceding five years owned, of record or beneficially, more than five percent of the outstanding equity securities having ordinary voting rights or power of any corporation or partnership or other legal entity. The Company does not have any Subsidiaries. The stock records, minute books and other records of the Company are accurate, up to date and complete in all materials respects.

#### 4.2 Capital Structure.

(a) The authorized capital stock of the Company consists of 200,000,000 shares of Company Common Stock, 4,687,684 shares of the Company Class C Special Stock, \$0.0001 par value (the "**Company Class C Special Stock**") and 10,000,000 shares of preferred stock, par value \$0.0001 per share (the "**Company Preferred Stock**"). As of the close of business October 2, 2012, (i) 24,422,240 shares of Company Common Stock were issued and outstanding, (ii) 65,211 shares of the Company Class C Special Stock were issued and outstanding, (iii) 1,164,470 shares of Company Common Stock were reserved for issuance upon the exercise of stock options outstanding on such date, with a weighted average exercise price of \$14.33 per share, (iv) 4,738,093 shares of Company Common Stock were reserved for issuance upon the exercise of warrants outstanding on such date, with a weighted average exercise price of \$12.22 per share, of which warrants to purchase an aggregate of 1,039,254 shares of Company Common Stock were issued in or around August 2012 (the "**August Warrants**") and (v) 370,871 shares of Company Common Stock were issuable upon the conversion of an aggregate of \$8,277,850 in outstanding principal amount of 3.125% convertible senior notes due May 1, 2013 (the "**Company Convertible Notes**"). No shares of Company Preferred Stock are issued and outstanding or reserved for issuance and as of the date hereof, no shares of Company Common Stock, the Company Class C Special Stock or Company Preferred Stock are held by the Company in its treasury. All outstanding shares of Company Common Stock and the Company Class C Special Stock have been duly authorized and validly issued and are fully paid and non-assessable and not subject to preemptive rights. The shares of Company Common Stock to be issued pursuant to or as specifically contemplated by this Agreement will have been duly authorized as of the Effective Time and, if and when issued in accordance with the terms hereof or thereof, will be validly issued, fully paid and non-assessable and will not be subject to preemptive rights.

(b) No outstanding options or warrants to purchase shares of the Company Class C Special Stock or Company Preferred Stock are issued or outstanding.

(c) Except for the August Warrants, no outstanding options or warrants to purchase shares of the Company Common Stock have an exercise price of less than \$2.00 per share, equitably adjusted to reflect the Reverse Stock Split.

(d) No Voting Debt of the Company is issued or outstanding, except for the Company Convertible Notes.

(e) The consummation of the Merger will not constitute a Fundamental Change (as defined in the indenture dated as of June 24, 2009 between Cell Genesys, Inc., a Delaware corporation, and U.S. Bank National Association, as Trustee, as supplemented by the supplemental indenture dated as of October 14, 2009 between the Company and U.S. Bank National Association, as Trustee (as supplemented, the "**Indenture**"). The Company Board has approved the appointment and election of the individuals to comprise the Company Board upon the Effective Time of the Merger in accordance with the requirements applicable under the definition of "Continuing Director" (as such term is defined in the Indenture).

(f) Except for (i) this Agreement, (ii) the options, warrants, calls, rights, commitments or agreements described in paragraph (a) above, and (iii) agreements entered into and securities and other instruments issued after the date of this Agreement as permitted by *Section 5.2*, and except as set forth in *Section 4.2* of the Company Disclosure Schedule, there are no options, warrants, calls, rights, commitments or agreements of any character to which the Company is a party or by which it is bound obligating the Company to issue, deliver or sell, or cause to be issued, delivered or sold, additional shares of capital stock or any Voting Debt or stock appreciation rights of the Company or obligating the Company to grant, extend or enter into any such option, warrant, call, right, commitment or agreement. Except as set forth in *Section 4.2(f)* of the Company Disclosure Schedule or in accordance with the terms of this Agreement, there are no outstanding contractual obligations of the Company (x) to repurchase, redeem or otherwise acquire any shares of capital stock of the Company or (y) pursuant to which the Company is or could be required to register shares of Company Common Stock or other securities under the Securities Act, except any such contractual obligations entered into after the date hereof as permitted by *Section 5.2*. Except as set forth in *Section 4.2(f)* of the Company Disclosure Schedule and as set forth in the Voting Agreements, there are no agreements, trusts or proxies that relate to the voting or control of any issued and outstanding capital stock of the Company or of any shares of capital stock of the Company that are issuable upon conversion or exercise of issued and outstanding securities of the Company.

(g) Since January 1, 2012, except as permitted by *Section 5.2* after the date hereof, the Company has not (i) issued or permitted to be issued any shares of capital stock, stock appreciation rights or securities exercisable or exchangeable for or convertible into shares of capital stock of the Company; (ii) repurchased, redeemed or otherwise acquired, directly or indirectly, any shares of capital stock of the Company; or (iii) declared, set aside, made or paid to the stockholders of the Company dividends or other distributions on the outstanding shares of capital stock of the Company.

#### 4.3 Authority; Non-Contravention; Consent.

(a) The Company has all requisite corporate power and authority to execute and deliver this Agreement, and assuming Company Stockholder Approval, to consummate the transactions contemplated by this Agreement, including the Merger. "**Company Stockholder Approval**" means: (i) the adoption of this Agreement and the transactions contemplated thereby, including the Merger and the issuance of Company Common Stock in the Merger by the holders of a majority of the outstanding shares of Company Common Stock and the Company Class C Special Stock, voting together as a single class, entitled to vote thereon at the Company Special Meeting (or at any adjournment or postponement thereof) and (ii) the approval of the Company Charter Amendments to change the corporate name of the Company and effect the Reverse Stock Split by the holders of a majority of the outstanding shares of Company Common Stock and Company Class C Special Stock, voting together as a single class, entitled to vote thereon at the Company Special Meeting (or at any adjournment or postponement thereof).

(b) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will, (i) result in any Violation pursuant to any provision of the Certificate of Incorporation or By-laws of the Company, or (ii) subject to obtaining or making the consents, approvals, orders, authorizations, registrations, declarations and filings set forth in *Section 4.3(b)* of the Company Disclosure Schedule, result in any Violation of any loan or credit agreement, note, mortgage, indenture, lease, Company Benefit Plan (as defined in *Section 4.9(a)*) or other agreement, obligation, instrument, permit, concession, franchise, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to the Company or its properties or assets which Violation, in the case of clause (ii), individually or in the aggregate, would reasonably be expected to be material to the Company.

(c) No consent, approval, order or authorization of, or registration, declaration or filing with, any Government Authority is required by or with respect to the Company in connection with the execution and delivery of this Agreement by the Company or the consummation by the Company of the transactions contemplated hereby, except for (i) the filing with the SEC of the Registration Statement and such other reports under the Securities Act and the Exchange Act as may be required in connection with this Agreement and the transactions contemplated hereby and the obtaining from the SEC of such orders as may be required in connection therewith, (ii) such filings and approvals as are required to be made or obtained under the securities or blue sky laws of various states in connection with the transactions contemplated by this Agreement, (iii) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware, (iv) the approval of the listing of Company Common Stock to be issued in the Merger on The NASDAQ Stock Market, Inc. ("**NASDAQ**"), (v) the healthcare approvals set forth in *Section 4.3(c)* of the Company Disclosure Schedule and (vi) actions required by or notices or filings required by Government Authorities with jurisdiction over or otherwise relating to the Company Regulatory Filings, as disclosed in *Section 3.3(c)* of the Company Disclosure Schedule.

#### **4.4 SEC Documents; Undisclosed Liabilities.**

(a) The Company has timely filed, or furnished, as applicable, all required reports, schedules, forms, registration statements and other documents with the SEC since January 1, 2010 (the "**Company SEC Documents**"). As of their respective dates of filing with the SEC (or, if amended or superseded by a filing prior to the date hereof, as of the date of such filing), the Company SEC Documents complied in all material respects, with the requirements of the Securities Act or the Exchange Act, as the case may be, and the rules and regulations of the SEC thereunder applicable to such Company SEC Documents, and none of the Company SEC Documents when filed contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the Company SEC Documents (including any related notes thereto), including the Company Financial Statements, complied as to form, as of their respective dates of filing with the SEC, in all material respects with all applicable accounting requirements and with the published rules and regulations of the SEC with respect thereto (except, in the case of the unaudited statements, as permitted by Form 10-Q of the SEC), have been prepared in accordance with GAAP applied on a consistent basis throughout the periods involved, and fairly present the financial position of Company as of the respective dates thereof and the results of its operations, changes in stockholders' equity and cash flows for the respective periods indicated, except that the unaudited consolidated financial statements included in the Company Financial Statements do not contain footnotes and are subject to normal recurring year-end adjustments, which will not, individually or in the aggregate, be material. The Company has established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) and has designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

(b) The Company keeps books, records and accounts that, in reasonable detail, accurately and fairly reflect the transactions and acquisitions and dispositions of assets of the Company. The Company has designed and maintains a system of internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such

date, the "**Evaluation Date**"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting of the Company that has materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company.

(c) Except for (i) those liabilities that are fully reflected or reserved for in the consolidated financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC, in its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2012 or the unaudited consolidated financial statements of the Company for the seven (7) months ended July 31, 2012, a true, correct and complete copy of which has been delivered to ANI, in each case prior to the date of this Agreement (together, the "**Company Financial Statements**"), (ii) liabilities incurred since July 31, 2012 in the ordinary course of business consistent with past practice and not arising out of any breach of its material obligations under any Company Contract, (iii) liabilities (other than as a result of a breach of contract, breach of warranty, product liability, tort or intellectual property infringement or violation of Applicable Law or an Action) which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect on the Company, (iv) liabilities incurred pursuant to the transactions contemplated by this Agreement, and (v) liabilities or obligations discharged or paid in full prior to the date of this Agreement in the ordinary course of business consistent with past practice, the Company does not have, and since June 30, 2012, the Company does not have outstanding and has not incurred (except as permitted by *Section 5.2*), any liabilities or obligations of any nature whatsoever (whether accrued, absolute, material, determined, contingent or otherwise and whether or not required to be reflected in the Company's Financial Statements in accordance with GAAP).

(d) As of the date hereof, the Company has Net Cash as set forth in *Section 4.4* of the Company Disclosure Schedule. As of the date hereof, all remaining costs associated with the Company's LibiGel® program (including the completion and/or conclusion of any clinical trials, safety studies or other research studies) and the cost of keeping in effect any related product liability and/or similar insurance policies providing coverage for personal injury claims arising out of such trials for the remaining statute of limitations thereof are set forth in *Section 4.4* of the Company Disclosure Schedule.

(e) From and after the Determination Date, the Company will not have any material payables or other payment obligations relating to the period prior to the Closing Date under any contract or otherwise, except those taken into consideration in the calculation of Net Cash as of the Determination Date.

(f) The Company's external auditors have not identified to the Company any material weaknesses in the Company's internal controls impacting on the reliability of the Company Financial Statements.

(g) No financial statements of any Person other than the Company are required by GAAP to be included in the Company Financial Statements. Except as required by GAAP, the Company has not, between the last day of its most recently ended fiscal year and the date of this Agreement, made or adopted any material change in its accounting methods, practices or policies in effect on such last day of its most recently ended fiscal year. The Company has not had any material dispute with any of its auditors regarding accounting matters or policies during any of its past three (3) full fiscal years or during the current fiscal year and the Company has no reason to believe that there will be an adjustment to, or any restatement of, the Company Financial Statements. No current or former independent auditor for the Company has resigned or been dismissed from such capacity as

a result of or in connection with any disagreement with the Company on a matter of accounting practices. The Company Financial Statements were prepared from, and are consistent with, the accounting records of the Company. The Company has also delivered to the Company copies of all letters from the Company's auditors to the Company Board or audit committee thereof since January 1, 2010, together with copies of all responses thereto.

**4.5 Compliance with Applicable Laws.** The Company has not violated or failed to comply with any Applicable Law material to the operation of the Company's business.

**4.6 Legal Proceedings.** Except as set forth in *Section 4.6* of the Company Disclosure Schedule, there is no Action pending or, to the knowledge of the Company, threatened, against or affecting the Company nor is there any Order outstanding against the Company. To the knowledge of the Company, no investigation by any Government Authority with respect to the Company is pending or threatened. With respect to each Action set forth in *Section 4.6* of the Company Disclosure Schedule, the Company has delivered to ANI all applicable pleadings, motions and other filings. With respect to each Action set forth in *Section 4.6* of the Company Disclosure Schedule that is being defended by counsel for or otherwise appointed by one or more insurance carriers of the Company, (a) the defense thereof has been assumed by one or more insurance carriers of the Company, subject to a standard reservation of rights letter which has been provided to ANI, (b) the Company has previously paid all deductibles, reserves or co-payments required under the applicable insurance policy pursuant to which such matter is being defended, and (c) all further amounts which may become payable in respect thereof will be paid by the applicable insurance carrier, subject to the standard reservation of rights letter which has been provided to ANI, subject to the aggregate applicable coverage limits under such policies and (d) the Company has no reason to expect that any insurance company currently defending any such Action will disclaim coverage of any such Action.

**4.7 Taxes.**

(a) The Company has timely filed all material Tax Returns required to be filed by it and all such Tax Returns are correct and complete in all material respects. The Company has timely paid all material amounts of Taxes due and payable (whether or not shown on such Tax Returns) and the most recent financial statements contained in the Company SEC Documents reflect an adequate reserve, in accordance with GAAP, for all Taxes payable by the Company accrued through the date of such financial statements.

(b) There is no Tax deficiency outstanding, proposed or assessed against the Company. No audit or other examination of any Tax Return of the Company by any Government Authority is presently in progress, nor has the Company been notified in writing or, to the knowledge of the Company, otherwise notified of any request for such an audit or other examination. There are no Liens for Taxes upon the Company, or any assets of the Company, except for Liens for taxes not yet due and payable.

(c) The Company has not constituted either a "distributing corporation" or a "controlled corporation" within the meaning of Section 355(a)(1)(A) of the Code in a distribution of stock qualifying for tax-free treatment under Section 355 of the Code (i) in the two (2) years prior to the date of this Agreement or (ii) in a distribution which could otherwise constitute part of a "plan" or "series of related transactions" (within the meaning of Section 355(e) of the Code) in conjunction with the transactions contemplated by this Agreement.

(d) No claim in writing has been made by a Government Authority in a jurisdiction where the Company does not file Tax Returns that the Company is or may be subject to Tax in that jurisdiction.

(e) The Company is not a party to any Tax sharing, allocation, indemnity or similar agreement or arrangement (whether or not written) pursuant to which it could have any obligation to make any payments after the Closing. The Company has never been a member of any consolidated, combined, affiliated or unitary group of corporations for any Tax purposes, nor does it have any liability for Taxes of any other Person.

(f) The Company has disclosed on its US federal income Tax Returns all positions taken therein that could give rise to substantial understatement of US federal income Tax within the meaning of Section 6662 of the Code. The Company has not entered into any transaction identified as a "reportable transaction" for purposes of Treasury Regulations Section 1.6011-4(b).

(g) There is no taxable income of the Company that will be required under any Applicable Law to be reported in a Taxable period beginning after the Closing Date which Taxable income was realized (or reflects economic income) arising prior to the Closing Date as a result of any: (i) change in method of accounting for a taxable period ending on or prior to the Closing Date; (ii) "closing agreement" as described in Section 7121 of the Code executed on or prior to the Closing Date; (iii) installment sale or open transaction disposition made on or prior to the Closing Date; (iv) prepaid amount or deferred revenue received on or prior to the Closing Date or (v) election under Section 108(i) of the Code.

(h) The Company has not taken any action or knows of any fact, agreement, plan or other circumstance that could reasonably be expected to prevent the Merger from qualifying as a reorganization within the meaning of Section 368(a) of the Code.

(i) As of December 31, 2011, the Company had approximately \$170,401,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. These net operating loss carryforwards expire in the years 2018 to 2031 and their utilization in future years may be limited as prescribed by Section 382 of the Code.

#### 4.8 Certain Agreements.

(a) Except as set forth in *Section 4.8* of the Company Disclosure Schedule and except for this Agreement, the Company is not bound by any Contract:

(i) that constitutes a partnership, joint venture, technology sharing or similar agreement between the Company and any other Person;

(ii) with respect to the service of any directors, officers, employees, or independent contractors or consultants that are natural persons, involving the payment of \$100,000 or more in any 12 month period, other than those that are terminable by the Company on no more than 30 days' notice without penalty;

(iii) which limits the ability of the Company to compete or enter into in any line of business, in any geographic area or with any person, or which requires referrals of business to a third party and, in each case, which limitation or requirement would reasonably be expected to be material to the Company;

(iv) with or to a labor union, works council or guild (including any collective bargaining agreement or similar agreement);

(v) relating to the use or right to use Intellectual Property, including any license and royalty agreements and any Company IP Contract;

(vi) that provides for indemnification by the Company to any Person, other than an agreement entered into in the ordinary course of business or that is not material to the Company;

(vii) between the Company and any current or former director or officer of the Company, or any affiliate of any such Person (other than a Company Benefit Plan);

(viii) with respect to (A) any Indebtedness, (B) any capital lease obligations to any Person other than the Company, (C) any obligations to any Person other than the Company in respect of letters of credit and bankers' acceptances, (D) any indebtedness to any Person other than the Company under interest rate swap, hedging or similar agreements, (E) any obligations to pay to any Person other than the Company the deferred purchase price of property or services, (F) indebtedness secured by any Lien on any property owned by the Company even though the obligor has not assumed or otherwise become liable for the payment thereof, or (G) any guaranty of any such obligations described in clauses (A) through (F) of any Person other than the Company, in each case, having an outstanding amount in excess of \$50,000 individually or \$100,000 in the aggregate;

(ix) that is material to the Company or that contains any so called "most favored nation" provision or similar provisions requiring the Company to offer to a Person any terms or conditions that are at least as favorable as those offered to one or more other Persons;

(x) pursuant to which any agent, sales representative, distributor or other third party markets or sells any Company Product;

(xi) which involves the payment of \$200,000 or more in any 12 month period after the date hereof;

(xii) pursuant to which the Company is a party granting rights of first refusal, rights of first offer or similar rights to acquire any business or assets of the Company;

(xiii) relating to the purchase or sale of assets outside the ordinary course of business of the Company;

(xiv) relating to the issuance of any securities of the Company;

(xv) pursuant to which any material asset of the Company is leased;

(xvi) relates to the purchase of (A) any equipment entered into since December 31, 2011 and (B) any materials, supplies, or inventory since December 31, 2011, other than any agreement which, together with any other related agreement, involves the expenditure by the Company of less than Fifty Thousand Dollars (\$50,000);

(xvii) that represents a purchase order with any supplier for the purchase of inventory items in an amount in excess of Fifty Thousand Dollars (\$50,000) of materials;

(xviii) pursuant to which the Company is a party and having a remaining term of more than one (1) year after the Closing Date or involving a remaining amount payable thereunder (either to or from the Company) as of the Closing Date, of at least One Hundred Thousand Dollars (\$100,000);

(xix) that relates to an essential function or role of any efficacy or safety study or pharmacokinetic study in respect of LibiGel or any other Company Product, or which is otherwise material to the Company; or

(xx) which would prevent, delay or impede the consummation, or otherwise reduce the contemplated benefits, of any of the transactions contemplated by this Agreement.

The Company has previously made available to ANI or its representatives complete and accurate copies of each Contract of the type described in this Section 4.8(a) (collectively referred to herein as "**Company Contracts**").



(b) All of the Company Contracts were entered into at arms' length in the ordinary course of business and are valid and in full force and effect, except to the extent they have previously expired in accordance with their terms. The Company has not given or received a notice of cancellation or termination under any Company Contract, or has, or is alleged to have, and to the knowledge of the Company, none of the other parties thereto have, violated any provision of, or committed or failed to perform any act, and no event or condition exists, which, with or without notice, lapse of time or both would constitute a default under the provisions of, any Company Contract. Notwithstanding the Company's receipt of that certain letter dated September 26, 2012 from counsel to Antares Pharma IP AG, that certain License Agreement effective June 13, 2000, as amended, with Antares Pharma IP AG is in full force and effect with respect to all Company Products set forth therein.

#### 4.9 Benefit Plans.

(a) Section 4.9 of the Company Disclosure Schedule sets forth a true and complete list of each Company Benefit Plan. A "**Company Benefit Plan**" is any "employee benefit plan" within the meaning of Section 3(3) of ERISA, and whether or not subject to ERISA, any material employment, termination or severance agreement, and any material bonus, deferred compensation, incentive compensation, stock ownership, stock purchase, stock option, phantom stock, equity-based, vacation, severance, retention, change in control, profit sharing, retirement, welfare, disability, death benefit, hospitalization or insurance plan, and any other material plan, agreement, or program providing compensation or benefits to any current or former employee, director or independent contractor of the Company or any ERISA Affiliate of the Company or maintained, contributed to, or required to be contributed to by the Company or other ERISA Affiliate or that the Company or any ERISA Affiliate has committed to establish, adopt or contribute to, or under which the Company or any ERISA Affiliate otherwise has or may have any liability.

(b) No Company Benefit Plan is a multiemployer plan within the meaning of ERISA Section 3(37).

(c) No Company Benefit Plan is a "defined benefit pension plan" within the meaning of Code Section 414(j) or subject to Title IV of ERISA; no Company Benefit Plan is subject to the minimum funding standards of Code Section 412 and/or ERISA section 302; and neither the Company nor any ERISA Affiliate has any liability to the PBGC or any other person, arising directly or indirectly under Title IV of ERISA.

(d) Each Company Benefit Plan has been maintained in material compliance with its terms and with all applicable laws, including, but not limited to ERISA and the Code and with respect to Company Benefit Plans, individually and in the aggregate, no event has occurred and, to the knowledge of the Company, there exists no condition or set of circumstances in connection with which the Company or any ERISA Affiliates could be subject to any liability under ERISA, the Code or any other Applicable Law.

(e) There are no actions, suits or claims pending (other than routine claims for benefits) or, to the knowledge of the Company, threatened against, or with respect to, any Company Benefit Plan.

(f) All required contributions to Company Benefit Plans due on or before the Closing Date have been, or will have been, made or properly accrued on or before the Closing Date.

(g) The execution and delivery by the Company of this Agreement does not, and the consummation of the Merger and compliance with the terms hereof (whether alone or in combination with any other event) will not, (A) entitle any current or former employee or director or independent contractor of the Company to severance pay, (B) except as expressly required by this Agreement, accelerate the time of payment or vesting or trigger any payment or funding

(through a grantor trust or otherwise) of compensation or benefits under, increase the amount payable or trigger any other material obligation pursuant to, any Company Benefit Plan, (C) result in any breach or violation of, or a default under, any Company Benefit Plan, or (D) cause any amounts payable under any Company Benefit Plan (whether in cash, in property or in the form of benefits) to fail to be deductible for federal income tax purposes by virtue of Sections 162(m) or 280G of the Code.

(h) None of the Company, any ERISA Affiliate, or Company Benefit Plan has engaged in a transaction in connection with which the Company or any ERISA Affiliate, or any such trust, or any trustee or administrator thereof, or any party dealing with any Company Benefit Plan or any such trust could be subject to either a civil penalty assessed pursuant to Sections 409 or 502(i) of ERISA or a Tax imposed pursuant to Sections 4975 or 4976 of the Code.

(i) Each Company Benefit Plan and related trust intended to qualify under Sections 401 and 501(a) of the Code is subject to a current favorable determination or opinion letter from the IRS and, to the Company's knowledge, nothing has occurred that is reasonably likely to result in the revocation of such letter. The Company has not sponsored, maintained or contributed to or had any liability with respect to any qualified pension plan which, during the preceding two (2) years, has been terminated, including by way of merger with or into a Company Benefit Plan or another plan.

(j) The Company does not contribute to, has or could have any liability with respect to retiree medical coverage or other medical, health, life or other welfare benefits for present or future terminated employees or their spouses or dependents other than as required by COBRA or any comparable state Applicable Law.

(k) No employer other than the Company or an ERISA Affiliate is permitted to participate in any Company Benefit Plan and no leased employees (as defined in Code Section 414(n)) or independent contractors are eligible for, or participate in, any Company Benefit Plan.

(l) Except as set forth on *Section 4.9* of the Company Disclosure Schedule, no Company Benefit Plan is a "nonqualified deferred compensation plan" subject to Section 409A of the Code and the regulations and other guidance promulgated thereunder (unless such Company Benefit Plan complies with an exemption or exception to Code Section 409A). Neither the Company nor any ERISA Affiliates are a party to any agreement, or otherwise obligated under any Company Benefit Plan, to provide for a gross up of Taxes imposed by Section 409A of the Code. Each nonqualified deferred compensation plan (as defined in Section 409A(d)(1) of the Code) maintained or sponsored by the Company or its ERISA Affiliates has since (i) January 1, 2005, been maintained and operated in good faith compliance with Section 409A of the Code and Notice 2005-1, (ii) October 3, 2004, not been "materially modified" (within the meaning of Notice 2005 1) with respect to any amounts that are "grandfathered" from the application of Section 409A of the Code, and (iii) January 1, 2010, been in documentary and operational compliance with final regulations under Section 409A of the Code.

(m) No Company Benefit Plan is now, or in the past seven years been, "top-heavy" pursuant to Code Section 416.

(n) The Company has delivered or made available to ANI true and complete copies of:

(i) all Company Benefit Plan documents and related trust agreements or other agreements or contracts evidencing any funding vehicle with respect thereto;

(ii) the three most recent annual reports on Form 5500, including all schedules, attachments and/or audits thereto, with respect to any Company Benefit Plan for which such a report (and/or audit) is required;

(iii) the summary plan description, including any summary of material modifications thereto or other modifications communicated to participants, currently in effect with respect to each Company Benefit Plan;

(iv) the most recent determination letter or opinion letter issued by the IRS with respect to each Company Benefit Plan intended to qualify under section 401(a) of the Code and with respect to any determination letter the full and complete application therefore submitted to the IRS; and

(v) material correspondence in the past seven years with regulatory authorities (such as a copy of all documents relating to any audit or investigation by any regulatory authority or any voluntary correction submission with the Department of Labor or the IRS) with respect to any Company Benefit Plan.

**4.10 Absence of Certain Changes or Events.** (i) Since December 31, 2011, except as permitted by *Section 5.2* in the case of actions taken after the date hereof, there has not been any change, circumstance or event (including any event involving a prospective change) which, individually or in the aggregate, has had, or would reasonably be expected to have, a Material Adverse Effect on the Company, and (ii) since December 31, 2011, except as contemplated by this Agreement the Company has conducted its respective business in the ordinary course consistent with its past practice.

**4.11 Board Approval.** The Company's board of directors (the "**Company Board**"), by resolutions duly adopted at a meeting duly called and held has (a) approved the Company Charter Amendments providing for (i) the Reverse Stock Split, (ii) an increase to the number of authorized shares of Company Common Stock to a number to be determined by ANI, and (iii) a change of the name of the Company to "ANI Pharmaceuticals, Inc." or any other name designated by the Company; (b) approved the change of the Company's trading symbol to a symbol chosen by ANI; (c) approved and adopted, and declared the advisability of, this Agreement and the transactions contemplated hereby, including the Merger; (d) determined that this Agreement and the transactions contemplated hereby, including the Merger, are fair to and in the best interests of the Company and the Company's stockholders; and (e) subject to *Section 5.4(d)*, resolved to make and maintain the Company Board Recommendation.

**4.12 Takeover Statutes.** The Company has taken all action necessary to exempt or exclude this Agreement and the transactions contemplated hereby, including the Merger, from all applicable Takeover Statutes. Accordingly, no Takeover Statute applies to this Agreement or the transactions contemplated hereby, including the Merger, with respect to the Company. The Company does not have any stockholder rights plan, "poison pill" or similar plan or arrangement in effect.

**4.13 Properties.** Except as set forth in *Section 4.13* of the Company Disclosure Schedule, the Company (a) has good and valid title to all of its properties and assets including those reflected in the Company Financial Statements as being owned by the Company or acquired after the date thereof that are material to the Company's business (except properties sold or otherwise disposed of since the date thereof in the ordinary course of business and as permitted under *Section 5.2*), free and clear of all Liens, except (i) statutory liens securing payments not yet due or liens which are being properly contested by the Company in good faith and by proper legal proceedings and for which adequate reserves related thereto are maintained on the Company Financial Statements and provided the amount of such reserves or payments not yet due will be included as a Liability for purposes of calculating Net Cash, (ii) such imperfections or irregularities of title, claims, liens, charges, security interests, easements, covenants and other restrictions or encumbrances as do not materially affect the use or value of the properties or assets subject thereto or affected thereby or otherwise adversely impair business operations at such properties, (iii) mortgages, or deeds of trust, security interests or other encumbrances on title related to indebtedness reflected in the Company Financial Statements and which have been or will be satisfied and released at or prior to the Closing Date and any Indebtedness or other obligations secured thereby will be included as a Liability for purposes of calculating Net

Cash, and (iv) rights granted to any non-exclusive licensee of any the Company Intellectual Property in the ordinary course of business consistent with past practices (such liens, imperfections and irregularities in clauses (i), (ii), (iii) and (iv), "**Company Permitted Liens**"), and (b) has a valid leasehold interest as a lessee of all leasehold estates set forth in *Section 4.13* of the Company Disclosure Schedule (except for leases that have expired by their terms since the date thereof) and is in possession of the properties purported to be leased thereunder, and each such lease is valid without default thereunder by the lessee or, to the Company's knowledge, the lessor.

#### 4.14 Intellectual Property.

(a) For purposes of this Agreement:

(i) "**Company Owned IP**" means all Intellectual Property Rights and Intellectual Property owned (solely or jointly) by the Company.

(ii) "**Company Licensed IP**" means all Intellectual Property Rights and Intellectual Property licensed to the Company.

(b) *Section 4.14(b)* of the Company Disclosure Schedule accurately identifies and describes each proprietary product or service currently developed, manufactured, marketed, performed or sold by or on behalf of the Company, including products or services currently designated as development candidates with a unique internal name by the Company.

(c) *Section 4.14(c)* of the Company Disclosure Schedule accurately identifies: (i) each item of Company Owned IP in which the Company has or purports to have an ownership interest of any nature (whether exclusively, jointly with another Person, or otherwise); (ii) in the case of Registered IP, the jurisdiction in which such item of Registered IP has been registered or filed and the applicable registration or serial number; and (iii) in the case of Registered IP, any other Person that has an ownership interest in such item of Registered IP and the nature of such ownership interest; and (iv) each the Company IP that is a granted patent that in any way covers any product or service identified in *Section 4.14(b)* of the Company Disclosure Schedule. The Company has provided to ANI accurate and complete copies of all applications and correspondence to and from the Government Authority related to each such item of Company Owned IP. For the avoidance of doubt, for published applications and patents, the Company furnishing to ANI the relevant application, serial or patent number of the Registered IP will be considered reasonable.

(d) *Section 4.14(d)* of the Company Disclosure Schedule accurately identifies: (i) all Intellectual Property Rights or Intellectual Property licensed to the Company (other than any non-customized software that (x) is so licensed solely in executable or object code form pursuant to a non-exclusive, internal use software license, (y) is not incorporated into, or used directly in the development, manufacturing or distribution of, any of the Company's products or services and (z) is generally available on standard terms for less than \$25,000); (ii) the corresponding Contract(s) pursuant to which such Intellectual Property Rights or Intellectual Property is licensed to the Company; and (iii) whether the license or licenses granted to the Company are exclusive or non-exclusive.

(e) *Section 4.14(e)* of the Company Disclosure Schedule accurately identifies each Contract pursuant to which any Person has been granted by the Company any license under, or otherwise has received or acquired any right (whether or not currently exercisable) or interest in, any Company IP. Except as set forth in *Section 4.14(e)* of the Company Disclosure Schedule, the Company is not by, and no Company IP is subject to, any Contract containing any covenant or other provision that in any way limits or restricts the ability of the Company to use, exploit, assert or enforce any Company IP anywhere in the world, except field and geographical restrictions in applicable licenses to Company IP granted to the Company.

(f) The Company has provided to ANI an accurate and complete copy of each standard form of any Contract to which the Company is a party or by which the Company is bound, that contains any assignment or license of, covenant not to assert or enforce or granting of any other rights in, any Intellectual Property Right, including any Company IP or other Intellectual Property developed by, with, or for the Company (a "**Company IP Contract**") that has been used by the Company at any time since January 1, 2010, including each standard form of: (i) employee agreement containing any intellectual property assignment or license of Intellectual Property or Intellectual Property Rights or any confidentiality provision; (ii) consulting or independent contractor agreement containing any intellectual property assignment or license of Intellectual Property or Intellectual Property Rights or any confidentiality provision; and (iii) confidentiality or nondisclosure agreement. *Section 4.14(e)* of the Company Disclosure Schedule accurately identifies each Company IP Contract that deviates in any material respect from the corresponding standard form agreement provided to ANI.

(g) Except as set forth in *Section 4.14(g)* of the Company Disclosure Schedule:

(i) the conduct of the business of the Company as currently conducted does not infringe upon, misappropriate or otherwise violate the Intellectual Property Rights of any third party, and no claim has been asserted to the Company in writing that the conduct of the business of the Company as currently conducted infringes upon or misappropriates or otherwise violates the Intellectual Property rights of any third party;

(ii) with respect to each item of Company Owned IP, the Company is the owner of the entire right, title and interest in and to such Company Owned IP and the Company has not granted to any third party exclusive rights to any Company Owned IP under terms that would prevent the Company from using such Company Owned IP in the operation of its respective business as currently conducted;

(iii) with respect to each item of Company Licensed IP, the Company has the right to use such Company Licensed IP in the operation of its business as currently conducted in accordance with the terms of the license agreement governing such Company Licensed IP;

(iv) none of the Company Owned IP has been adjudged invalid or unenforceable in whole or in part and the Company Registered IP is valid, subsisting and enforceable (except for prospective challenges that may be received in the ordinary course of patent prosecution and maintenance);

(v) no person is engaging in any activity that infringes upon, misappropriates or otherwise violates the Company Owned IP or, to the Company's knowledge, the Company Licensed IP, in any material respect;

(vi) each license of Company Licensed IP is binding on the Company and each of the other parties thereto, and is in full force and effect and no party to any license of Company Licensed IP (other than the Company) is in breach thereof or default thereunder; and

(vii) neither the execution of this Agreement nor the consummation of any transaction contemplated hereby will terminate, suspend or modify any of the Company's rights with respect to any Company Owned IP or material Company Licensed IP.

(h) Each Person who is or was an employee or contractor of the Company and who is or was involved in the creation or development of any Company IP has signed an agreement containing an assignment of Intellectual Property Rights to the Company. No current or former stockholder, officer, director, employee, consultant or contractor of the Company has any claim, right (whether or not currently exercisable) or interest to or in any Company IP. To the Company's knowledge, no employee of the Company is: (x) bound by or otherwise subject to any Contract restricting him or

her from performing his or her duties for the Company; or (y) in breach of any Contract with any former employer or other Person concerning Intellectual Property Rights or confidentiality obligations. Since January 1, 2010, the Company has not assigned or otherwise transferred ownership of, or agreed to assign or otherwise transfer ownership of, any Intellectual Property Right to any other Person.

(i) The Company has taken all commercially reasonable steps to maintain the confidentiality of and otherwise protect and enforce their rights in all material proprietary information that the Company holds, or purports to hold, as a trade secret.

(j) The Company is not and never was a contributor to any industry standards body or similar organization that could require or obligate the Company to grant or offer to any other Person any license or right to any Company IP.

#### 4.15 Regulatory Matters.

(a) Each of the products under development by the Company is identified in *Section 4.15(a)* of the Company Disclosure Schedule (the "**Company Products**"). The Company is not currently marketing any product. The Company holds all material licenses, permits, franchises, variances, registrations, exemptions, orders and other governmental authorizations, consents, approvals and clearances, and have submitted all material notices to, all Government Authorities, including all required authorizations under the FDCA, PHSA and the regulations of the FDA promulgated thereunder, and any other Government Authority that regulates the quality, identity strength, purity, safety, efficacy or manufacturing of the Company Products (any such Government Authority a "**Company Regulatory Agency**") required for the lawful operation of the business of the Company (the "**Company Permits**"), except, in each case, as would not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect on the Company. All such Company Permits are valid and in full force and effect. None of such Company Permit will be terminated or impaired or become terminable, in whole or in part, as a result of the transactions contemplated by this Agreement. The Company is the sole and exclusive owner of Company Permit and the associated filings and applications with the FDA, including any biologics license application, new drug application, abbreviated new drug application, drug master files, biologics master files, master files for devices, 510(k) submission, premarket approval, investigational new drug or investigational device exemption application, comparable regulatory application or filing made or held by or issued to the Company (collectively, the "**Company Regulatory Filings**") and hold all right, title and interest in and to all Company Regulatory Filings free and clear of any encumbrance. The Company has not granted any third party any right or license to use, access or reference any of the Company Regulatory Filings, including any of the know-how contained in any of the Company Regulatory Filings or rights (including any regulatory exclusivities) associated with each such Company Regulatory Filing.

(b) Since January 1, 2010, there has not occurred any breach or violation of, default (with or without notice or lapse of time or both) under or event giving rise to any right of termination, amendment or cancellation of (with or without notice or lapse of time or both), any Company Permit. The Company is in compliance in all material respects with the terms of all Company Permit, and no event has occurred and no facts or circumstances exist that, to the knowledge of the Company, would reasonably be expected to result in the revocation, cancellation, non-renewal or adverse modification of any the Company Permit.

(c) Since January 1, 2010, all material applications, submissions, information and data used by the Company as the basis for, or submitted by or, to the knowledge of the Company, on behalf of the Company in connection with, any and all requests for Company Permit when submitted to the FDA or other Company Regulatory Agency, were, to the Company's knowledge, accurate and complete in all material respects as of the date of submission, and any updates, changes,

corrections or modifications to such applications, submissions, information and data required under Applicable Law have been submitted to the FDA or other Company Regulatory Agency.

(d) Since January 1, 2010, the Company has not committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA or any other Company Regulatory Agency to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" or similar policies under Applicable Law. Neither the Company nor, to the knowledge of the Company, any agent, subcontractor, director, officer, employee or other Person associated with or acting on behalf of the Company has been convicted of any crime or engaged in any conduct which has resulted or could result in debarment or disqualification by the FDA or any other Government Authority, and there are no proceedings pending or threatened that reasonably might be expected to result in criminal or civil liability or debarment or disqualification by the FDA or any other Government Authority.

(e) The Company nor, to the knowledge of the Company, any director, officer, agent, employee or other Person associated with or acting on behalf of the Company, has: (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any similar Applicable Law; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment. There are no pending or, to the knowledge of the Company, threatened filings against the Company of an action relating to the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)).

(f) Since January 1, 2010, there has not been any voluntarily or involuntarily initiated, conducted, or issued recall, field notification, field correction, market withdrawal or replacement, safety alert, warning, "dear doctor" letter, market correction, or investigator notice relating to an alleged material lack of safety or efficacy of any Company Product.

(g) The Company is in compliance in all material respects with all Applicable Laws and any other letters, notices or guidance issued by the FDA or any Government Authority which regulate the clinical investigation, manufacture, sale, promotion, sampling and distribution of pharmaceutical products or biological, or device products in any jurisdiction. The Company has at all times and is currently distributing, marketing, promoting, labeling and selling its products in accordance with the FDCA and Prescription Drug Marketing Act of 1987. There are no pending or, to the knowledge of the Company, threatened regulatory Actions (other than non-material routine or periodic inspections or reviews) against the Company. Since January 1, 2010 there have been no written notices, reports, FDA Form 483 observations that have not been disclosed by the Company warning letters, or untitled letters alleging or asserting noncompliance in any material respect with any Applicable Law relating to the Company or any Company Product or any subpoenas or investigative demands or other written inquiries that would reasonably be interpreted as raising a compliance concern sent or delivered by any Government Authority with regard to any Company Product.

(h) The manufacture of Company Products is being conducted in compliance in all material respects with current "good manufacturing practices," as defined by the FDA. The Company has been in material compliance with FDA's registration and listing requirements to the extent required by FDA.

(i) The Company is and has been in compliance in all material respects with all Applicable Laws requiring the maintenance or submission of reports or records under requirements administered by the FDA or any other Government Authority, including Adverse Experiences, Serious Adverse Events, and Serious Injuries. There have been no Serious Adverse Events or

Serious Injuries associated with the use (including in clinical trials) of any Company Products that have not been reported to the FDA in accordance with Applicable Law.

(j) To the knowledge of the Company, all studies, tests, and preclinical and clinical research being conducted by the Company, and to the knowledge of the Company, on behalf of the Company, are being, and at all times have been, conducted in compliance in all material respects with all Applicable Laws, including, as applicable, good laboratory practice regulations set forth in 21 C.F.R. Part 58, good clinical practices, as defined or recognized by the FDA, including the ICH Tripartite Guideline for Good Clinical Practice, other applicable provisions of the FDCA and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812, and comparable laws of any other Government Authority. No clinical trial conducted by the Company or, to the knowledge of the Company, on behalf of the Company, has been terminated or suspended prior to completion for safety or non-compliance reasons, and neither the FDA nor any other Government Authority, clinical investigator or institutional review board that has or had jurisdiction over or participated in any such clinical trial has initiated, or, to the knowledge of the Company, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, materially delay or suspend, any such ongoing clinical trial, or to disqualify, restrict or debar any clinical investigator or other Person or entity involved in any such clinical trial.

(k) Neither the Company nor any officer, director, managing employee (as those terms are defined in 42 C.F.R. § 1001.1001) of the Company, nor, to the knowledge of the Company, any agent (as such term is defined in 42 C.F.R. § 1001.1001(a)(1)(ii)) of the Company is a party to, or bound by, any order, individual integrity agreement, corporate integrity agreement, monitoring agreement, consent decree, settlement order, deferred prosecution agreement or other formal or informal agreement with any Government Authority concerning compliance with the laws governing any Federal Health Care Program. The Company meets all the requirements of participation and payment of Medicare, Medicaid, and any Programs to the extent in which it participates. There is no action pending, received or, to the Company's knowledge, threatened against the Company which relates in any way to a violation of any health care laws or which could result in the imposition penalties against or the exclusion of the Company from participation in any Programs. Neither the Company nor any officer, director or managing employee has engaged in any activities which are cause for civil penalties or mandatory or permissive exclusion from any Program. To the Company's knowledge, there is no pending, proposed or final Medicare national or local coverage determination that, if finalized, would restrict coverage for the Company's products. The Company has not established any reimbursement support program, such that payment for the Company product is contingent upon a purchaser's receipt of payment from a third party payer. The Company does not furnish any coverage, coding or billing advice to any health care professionals regarding off-label indications of the Company products.

(l) Neither the Company nor any officer, director, managing employee (as those terms are defined in 42 C.F.R. § 1001.1001) of the Company, nor, to the knowledge of the Company, any agent (as such term is defined in 42 C.F.R. § 1001.1001(a)(1)(ii)) of the Company: (i) has been debarred, excluded or suspended under 21 U.S.C. § 335a, or (ii) any similar law, from participation in any Federal Health Care Program; (ii) has had a civil monetary penalty assessed against it, him or her under Section 1128A of the Social Security Act; (iii) is currently listed on the General Services Administration published list of parties excluded from federal procurement programs and non-procurement programs; (iv) to the knowledge of the Company, is the target or subject of any current investigation by a Government Authority relating to any Federal Health Care Program related offense; or (v) is currently charged with or convicted of any criminal offense relating to the delivery of an item or service under any Federal Health Care Program; or (vi) is the subject of any pending or threatened investigation by the FDA pursuant to its "Fraud, Untrue Statements of



(m) There are no pending or, to the knowledge of the Company, threatened filings against the Company of an action relating to the Company under any federal or state whistleblower statute, including under the civil False Claims Act of 1863 (31 U.S.C. § 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)) or the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)).

(n) To the knowledge of the Company, the Company is not under investigation by any Government Authority for a violation of HIPAA, or the regulations contained in 45 C.F.R. Parts 160 and 164, including receiving any notices from the United States Department of the Company and Human Services Office of Civil Rights relating to any such violations, or any comparable state or local laws. The Company is not a "covered entity" as that term is defined in HIPAA. The Company has been in compliance in all material respects with federal and state data breach laws.

(o) The Company is and has been in compliance in all material respects with all Applicable Laws requiring state registration, state reporting of applicable sales and marketing expenditures and transactions to health care professionals, and state compliance program requirements, which may include (depending on the state) but is not limited to adoption of the OIG Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, the AdvaMed Code, and/or the PhRMA Code. See Cal. Health & Safety Code §§ 119400 - 119402; Connecticut, Subst. Senate Bill No. 270, File No. 468, Cal. No. 333; D.C., D.C. Code Ann. §§ 48-833.01-48-833.09; Maine, Maine Rev. Stat. Ann. tit. 22, § 2698-A; Massachusetts, Mass. Chapter 111N of the Massachusetts General Acts; Minnesota, Minn.Stat. § 151.47 (general); Minn.Stat. § 151.461 (gifts); Nevada, Nev. Rev. Stat. §639.570; Vermont, 18 V.S.A. Sec. 4631a; 18 V.S.A. Sec. 4632.; West Virginia, W. Va. Code § 5A-3C-13, W. Va. Code §16-29H-8.

**4.16 Environmental Matters.** Except as set forth in *Section 4.16* of the Company Disclosure Schedules, (a) the Company holds, and is currently, and at all prior times have been, in continuous compliance with all Environmental Permits, and is currently, and at all prior times have been, otherwise in continuous compliance with all applicable Environmental Laws and, to the knowledge of the Company, there is no condition that would reasonably be expected to prevent or interfere with compliance with all applicable Environmental Laws and all applicable Environmental Permits in the future, (b) the Company has not received any Environmental Claim, and there is no pending or, to the knowledge of the Company, threatened Environmental Claim, (c) no Hazardous Materials have been generated, transported, treated, stored, installed, disposed of, arranged to be disposed of, released or threatened to be released at, on, from or under any of the properties or facilities currently or formerly owned, leased or otherwise used by the Company, in violation of, or in a manner or to a location that could give rise to liability to the Company under Environmental Laws, and (d) the Company has not assumed, contractually or by operation of law, any liabilities or obligations under or relating to any Environmental Laws.

**4.17 Labor and Employment Matters.** Except as set forth in *Section 4.17* of the Company Disclosure Schedule, (a) there is no labor strike, dispute, slowdown, stoppage or lockout actually pending or, to the knowledge of the Company, threatened against the Company, (b) no union, works council or other labor organization represents, or claims to represent, any group of employees with respect to their employment by the Company and no union organizing campaign with respect to the employees of the Company is threatened or underway, (c) there is no unfair labor practice charge or complaint against the Company pending or, to the knowledge of the Company, threatened before the National Labor Relations Board or any similar state or foreign agency, (d) there is no grievance pending relating to any collective bargaining agreement or other grievance procedure, (e) no charges with respect to or relating to the Company are pending before the Equal Employment Opportunity Commission or any other state or foreign agency responsible for the prevention of unlawful employment practices, (f) no employee of the Company is in violation of (and to the knowledge of the Company no written allegation has been made

that any employee is in violation of) any term of any restrictive covenant, common law nondisclosure obligation, fiduciary duty, or other obligation to a former employer of any such employee relating (i) to the right of any such employee to be employed by the Company or (ii) to the knowledge or use of trade secrets or proprietary information, and (g) since January 1, 2011, the Company has not employed more than 75 employees at any one time and (h) since January 1, 2011, all Company employees have been employed in the State of Illinois. The Company is not a party to a current conciliation agreement, consent decree, or other agreement or order with any Government Authority with respect to labor or employment practices.

#### 4.18 Insurance.

(a) *Section 4.18(a)* of the Company Disclosure Schedule sets forth, as of the date hereof, an accurate and complete list of the policies of insurance currently maintained by or for the benefit of the Company (including any policies of insurance maintained for purposes of providing benefits such as workers' compensation and employers' liability coverage) (collectively, the "**Company Policies**"). All such Company Policies are in full force and effect and the limits of liability thereunder have not been exhausted by the payment of claims. There has not been any interruption in insurance coverage for the types of risks covered under such Policies since January 1, 2010. The Company and, to the knowledge of the Company, its counterparties are not in default under the Policies, and no event has occurred that, with the lapse of time or the giving of notice or both, would constitute a default under any Policy by the Company or, to the knowledge of the Company, any other Person. No written notice of cancellation or termination has been received with respect to any such Policy (except Policies replaced in the ordinary course). To the knowledge of the Company, no insurer on any such Policy has been declared insolvent or placed in receivership or liquidation.

(b) *Section 4.18(b)* of the Company Disclosure Schedule sets forth a list of all pending claims (including with respect to insurance obtained but not currently maintained) and the claims history for the Company since January 1, 2010 (including with respect to insurance obtained but not currently maintained), in each case with respect to each claim (or series of related claims) involving amounts in excess of \$25,000. The Company has not been refused any insurance coverage with respect to any aspect of its operations nor has its coverage been limited by any insurance carrier to which it has applied for insurance or with which it has carried insurance since January 1, 2010. There is no claim by the Company pending under any such Policies in excess of \$50,000 as to which coverage has been questioned, denied or disputed by the underwriters of such Policies.

**4.19 Registration Statement; Joint Proxy Statement/Prospectus.** The registration statement on Form S-4 to be filed with the SEC by the Company in connection with the issuance of Company Common Stock pursuant to this Agreement (the "**Registration Statement**") (and any amendment or supplement thereto), at the time the Registration Statement (and any amendment or supplement thereto) is filed, at the time the Registration Statement (and any amendment or supplement thereto) is declared effective by the SEC and at the Effective Time, will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Joint Proxy Statement/Prospectus, at the date the Joint Proxy Statement/Prospectus (and any amendment or supplement thereto) is first mailed to the Company and ANI stockholders and at the time of the Company Special Meeting and the ANI Special Meeting (or any adjournment or postponement thereof), will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The representations and warranties contained in this *Section 4.19* will not apply to statements or omissions included in the Registration Statement or Joint Proxy Statement/Prospectus (and, in each case, any amendment or supplement thereto) based upon information regarding ANI or any ANI Subsidiary supplied to the Company in writing by ANI for use therein (it being understood that all other information in the Registration Statement and Joint Proxy Statement/Prospectus (and, in each case, any amendment or

supplement thereto) will be deemed to have been supplied by the Company). The Registration Statement and Joint Proxy Statement/Prospectus (and, in each case, any amendment or supplement thereto) will, when filed, comply as to form in all material respects with the applicable requirements of the Securities Act and the Exchange Act and, subject to *Section 5.4(d)*, the Joint Proxy Statement/Prospectus will include the Company Board Recommendation.

**4.20 Affiliate Transactions.** Since January 1, 2010, there have been no transactions, or series of related transactions, agreements, arrangements or understandings, nor are there any currently proposed transactions, or series of related transactions, that would be required to be disclosed under Item 404 of Regulation S-K promulgated under the Securities Act that have not been otherwise disclosed in the Company SEC Documents.

**4.21 Brokers or Finders.** No agent, broker, investment banker, financial advisor or other firm or person except Oppenheimer & Co. Inc. (the "**Company Financial Advisor**") has been retained by or is authorized to act on behalf of the Company and is or might be entitled to any broker's or finder's fee or any other similar commission or fee in connection with any of the transactions contemplated by this Agreement. The Company has provided to ANI a copy of its engagement agreement with the Company Financial Advisor.

**4.22 Exchange Act Registration; NASDAQ Listing.** The Company Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on The NASDAQ Global Market. No event has occurred that is reasonably likely to have the effect of terminating the registration of Company Common Stock under the Exchange Act or delisting Company Common Stock from The NASDAQ Global Market, nor has the Company received any notification that the SEC or the NASDAQ is contemplating terminating such registration or such delisting.

**4.23 News Releases.** No statement made by the Company in either of the news releases issued by it in respect of the LibiGel Product on February 22, 2010 or May 31, 2011, as of the respective dates on which such news releases were issued, contained any untrue statement of material fact or omitted to state a material fact necessary to make any of the statements made, in light of the circumstances in which they were made, not misleading. No other public statement made by the Company concerning the results of any clinical trials, anticipated results of any clinical trials, potential for FDA approval or financial prospects for the Company or its products, including without limitation all SEC filings, news releases and statements to the financial press, to the knowledge of any officer or director of the Company, contained any untrue statements of material fact or omitted to state a material fact necessary to make any of the statements made, in light of the circumstances in which they were made, not misleading, as of the date such statements were made. No officers or directors of the Company had any knowledge of the results of the two pivotal efficacy trials of the LibiGel Product, known as TESTW006 and TESTW008, until shortly before the public announcement of such results on December 14, 2011, and such officers and directors reasonably believed that the results of such trials would be positive and consistent with all prior public statements in all material respects.

**4.24 Disclosure.** No representation or warranty or other statement made by the Company in this Agreement, the Company Disclosure Schedules, the certificates delivered pursuant to *Section 6.2(d)(i)* or otherwise in connection with the transactions contemplated herein contains any untrue statement or omits to state a material fact necessary to make any of them, in light of the circumstances in which it was made, not misleading.

## **ARTICLE V. Covenants**

**5.1 Conduct of ANI Business During Interim Period.** Except as contemplated or required by this Agreement or as expressly consented to in writing by the Company (which consent will not be unreasonably withheld, delayed or conditioned), or as set forth in *Section 5.1* of the ANI Disclosure Schedule, during the

period from the date of this Agreement to the earlier of the termination of this Agreement or the Effective Time (the "**Interim Period**"), each of ANI and the ANI Subsidiaries will: (i) conduct its operations according to its ordinary course of business and consistent with past practice; (ii) use its reasonable best efforts to preserve intact its business, to keep available the services of its officers and employees and to maintain existing relationships with licensors, licensees, suppliers, distributors, consultants, customers and others having business relationships with it, except in each case, to the extent that the termination of any such services or relationships is in the ordinary course of business and consistent with past practice; and (iii) not take any action which would reasonably be expected to adversely affect its ability to consummate the Merger or the other transactions contemplated hereby. Without limiting the generality of the foregoing, and except as otherwise expressly provided in this Agreement or as set forth in *Section 5.1* of the ANI Disclosure Schedule, during the Interim Period ANI will not, and will not permit ANI Subsidiaries to, without the prior written consent of the Company (which consent will not be unreasonably withheld, conditioned or delayed), directly or indirectly, do any of the following:

- (a) other than in the ordinary course of business, (i) enter into any Contract that would have been an ANI Contract were ANI or any of ANI Subsidiaries a party or subject thereto on the date of this Agreement; or (ii) terminate or amend in any material respect any ANI Contract or waive any material right thereunder;
- (b) adopt any new severance plan or grant any severance or termination payments to any officer or director of ANI or any of ANI Subsidiaries, except payments substantially pursuant to written agreements or policies existing on the date hereof and set forth on *Section 5.1(b)* of the ANI Disclosure Schedule;
- (c) declare or pay any dividends on or make any other distributions (whether in cash, stock or property) in respect of any capital stock or other equity security or split, combine or reclassify any capital stock or other equity security or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for any capital stock or other equity security;
- (d) cause, permit or propose any material amendments to the certificate of incorporation, bylaws, certificate of formation or limited liability company agreement (in each case, as applicable) of ANI or any of ANI Subsidiaries in a manner that would reasonably be expected to adversely affect the ability of ANI to consummate the Merger;
- (e) other than in the ordinary course of business, subject to any Lien (other than an ANI Permitted Lien) or otherwise dispose of any properties or assets which are material, individually or in the aggregate, to the business of ANI and ANI Subsidiaries, taken as a whole;
- (f) incur any indebtedness for borrowed money or guarantee any such indebtedness, in each case, other than in the ordinary course of business, or issue or sell any debt securities or warrants or rights to acquire debt securities of ANI or any ANI Subsidiary, as the case may be;
- (g) enter into any "keep well" or other contract to maintain any financial statement condition of any Person other than a wholly owned ANI Subsidiary or enter into any arrangement having the economic effect of the foregoing;
- (h) adopt or amend any ANI Benefit Plan, except for adoptions and amendments made in the ordinary course of business, or required by Applicable Law or made in contemplation of the consummation of the transactions pursuant to this Agreement as set forth in *Section 5.1(h)* of the ANI Disclosure Schedule, enter into any employment Contract other than a Contract for at-will employment or to replace a departing executive employee, pay any special bonus or special remuneration to any director or employee of ANI or any ANI Subsidiary, except in the ordinary course of business consistent with past practice, or increase the salaries or wage rates of the officers or employees of ANI or any ANI Subsidiary, except increases in the salaries or wage rates of employees

in the ordinary course of business or except as required by the terms of an ANI Contract or ANI Benefit Plan as in existence on the date hereof or disclosed in the ANI Disclosure Schedule;

(i) pay, discharge, settle, compromise or satisfy any material pending or threatened Action, claim, liability or obligation (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than (i) the payment or discharge of liabilities or obligations of ANI with respect to amounts owed to vendors or suppliers in the ordinary course of business, (ii) settlements or compromises of Actions in the ordinary course of business, (iii) settlements or compromises involving payments by ANI or any ANI Subsidiary not in excess of \$100,000 individually, or more than \$250,000 in the aggregate, and (iv) with respect to Taxes;

(j) authorize, solicit, propose or announce an intention to authorize, recommend or propose, or enter into any Contract with respect to, any plan of liquidation or dissolution, any acquisition of a material amount of assets or securities, any disposition of a material amount of assets, equity or other securities, except as set forth in *Section 5.1* of the ANI Disclosure Schedule;

(k) (i) purchase any insurance policy except replacement policies for Policies that expire on their terms after the date hereof and except for directors' and officers' liability 'tail' insurance policy or policies; (ii) fail to renew any insurance policy naming it as a beneficiary or a loss payee; or (iii) take any steps or fail to take any steps that would permit any insurance policy naming it as a beneficiary or a loss payee to be canceled, terminated or materially altered;

(l) fail to properly maintain any material Registered IP, including payments of all fees or otherwise let lapse or impair any material ANI Owned IP or ANI Licensed IP;

(m) maintain its books and records in a manner other than in the ordinary course of business consistent with past practice;

(n) enter into any hedging, option, derivative or other similar transaction or any foreign exchange position or contract for the exchange of currency;

(o) institute any material change in its accounting methods, principles or practices other than as required by GAAP;

(p) in respect of any Taxes: (i) except as required by Applicable Law, change any material election, change any material accounting method, enter into any material closing agreement, settle any material claim or assessment or consent to any material extension or waiver of the limitation period applicable to any material claim or assessment or amend any material Tax Return; or (ii) enter into any material Tax-sharing agreement or similar arrangement (including any Tax indemnity arrangement) the principal subject of which is Taxes;

(q) (i) issue, deliver or sell, or authorize the issuance, delivery or sale of, any securities of ANI or its Subsidiaries, other than issuance of ANI Series D Preferred Stock pursuant to the transaction bonus agreements with certain members of ANI's management team described in *Section 3.8* of the ANI Disclosure Schedule; (ii) file a registration statement under the Securities Act with respect to an initial public offering of any ANI Securities; or (iii) merge or consolidate with or otherwise acquire any other Person or create any Subsidiary;

(r) enter into any agreement that, prior to the Effective Time, would limit ANI or any of ANI Subsidiaries, or following the Effective Time, would limit the Company or any of the Company Subsidiaries, from engaging in any line of business, competing with any Person or selling any product or service;

(s) allow to lapse or fail to make an application for renewal as and when required of any material ANI Permit;

(t) make capital expenditures in excess of \$100,000 in the aggregate that are not reflected on the capital expenditures budget of ANI provided to the Company, except acquisitions permitted pursuant to clause (j) above;

(u) take any action that would prevent the Merger from qualifying as a reorganization under Section 368(a) of the Code; or

(v) agree or commit to do any of the foregoing.

**5.2 Conduct of the Company Business During Interim Period.** Except as contemplated or required by this Agreement (including pursuant to *Section 5.22* or *Section 5.23*) or as expressly consented to in writing by ANI (which consent will not be unreasonably withheld, delayed or conditioned), or as set forth in *Section 5.2* of the Company Disclosure Schedule, during the Interim Period, the Company will: (i) conduct its operations according to its ordinary course of business and consistent with past practice; (ii) use its reasonable best efforts to preserve intact its business, to keep available the services of its officers and employees and to maintain existing relationships with licensors, licensees, suppliers, distributors, consultants, customers and others having business relationships with it, except in each case, to the extent that the termination of any such services or relationships is in the ordinary course of business and consistent with past practice; (iii) file all required Company SEC Documents required to be filed by it with the SEC under Applicable Law in a timely manner, with such Company SEC Documents complying, when filed, with Applicable Law; (iv) maintain compliance with the applicable listing requirements of NASDAQ; (v) take all such actions as may be necessary or advisable to effect a conclusion of the LibiGel Product clinical trials and safety study in accordance with the budget and timeline set forth in *Section 5.2* of the Company Disclosure Schedule and (vi) not take any action which would reasonably be expected to adversely affect its ability to consummate the Merger or the other transactions contemplated hereby. Without limiting the generality of the foregoing, and except as otherwise expressly provided in this Agreement (including pursuant to *Section 5.22* or *Section 5.23*) or as set forth in *Section 5.2* of the Company Disclosure Schedule, during the Interim Period, the Company will not, without the prior written consent of ANI (which consent will not be unreasonably withheld, conditioned or delayed), directly or indirectly, do any of the following:

(a) other than in the ordinary course of business, (i) enter into any Contract that would have been a Company Contract were the Company a party or subject thereto on the date of this Agreement; or (ii) terminate or amend in any material respect any Company Contract or waive any material right thereunder;

(b) adopt any new severance plan or grant or make any severance or termination payments to any officer or director of the Company, except payments (i) substantially pursuant to written agreements or policies existing on the date hereof and set forth on *Section 5.2(b)* of the Company Disclosure Schedule or (ii) additional payments not to exceed an aggregate of \$300,000 authorized by the Company Board during the Interim Period; provided that (A) such payments (to the extent not paid prior to the Determination Date) will be included as a Liability for purposes of calculating Net Cash and (B) any additional payments pursuant to *clause (b)(ii)* will only be permitted to extent that they (x) are authorized on or before the Determination Date and are included as a Liability for purposes of calculating Net Cash as of such date, (y) are not payable until on or after the Closing Date and (z) in any event subject to, conditioned upon and payable only so long as payment of any thereof will not cause Net Cash determined pursuant to *Section 5.21* to be less than the Minimum Net Cash;

(c) declare or pay any dividends on or make any other distributions (whether in cash, stock or property) in respect of any capital stock or other equity security or split, combine or reclassify any capital stock or other equity security or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for any capital stock or other equity security, *provided, however*, that the Company will have the right to issue to the holders of its outstanding shares of

Company Common Stock a dividend of contingent value rights (the "**Contingent Value Rights**") with respect to certain payments arising from the sale, transfer, license or a similar transaction relating to the Company's LibiGel program, pursuant to the terms of a contingent value rights agreement (the "**CVR Agreement**"), a substantially final draft of which has been provided to ANI and the form and substance of which has been agreed to by the Company and ANI prior to the date of this Agreement (and which will not be amended or modified without the prior consent of ANI), and which dividend of Contingent Value Rights is to be issued in the sole and absolute discretion of the Company Board;

(d) repurchase or otherwise acquire, directly or indirectly, any shares of capital stock or other equity security, except as a result of a holder's right to exercise any outstanding warrant or any outstanding option under any Company Benefit Plan on a 'cashless' basis;

(e) cause, permit or propose any material amendments to the certificate of incorporation, bylaws, certificate of formation or limited liability company agreement (in each case, as applicable) of the Company;

(f) sell, lease or encumber or subject to any Lien (other than a Company Permitted Lien) or otherwise dispose of any properties or assets which are material, individually or in the aggregate, to the business of the Company;

(g) incur any Indebtedness, for borrowed money or otherwise, or guarantee any such Indebtedness or issue or sell any debt securities or warrants or rights to acquire debt securities of the Company or any Company Subsidiary, as the case may be;

(h) enter into any "keep well" or other contract to maintain any financial statement condition of any Person other than a wholly owned the Company Subsidiary or enter into any arrangement having the economic effect of the foregoing;

(i) adopt or amend any Company Benefit Plan, hire any employee or otherwise enter into any employment Contract, pay any special bonus or special remuneration to any director or employee of the Company or any Company Subsidiary, except any such amendments to Company Benefit Plans required by Applicable Law, or increase the salaries or wage rates of the officers or employees of the Company or any Company Subsidiary except as required by the terms of a Company Contract as in existence on the date hereof and except for severance and release agreements entered into with employees who are being terminated effective no later than the Closing Date, solely to the extent that any amount payable in respect thereof is included as a Liability for purposes of calculating Net Cash;

(j) pay, discharge, settle, compromise or satisfy any pending or threatened Action, claim, liability or obligation (whether absolute, accrued, asserted or unasserted, contingent or otherwise), other than (i) the payment or discharge of liabilities or obligations of the Company with respect to amounts owed to vendors, suppliers or taxing authorities in the ordinary course of business (and not as a result of a breach of contract, Violation or settlement of any Action or claim) and (ii) settlements or compromises of any Action outstanding on the date hereof, involving payments by the Company or any Company Subsidiary not in excess of \$50,000 individually, or more than \$100,000 in the aggregate;

(k) authorize, solicit, propose or announce an intention to authorize, recommend or propose, or enter into any Contract with respect to, any plan of liquidation or dissolution, any acquisition of assets out of the ordinary course of business or securities, or any partnership, association or joint venture;

(l) (i) purchase any insurance policy other than the Company Tail Policies, product liability insurance related to the LibiGel program or replacement policies for Policies that expire on their

terms after the date hereof, on terms no less favorable to the Company; (ii) fail to renew any insurance policy naming it as a beneficiary or a loss payee; (iii) take any steps or fail to take any steps that would permit any insurance policy naming it as a beneficiary or a loss payee to be canceled, terminated or materially altered or (iv) cancel or allow to lapse any product liability or clinical administration insurance in respect of the LibiGel Program;

(m) fail to properly maintain any material Registered IP, including payments of all fees or otherwise let lapse or impair any material Company Owned IP or Company Licensed IP;

(n) maintain its books and records in a manner other than in the ordinary course of business consistent with past practice;

(o) enter into any hedging, option, derivative or other similar transaction or any foreign exchange position or contract for the exchange of currency;

(p) institute any change in its accounting methods, principles or practices other than as required by GAAP or the rules and regulations promulgated by the SEC;

(q) in respect of any Taxes: (i) except as required by Applicable Law, change any material election, change any material accounting method, enter into any material closing agreement, settle any material claim or assessment or consent to any material extension or waiver of the limitation period applicable to any material claim or assessment or amend any material Tax Return; or (ii) enter into any Tax-sharing agreement or similar arrangement (including any Tax indemnity arrangement) the principal subject of which is Taxes;

(r) issue, deliver or sell, or authorize the issuance, delivery or sale of, any Company securities, other than the issuance of any shares of Company Common Stock upon the exercise of the Company Stock Options or warrants and the issuance of Company Common Stock in satisfaction of any Company Convertible Note; or (ii) amend any term of any security of the Company or any Company Subsidiary (in each case, whether by merger, consolidation or otherwise);

(s) enter into any agreement that would limit the Company from engaging in any line of business, competing with any Person or selling any product or service;

(t) allow to lapse or fail to make an application for renewal as and when required of any material Company Permit;

(u) make capital expenditures in excess of \$50,000 in the aggregate;

(v) take any action that would prevent the Merger from qualifying as a reorganization under Section 368(a) of the Code;

(w) enter into a new clinical drug trial program or continue or extend the LibiGel Product trial and/or safety study; or

(x) agree or commit to do any of the foregoing.

### 5.3 No Solicitation by ANI.

(a) During the Interim Period, ANI will not, nor will it authorize or permit any of the ANI Subsidiaries or any of its or their respective officers, directors, employees, agents, attorneys, accountants, advisors or other representatives (the "**Representatives**") to, directly or indirectly: (i) solicit, initiate or encourage or facilitate (including by way of furnishing any non-public information relating to ANI or any ANI Subsidiary), or induce or take any other action which would reasonably be expected to lead to the making, submission or announcement of, any proposal or inquiry that constitutes, or is reasonably likely to lead to, an Acquisition Proposal (as defined below); (ii) other than informing Persons of the provisions contained in this Section 5.3, enter into,



continue or participate in any discussions or any negotiations regarding any Acquisition Proposal or otherwise take any action to facilitate or induce any effort or attempt to make or implement an Acquisition Proposal (including any Acquisition Proposal received prior to the date of this Agreement; (iii) approve, endorse or recommend an Acquisition Proposal or any letter of intent, memorandum of understanding or Contract contemplating an Acquisition Proposal or requiring ANI to abandon or terminate its obligations under this Agreement, or enter into any of the foregoing; or (iv) agree, resolve or commit to do any of the foregoing. ANI will, and will cause ANI Subsidiaries and its and their respective Representatives to, immediately cease and cause to be terminated all discussions or negotiations with any Person previously conducted with respect to any Acquisition Proposal. ANI will promptly deny to any third party access to any data room (virtual or actual) containing any confidential information previously furnished to any such third party relating to any Acquisition Proposal.

(b) For purposes of this Agreement, an "**Acquisition Proposal**" means, with respect to any Party, any offer, proposal or indication of interest (other than an offer, proposal or indication of interest by another Party) contemplating or otherwise relating to any transaction or series of related transactions involving any:

(i) merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction in which: (i) a Person or "group" (as defined in the Exchange Act and the rules promulgated thereunder) of Persons directly or indirectly acquires beneficial or record ownership of securities representing 15% or more of the outstanding shares of any class of voting securities of such Party; or (ii) such Party issues securities representing 15% or more of the outstanding shares of any class of voting securities of such Party;

(ii) sale, lease, exchange, transfer or disposition of any assets that constitute or account for: (i) 15% or more of the consolidated net revenues of such Party, consolidated net income of such Party or consolidated book value of such Party; or (ii) 15% or more of the fair market value of the assets of such Party; or

(iii) liquidation or dissolution of such Party.

(c) ANI will promptly, but in no event later than twenty four (24) hours, notify the Company in writing if any proposal, offer or inquiry is received by, or any discussions or negotiations are sought to be initiated or continued with, ANI in respect of any Acquisition Proposal. Such notice will indicate the identity of the Person making such proposal, offer, inquiry or other contact and the material terms and conditions of any proposals or offers (and will include with such notice copies of any written materials received from or on behalf of such Person relating to such proposal, offer, inquiry or other request), and ANI thereafter will promptly keep the Company informed of all material developments affecting the status and the material terms of any such proposal, offer, inquiry or other request (including providing the Company with any additional written materials received relating to such proposal, offer, inquiry or other request).

(d) Unless a Change in Company Board Recommendation has occurred, the Company has taken any of the actions permitted under *Section 5.4(b)*, or ANI has terminated the Agreement pursuant to *Article VII*, the ANI Board will not: (i) fail to make ANI Board Recommendation to ANI's stockholders in accordance with *Section 5.8(b)*; (ii) withhold, withdraw, amend, qualify or modify in a manner adverse to the Company, or publicly propose to withhold, withdraw, amend, qualify or modify in a manner adverse to ANI, ANI Board Recommendation; (iii) adopt, approve, recommend, endorse or otherwise declare advisable the adoption of any Acquisition Proposal; or (iv) resolve, agree or publicly propose to take any such actions (each such foregoing action or failure to act in clauses (i) through (iv) being referred to as a "**Change in ANI Board Recommendation**").

#### 5.4 No Solicitation by the Company.

(a) Subject to *Section 5.4(b)* and *Section 5.4(d)*, during the Interim Period, the Company will not, nor will it authorize or permit any of the Company Subsidiaries or any of its or their respective Representatives to, directly or indirectly, except as otherwise provided below: (i) solicit, initiate or encourage or facilitate (including by way of furnishing any non-public information relating to the Company or any the Company Subsidiary), or induce or take any other action which would reasonably be expected to lead to the making, submission or announcement of, any proposal or inquiry that constitutes, or is reasonably likely to lead to, an Acquisition Proposal; (ii) other than informing Persons of the provisions contained in this *Section 5.4*, enter into, continue or participate in any discussions or any negotiations regarding any Acquisition Proposal or otherwise take any action to facilitate or induce any effort or attempt to make or implement an Acquisition Proposal (including any Acquisition Proposal received prior to the date of this Agreement); (iii) approve, endorse or recommend an Acquisition Proposal or any letter of intent, memorandum of understanding or Contract contemplating an Acquisition Proposal or requiring the Company to abandon or terminate its obligations under this Agreement, or enter into any of the foregoing; or (iv) agree, resolve or commit to do any of the foregoing. The Company will, and will cause the Company Subsidiaries and its and their respective Representatives to, immediately cease and cause to be terminated all discussions or negotiations with any Person previously conducted with respect to any Acquisition Proposal. The Company will promptly deny to any third party access to any data room (virtual or actual) containing any confidential information previously furnished to any such third party relating to any Acquisition Proposal.

(b) Notwithstanding anything in this *Section 5.4* to the contrary, at any time prior to obtaining Company Stockholder Approval, in response to an unsolicited written Acquisition Proposal that the Company Board determines in good faith (after consultation with its financial advisor and outside legal counsel) constitutes or would reasonably be expected to result in a Superior Proposal (and that did not result from a violation of *Section 5.4(a)*), the Company may, upon a good faith determination by the Company Board (after receiving the advice of its outside counsel) that failure to take such action would be inconsistent with the Company's board of directors' fiduciary duties to the Company's stockholders under Applicable Law: (x) furnish information with respect to the Company to the Person making such Acquisition Proposal (and such Person's Representatives), provided that the Company and such Person first enter into a confidentiality agreement with confidentiality provisions that are not less restrictive to such Person than the provisions of the Confidentiality Agreement are to ANI and that would not prohibit compliance by the Company with the provisions of this *Section 5.4*, and provided further that all such information will have been previously provided to ANI or is concurrently provided to ANI at the same time that it is provided to such Person; and (y) participate in discussions or negotiations with the Person making such Acquisition Proposal (and such Person's Representatives) regarding such Acquisition Proposal.

For purposes of this Agreement, "**Superior Proposal**" means a bona fide written Acquisition Proposal (provided that, for purposes of this definition, references to 15% in the definition of "Acquisition Proposal" are deemed to be references to 50%) which the board of directors of the Party that is the subject of the Acquisition Proposal determines in good faith (after consultation with its financial advisor): (i) to be reasonably likely to be consummated if accepted; and (ii) to be more favorable to such Party's stockholders from a financial point of view than the Merger, in each case, taking into account at the time of determination all relevant circumstances, including the various legal, financial and regulatory aspects of the proposal, all the terms and conditions of such proposal and this Agreement, any changes to the terms of this Agreement offered by the other party in response to such Acquisition Proposal and the ability of the Person making such Acquisition Proposal to consummate the transactions contemplated by such Acquisition Proposal (based upon, among other things, expectation of obtaining required approvals).

(c) The Company will promptly, but in no event later twenty four (24) hours, notify ANI in writing if any proposal, offer or inquiry is received by, or any discussions or negotiations are sought to be initiated or continued with, the Company in respect of any Acquisition Proposal. Such notice will advise ANI in writing of the Company's intention to participate or engage in discussions or negotiations with, or furnish non-public information to, such Person and will, in any such notice to ANI, indicate the identity of the Person making such proposal, offer, inquiry or other contact and the material terms and conditions of any proposals or offers (and will include with such notice copies of any written materials received from or on behalf of such Person relating to such proposal, offer, inquiry or other request), and thereafter will promptly keep ANI informed of all material developments affecting the status and the material terms of any such proposal, offer, inquiry or other request and of the status of any such discussions or negotiations relating thereto (including providing ANI with any additional written materials received relating to such proposal, offer, inquiry or other request).

(d) The Company Board will not: (i) fail to make the Company Board Recommendation to the Company's stockholders in accordance with *Section 5.7(b)*; (ii) withhold, withdraw, amend, qualify or modify in a manner adverse to ANI, or publicly propose to withhold, withdraw, amend, qualify or modify in a manner adverse to ANI, the Company Board Recommendation; (iii) adopt, approve, recommend, endorse or otherwise declare advisable the adoption of any Acquisition Proposal; or (iv) resolve, agree or publicly propose to take any such actions (each such foregoing action or failure to act in clauses (i) through (iv) being referred to as a "**Change in Company Board Recommendation**"). Notwithstanding the foregoing, the Company Board may, at any time prior to obtaining Company Stockholder Approval, take any of the actions set forth in *Section 5.4(d)(i)-(ii)* below, provided that prior to taking any such action, the Company complies with *Sections 5.4(e)* and 7.3 of this Agreement:

(i) effect a Change in Company Board Recommendation in response to an Acquisition Proposal if the Company Board concludes in good faith: (A) after consultation with outside counsel, that the failure to take such action would be inconsistent with its fiduciary duties to the Company's stockholders under Applicable Law; and (B) after consultation with the Company's financial advisor and outside counsel, that the Acquisition Proposal constitutes a Superior Proposal; and

(ii) following such a Change in Board Recommendation, terminate this Agreement for the purpose of causing the Company to enter into an acquisition agreement with respect to such Acquisition Proposal; provided, however, that the Company has paid the ANI Termination Fee prior to or concurrently with such termination of this Agreement in accordance with *Section 7.3*.

(e) Notwithstanding anything to the contrary set forth in *Section 5.4(d)*, the Company Board will not be entitled to make a Change in Company Board Recommendation as contemplated by *Section 5.4(d)(i)* or terminate this Agreement and enter into another acquisition agreement as contemplated by *Section 5.4(d)(ii)* unless: (i) the Company has first provided prior written notice to ANI that it intends to take any of the foregoing actions (a "**Company Notice**"), which Company Notice will contain a description of the material terms and conditions of such Superior Proposal, including a copy of the definitive acquisition agreement in the form to be entered into (it being understood and agreed that the delivery of such Company Notice will not, in and of itself, be deemed to be a Change in Company Board Recommendation); and (ii) ANI does not make, within three (3) Business Days after the receipt of such Company Notice, a proposal that would, in the good faith judgment of the Company Board (after consultation with outside counsel and its financial advisor), cause the Acquisition Proposal previously constituting a Superior Proposal to no longer constitute a Superior Proposal, as the case may be, *provided, however*, that (x) any amendment to any material term of such Superior Proposal or (y) with respect to any previous

Change in Company Board Recommendation, any material change in the principal stated rationale by the Company Board for such previous Change in Company Board Recommendation, will, in the case of either (x) or (y), require a new Company Notice and a new three (3) Business Day period.

(f) Nothing contained in this *Section 5.4* or elsewhere in this Agreement will prohibit the Company or the Company Board from: (i) taking and disclosing to the Company's stockholders a position contemplated by Rule 14d-9, Rule 14e-2(a) or Item 1012(a) of Regulation M-A promulgated under the Exchange Act; or (ii) making any disclosure to the Company's stockholders if, in the good faith judgment of the Company Board, after consultation with outside counsel, the failure to make such disclosure would be inconsistent with the Company's board of directors' fiduciary duties to the Company's stockholders under Applicable Law; *provided, however*, that this *Section 5.4(f)* will not affect the obligations of the Company and the Company Board and the rights of ANI under *Section 5.4(d)* and *Section 5.4(e)* to the extent applicable to such disclosure (it being understood that neither any "stop, look and listen" letter or similar communication of the type contemplated by Rule 14d-9(f) under the Exchange Act, nor any accurate disclosure of factual information (other than the Company or the Company Board taking any action set forth in *Section 5.4(d)* and *Section 5.4(e)* of this Agreement) to the Company's stockholders that is required to be made to such stockholders under Applicable Law or in satisfaction of the Company's board of directors' fiduciary duties under Applicable Law, will be deemed to be a Change in Company Board Recommendation).

**5.5 Access to Information.** During the Interim Period, each of the Company and ANI will, and will cause its respective Representatives to, upon reasonable notice and request: (i) furnish to each other and each other's Representatives reasonable access during normal business hours to its offices, properties, personnel, books and records; and (ii) furnish to each other and each other's Representatives such financial and operating data and other information as may be reasonably requested. Any investigation pursuant to this *Section 5.5* will be conducted in a manner so as not to interfere unreasonably with the conduct of the business of the Company or the Company Subsidiaries or ANI or ANI Subsidiaries, as applicable. In addition, nothing contained in this *Section 5.5* will require the Company or the Company Subsidiaries or ANI or the ANI Subsidiaries to take any action that would, in the good faith judgment of the Company or ANI, as applicable, constitute a waiver of the attorney-client or similar privilege or trade secret protection held by the Company or the Company Subsidiaries or ANI or ANI Subsidiaries, as applicable, or violate confidentiality obligations owing to third parties; *provided, however*, that each of the Company and ANI will make a good faith effort to accommodate any request from the other for access or information pursuant to this *Section 5.5* in a manner that does not result in such a waiver or violation. All information furnished pursuant to this *Section 5.5* will be subject to the Confidentiality Agreement, dated as of July 19, 2012, between the Company and ANI (the "**Confidentiality Agreement**").

#### **5.6 Registration Statement; Related Matters.**

(a) As soon as reasonably practicable following the date hereof, the Company will, with the assistance and approval of ANI (such approval not be unreasonably withheld, conditioned or delayed), prepare and file with the SEC the Registration Statement containing the Joint Proxy Statement/Prospectus (which Registration Statement and Joint Proxy Statement/Prospectus will comply in all material respects with the rules and regulations promulgated by the SEC). Each of the Company and ANI will cooperate and consult with each other in the preparation of the Registration Statement and Joint Proxy Statement/Prospectus and use its reasonable best efforts to (i) have the Registration Statement containing the Joint Proxy Statement/Prospectus declared effective by the SEC as promptly as practicable thereafter and (ii) keep the Registration Statement containing the Joint Proxy Statement/Prospectus effective through the Effective Time in order to permit the consummation of the Merger. In connection with the foregoing, the Company will promptly notify ANI of the receipt of all comments of the SEC with respect to the Registration

Statement containing the Joint Proxy Statement/Prospectus and of any request by the SEC for any amendment or supplement thereto or for additional information and will promptly provide to ANI copies of all correspondence between the Company and/or any of its Representatives and the SEC with respect to the Registration Statement containing the Joint Proxy Statement/Prospectus. ANI and its Representatives will be given a reasonable opportunity to be involved in the drafting of the Registration Statement containing the Joint Proxy Statement/Prospectus and any amendment or supplement thereto and any such correspondence prior to its filing with the SEC. Each of the Company and ANI will use its reasonable best efforts to resolve all SEC comments and provide responses to the SEC as promptly as practicable with respect to all comments received on the Registration Statement containing the Joint Proxy Statement/Prospectus from the SEC and to cause the Registration Statement containing the Joint Proxy Statement/Prospectus to be mailed to the Company's stockholders and ANI's stockholders as soon as practicable after the Registration Statement containing the Joint Proxy Statement/Prospectus is declared effective by the SEC, and the Company and ANI will use their reasonable best efforts to cause such mailing to occur prior to December 15, 2012. ANI will provide the Company with the information relating to it required by the Securities Act and the Exchange Act and the respective rules and regulations promulgated thereunder to be set forth in the Registration Statement and Joint Proxy Statement/Prospectus and each of the Company and ANI will promptly furnish to each other all other information, and take all such other actions (including using its reasonable best efforts to obtain any required consents of their respective independent auditors), as may reasonably be requested in connection with any action by any of them in connection with the preceding sentences of this *Section 5.6(a)*. Each of ANI and the Company agrees to correct any information provided by it for use in Registration Statement containing the Joint Proxy Statement/Prospectus that has become false or misleading. Whenever any Party learns of the occurrence of any event or the existence of any fact which is required to be set forth in an amendment or supplement to the Registration Statement containing the Joint Proxy Statement/Prospectus pursuant to Applicable Law, such Party will promptly inform the other of such event or fact and comply with all of its obligations pursuant to this *Section 5.6(a)* relating to effecting such amendment or supplement to the Registration Statement containing the Joint Proxy Statement/Prospectus.

(b) Prior to the Effective Time, the Company will use its reasonable best effort to obtain all regulatory approvals needed to ensure that Company Common Stock to be issued pursuant to the Merger will, to the extent required, be registered or qualified or otherwise exempt from registration or qualification under the securities law of every state of the United States in which any holder of ANI Series D Preferred Stock as of immediately prior to the Effective Time has an address of record.

#### **5.7 ANI Special Meeting; ANI Board Recommendation.**

(a) Following the date hereof and provided that a Change in the Company Board Recommendation has not occurred, ANI will take all action necessary in accordance with the DGCL and its Certificate of Incorporation and By-laws to duly call, give notice of, convene and hold as promptly as practicable a special meeting of ANI's stockholders (the "**ANI Special Meeting**") to seek ANI Stockholder Approval, including mailing the Joint Proxy Statement/Prospectus to its stockholders as promptly as reasonably practicable after the Registration Statement is declared effective under the Securities Act. ANI's obligation to call, convene and hold ANI Special Meeting will not be affected by a Change in ANI Board Recommendation, unless this Agreement is terminated pursuant to *Article VII*. ANI, subject to *Section 5.3*, will use its reasonable best efforts to solicit from its stockholders proxies in favor of the adoption of this Agreement and the approval of the transactions contemplated hereby, including the Merger, and will take all other action necessary or advisable to obtain ANI Stockholder Approval. Notwithstanding anything to the contrary contained in this Agreement, ANI may adjourn or postpone ANI Special Meeting to

the extent necessary to ensure that any necessary supplement or amendment to the Joint Proxy Statement/Prospectus (as determined by ANI in good faith and upon the advice of outside counsel) is provided to ANI's stockholders a reasonable time in advance of ANI Special Meeting (or at any adjournment or postponement thereof), or if as of the time for which ANI Special Meeting (or any adjournment or postponement thereof) is scheduled there are insufficient shares of ANI Common Stock represented in person or by proxy to constitute a quorum necessary to conduct the business of ANI Special Meeting or to adopt this Agreement and approve the transactions contemplated hereby, including the Merger.

(b) Except as permitted by *Section 5.3*: (i) the ANI Board will recommend that ANI's stockholders vote in favor of (A) the adoption of this Agreement and (B) the approval of the transactions contemplated by this Agreement, including the Merger, at the ANI Special Meeting (or any adjournment or postponement thereof) (the "**ANI Board Recommendation**"); and (ii) the Joint Proxy Statement/Prospectus will include the ANI Board Recommendation.

#### **5.8 Company Special Meeting; Company Board Recommendation.**

(a) Following the date hereof, the Company will take all action necessary in accordance with the DGCL and its Certificate of Incorporation and By-laws to duly call, give notice of, convene and hold as promptly as practicable a special meeting of the Company's stockholders (the "**Company Special Meeting**") to seek Company Stockholder Approval, including mailing the Joint Proxy Statement/Prospectus to its stockholders as promptly as reasonably practicable after the Registration Statement is declared effective under the Securities Act. The Company's obligation to call, convene and hold the Company Special Meeting will not be affected by a Change in Company Board Recommendation, unless this Agreement is terminated pursuant to *Article VII*. The Company, subject to *Section 5.4*, will use its reasonable best efforts to solicit from its stockholders proxies in favor of the approval of the issuance of shares of Company Common Stock pursuant to this Agreement, and will take all other action necessary or advisable to obtain Company Stockholder Approval. Notwithstanding anything to the contrary contained in this Agreement, the Company may adjourn or postpone the Company Special Meeting to the extent necessary to ensure that any necessary supplement or amendment to the Joint Proxy Statement/Prospectus (as determined by the Company in good faith and upon the advice of outside counsel) is provided to the Company's stockholders a reasonable time in advance of the Company Special Meeting (or at any adjournment or postponement thereof), or if as of the time for which the Company Special Meeting (or any adjournment or postponement thereof) is scheduled there are insufficient shares of Company Common Stock represented in person or by proxy to constitute a quorum necessary to conduct the business of the Company Special Meeting or to adopt this Agreement and approve the transactions contemplated hereby, including the Merger; *provided, however*, that the Company Special Meeting may not be adjourned for more than thirty (30) days in the aggregate from the date originally set forth in the initial Joint Proxy Statement/Prospectus without the prior consent of ANI, not to be unreasonably withheld, conditioned or delayed.

(b) Except as permitted by *Section 5.4*: (i) the Company Board will recommend that the Company's stockholders vote in favor of (A) the adoption of the Company Charter Amendments and this Agreement and (B) the approval of the transactions contemplated by this Agreement, including the Merger, at the Company Special Meeting (or any adjournment or postponement thereof) (the "**Company Board Recommendation**"); and (ii) the Joint Proxy Statement/Prospectus will include the Company Board Recommendation.

#### **5.9 Reasonable Best Efforts.**

(a) The Company and ANI will each: (i) cooperate and coordinate with the other in the making of any filings or submissions that are required to be made under any Applicable Laws or requested to be made by any Government Authority in connection with the transactions

contemplated by this Agreement, including the Merger; (ii) supply the other or its Representatives with any material information that may be required or requested by any Government Authority in connection with such filings or submissions; (iii) use their reasonable best efforts to cause the expiration or termination of the applicable waiting periods under any Applicable Laws as soon as reasonably practicable; and (iv) use their reasonable best efforts to offer to take, or cause to be taken, all actions and do, or cause to be done, all things necessary, proper or advisable to consummate and make effective the transactions contemplated hereby, including the Merger, including by taking all such actions and doing all such things necessary to resolve such objections, if any, as any Government Authority or Person may assert under any Applicable Laws and to avoid or eliminate each and every impediment under any Applicable Law that may be asserted by any Government Authority so as to enable the transactions contemplated hereby, including the Merger, to be consummated as soon as expeditiously possible.

(b) The Company and ANI will each use reasonable best efforts to structure the Merger to qualify as a reorganization under the provisions of Section 368 of the Code. Both prior to and after the Effective Time, each Party's books and records will be maintained, and all federal, state and local income tax returns and schedules thereto will be filed, in a manner consistent with the Merger being qualified as a reorganization under Section 368(a) of the Code (and comparable provisions of any applicable state or local laws), except to the extent the Merger is determined in a final administrative or judicial decision not to qualify as a reorganization within the meaning of Section 368(a) of the Code.

**5.10 Public Announcements.** Before issuing any news release or otherwise making any public statement with respect to any of the transactions contemplated hereby, including the Merger, the Company and ANI agree to consult with each other as to its form and substance, and agree not to issue any such news release or general communication to employees or make any public statement prior to obtaining the prior written consent of the other (which consent will not be unreasonably withheld, delayed or conditioned), except to the extent that the Company or ANI, as the case may be, is advised by outside counsel that such public statement is required by Applicable Law. Notwithstanding the foregoing, promptly following the date of this Agreement, the Company and ANI will issue a joint news release, in form and substance reasonably acceptable to each of the Company and ANI, with respect to this Agreement and the transactions contemplated hereby, including the Merger.

**5.11 Notification of Certain Matters.** ANI will give prompt notice to the Company of: (i) the occurrence or nonoccurrence of any event which would be likely to cause the failure of either of the conditions set forth in *Section 6.3(a)* or *Section 6.3(b)* to be met as of any time during the Interim Period; (ii) ANI's or any ANI Subsidiary's receipt of any notice or other communication from any third party alleging that the consent of such third party is or may be required in connection with the transactions contemplated by this Agreement, including the Merger (unless such consent has been previously identified in *Section 3.3* of the ANI Disclosure Schedule); (iii) the institution of any Action not previously identified in *Section 3.6* of the ANI Disclosure Schedule; or (iv) the existence of any facts or circumstances that would reasonably be expected to result in a Material Adverse Effect on ANI. The Company will give prompt notice to ANI of: (w) the occurrence or nonoccurrence of any event which would be likely to cause the failure of either of the conditions set forth in *Section 6.2(a)* or *Section 6.2(b)* to be met as of any time during the Interim Period; (x) the Company's or any Company Subsidiary's receipt of any notice or other communication from any third party alleging that the consent of such third party is or may be required in connection with the transactions contemplated by this Agreement, including the Merger (unless such consent has been previously identified on *Section 4.3* of the Company Disclosure Schedule); (y) the institution of any Action not previously identified in *Section 4.6* of the Company Disclosure Schedule; or (z) the existence of any facts or circumstances that would reasonably be expected to result in a material change to the most recent calculation of Net Cash, delivered pursuant to *Section 5.22* or in a Material Adverse Effect on the Company. The delivery of

any notice pursuant to this *Section 5.11* will not limit or otherwise affect the remedies available hereunder to the Party receiving such notice nor be deemed to have amended any of the disclosures set forth in the ANI Disclosure Schedule or the Company Disclosure Schedule, as applicable, to have qualified the representations and warranties contained herein or to have cured any misrepresentation or breach of a representation or warranty that otherwise might have existed hereunder by reason of such material development. No disclosure after the date of this Agreement of the untruth of any representation and warranty made in this Agreement will operate as a cure of any breach of the failure to disclose the information, or of any untrue representation or warranty made herein.

#### 5.12 Indemnification of Company Directors and Officers.

(a) From and after the Effective Time, the Company will continue to indemnify and hold harmless each present and former director or officer of the Company or any Company Subsidiary (each, together with such Person's heirs, executors or administrators, a "**Company Indemnified Person**") against any loss, damage, injury, liability, claim, demand, settlement, judgment, award, fine, penalty, Tax, fee (including reasonable attorneys' fees), charge, cost (including costs of investigation) or expense of any nature ("**Damages**") incurred in connection with any Action arising out of or pertaining to matters existing or occurring at or prior to the Effective Time or any Action instituted by any Company Indemnified Person to enforce this *Section 5.12* or any other indemnification or advancement right of such Company Indemnified Person, whether asserted or claimed prior to, at or after the Effective Time, to the fullest extent that the Company is currently permitted to indemnify such Company Indemnified Person under Applicable Law and under its certificate of incorporation and bylaws as in effect on the date of this Agreement (including the advancing of expenses to the fullest extent permitted under Applicable Law); *provided, however*, that the Company Indemnified Person to whom such expenses are advanced will be required to provide an undertaking to the Company to repay such advances if it is ultimately determined that such Company Indemnified Person is not entitled to indemnification.

(b) From and after the Effective Time, the Company will continue to honor and fulfill all obligations of the Company or any the Company Subsidiary pursuant to any written indemnification agreements with any Company Indemnified Persons in effect as of the date hereof.

(c) Prior to the Effective Time, the Company will purchase, and for a period of six (6) years following the Effective Time the Company will continue in effect, a directors' and officers' liability "tail" insurance policy or policies (the "**Company Tail Policies**") covering the Company Indemnified Persons for events occurring at or prior to the Effective Time, which insurance will be of at least the same coverage and amounts and contain terms and conditions which are no less advantageous to the Company Indemnified Persons than the coverage, amounts, terms and conditions of the directors' and officers' liability insurance policy maintained by the Company as of the date of this Agreement. The cost of the Company Tail Policy will be included as a Liability for purposes of calculating Net Cash.

(d) The rights of each Company Indemnified Person hereunder will be in addition to, and not in limitation of, any other rights such Company Indemnified Person may have under the certificate of incorporation and bylaws of the Company or any other similar organizational documents of the Company or any of its Subsidiaries, any other indemnification agreement or arrangement, the DGCL or otherwise. This *Section 5.12* will survive the consummation of the Merger, and is intended to be for the benefit of, and will be enforceable by, the Company Indemnified Persons, their heirs and personal representatives, will be binding on the Company and its successors and assigns and may not be amended, altered or repealed after the Effective Time without the prior written consent of the affected Company Indemnified Persons. In the event that the Company or any of its successors or assigns: (i) consolidates with or merges into any other Person and will not be the continuing or surviving corporation or entity in such consolidation or merger; or



(ii) transfers all or substantially all of its properties and assets to any Person, then, and in each case, proper provision will be made so that the successors and assigns of the Company are obligated to honor the indemnification obligations set forth in this *Section 5.12*. Nothing in this Agreement is intended to, will be construed to or will release, waive or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to the Company or any of the Company Subsidiaries or their respective officers, directors and employees, it being understood and agreed that the indemnification provided for in this *Section 5.12* is not prior to, or in substitution for, any such claims under any such policies.

### 5.13 Indemnification of ANI Directors and Officers.

(a) the Company agrees that all rights to exculpation, indemnification and advancement of expenses for acts or omissions occurring at or prior to the Effective Time, whether asserted or claimed prior to, at or after the Effective Time, now existing in favor of the current or former directors, officers or employees, as the case may be, of ANI or its Subsidiaries as provided in their respective certificates of incorporation or by-laws or other organization documents or in any agreement will survive the Merger and will continue in full force and effect. The Company will maintain in effect any and all exculpation, indemnification and advancement of expenses provisions of ANI's and any of its Subsidiaries' certificate of incorporation and by-laws or similar organization documents in effect immediately prior to the Effective Time or in any indemnification agreements of ANI or its Subsidiaries with any of their respective current or former directors, officers or employees in effect as of the date hereof, and will not amend, repeal or otherwise modify any such provisions in any manner that would adversely affect the rights thereunder of any individuals who at the Effective Time were current or former directors, officers or employees of ANI or any of its Subsidiaries, and all rights to indemnification in respect of any Action pending or asserted or any claim made within such period will continue until the disposition of such Action or resolution of such claim.

(b) From and after the Effective Time, the Company will continue to indemnify and hold harmless each present and former director, officer or employee of ANI or any of its Subsidiaries (each, together with such Person's heirs, executors or administrators, a "**ANI Indemnified Person**") against any Damages incurred in connection with any Action arising out of or pertaining to any action or omission occurring or alleged to have occurred whether before or after the Effective Time (including acts or omissions in connection with such Persons serving as an officer, director or other fiduciary in any entity if such service was at the request or for the benefit of ANI) or any Action instituted by any ANI Indemnified Person to enforce this *Section 5.13*, including, in each case, the advancing of expenses to the fullest extent permitted under Applicable Law; *provided, however*, that the ANI Indemnified Person to whom such expenses are advanced will be required to provide an undertaking to the Company to repay such advances if it is ultimately determined that such ANI Indemnified Person is not entitled to indemnification.

(c) Prior to the Effective Time, the Company will purchase, and for a period of six (6) years following the Effective Time the Company will continue in effect, a directors' and officers' liability "tail" insurance policy or policies covering ANI's directors and officers for events occurring at or prior to the Effective Time, which insurance will be of at least the same coverage and amounts and contain terms and conditions which are no less advantageous to ANI's directors and officers than the coverage, amounts, terms and conditions of the directors' and officers' liability insurance policy maintained by ANI as of the date of this Agreement.

(d) The rights of each ANI Indemnified Person hereunder will be in addition to, and not in limitation of, any other rights such ANI Indemnified Person may have under the certificate of incorporation and bylaws of ANI or any other similar organizational documents of ANI or any of its Subsidiaries or the Company, any other indemnification agreement or arrangement, the DGCL

or otherwise. This *Section 5.13* will survive the consummation of the Merger, and is intended to be for the benefit of, and will be enforceable by, ANI Indemnified Persons, their heirs and personal representatives, will be binding on the Company and its successors and assigns and may not be amended, altered or repealed after the Effective Time without the prior written consent of the affected ANI Indemnified Persons. In the event that the Company or any of its successors or assigns: (i) consolidates with or merges into any other Person and will not be the continuing or surviving corporation or entity in such consolidation or merger; or (ii) transfers all or substantially all of its properties and assets to any Person, then, and in each case, proper provision will be made so that the successors and assigns of the Company are obligated to honor the indemnification obligations set forth in this *Section 5.13*. Nothing in this Agreement is intended to, will be construed to or will release, waive or impair any rights to directors' and officers' insurance claims under any policy that is or has been in existence with respect to ANI or any of its Subsidiaries or their respective officers, directors and employees, it being understood and agreed that the indemnification provided for in this *Section 5.13* is not prior to, or in substitution for, any such claims under any such policies.

#### 5.14 Composition of the Company Board; Officers.

(a) Prior to the Effective Time, the Company will take all action necessary:

(i) to cause the number of members of the Company Board to be fixed at seven (7);

(ii) to cause, concurrently with the Effective Time, five (5) of such directors to be persons designated by ANI (who are identified as such on *Schedule III* to this Agreement as such schedule may be amended by ANI at any time prior to a date five (5) Business Days before the Registration Statement is expected to be declared effective) (one (1) of whom will be the Chief Executive Officer of the Surviving Corporation) (the "**ANI Director Designees**") and two (2) of such directors to be persons designated by the current Company Board from the list of persons identified as Company designees on *Schedule III* to this Agreement (one (1) of whom will be Stephen M. Simes, unless Mr. Simes' status as a non-independent director for purposes of the NASDAQ Global Market causes the Company not to comply with NASDAQ listing requirements, it being understood that three of the five persons designated by ANI (including the Chief Executive Officer) will not likely qualify as independent directors in accordance with the applicable NASDAQ Global Market rules and NASDAQ listing requirements (the "**Company Director Designees**"));

(iii) to obtain the necessary resignations of the directors of the Company serving immediately prior to the Effective Time who are among the directors designated above, which resignations will be effective concurrently with the effectiveness of the elections referred to in clauses (i) and (ii); and

(iv) to cause the officers of the Company to be as of the Effective Time those persons identified as such on *Schedule III* to this Agreement.

If any Company Director Designee is, prior to the Effective Time, unable or unwilling to hold office beginning concurrently with the Effective Time, the current Company Board will designate another to be appointed as a director in his or her place; provided such person so designated will qualify as an independent director in accordance with the applicable NASDAQ Global Market rules and NASDAQ listing requirements.

If any ANI Director Designee is, prior to the Effective Time, unable or unwilling to hold office beginning concurrently with the Effective Time, the current ANI Board will designate another to be appointed as a director in his or her place; provided that two of the total number of persons designated by the ANI Board will qualify as independent directors in accordance with the applicable NASDAQ Global Market rules and NASDAQ listing requirements.

(b) It is understood and agreed that both of the Company Director Designees (other than Stephen M. Simes in the circumstances set forth above) and two (2) of the directors identified on *Schedule III* to this Agreement will be independent for purposes of the listing requirements of the NASDAQ Global Market. It is further understood and agreed that pursuant to the terms of its Voting Agreement, Meridian Venture Partners II, L.P. will vote in favor of the Company Director Designees at the first annual meeting of the stockholders following the consummation of the Merger, which will be held no earlier than May 1, 2013.

**5.15 Listing of Shares.** The Company will use its reasonable best efforts to maintain its existing listing on The NASDAQ Global Market and to cause the shares of Company Common Stock to be issued in the Merger to be approved for listing (subject to notice of issuance) on The NASDAQ Global Market or The NASDAQ Capital Market at or prior to the Effective Time. ANI will promptly furnish to the Company all information concerning ANI that may be required or reasonably requested in connection with such listing.

**5.16 Convertible Notes.** The Company will take such reasonable actions as may be reasonably necessary so that upon the Effective Time, the Company will be in compliance with the terms of the Indenture. The Company agrees to give the notice required under Section 9.6 of the Indenture and any other notice required under the Indenture to be given by the Company prior to the Effective Time with respect to the Merger.

**5.17 Employee Benefit Matters.**

(a) Subject to the remaining provisions of this *Section 5.17*, as of and immediately following the Effective Time the Company will (i) continue Company Benefit Plans in effect immediately prior to the Effective Time, (ii) adopt ANI Benefit Plans, (iii) adopt new Benefit Plans or (iv) a combination of clauses (i), (ii) and (iii). The Company and ANI group health plans in effect from and after the Effective Time will provide COBRA group health plan continuation coverage to any qualified beneficiary entitled to coverage under such group health plans (which coverage will be no less favorable taken as a whole than the coverage provided under the ANI group health plans in effect as of the date hereof), regardless of whether such qualified beneficiary's qualifying event occurred on, before or after the Effective Time. The terms "qualified beneficiary," "qualifying event" and "group health plan" have the meanings ascribed to them in COBRA.

(b) Following the Effective Time, the Company will honor the terms of the employment agreements with each Company employee or officer listed on *Section 5.17(b)* of the Company Disclosure Schedule (individually and collectively referred to herein as the "**Company Executives**"). Prior to the Determination Date, the Company will obtain quotes for and determine the costs for (i) an individual health insurance policy that provides coverage that is not materially less than the Company Executive's coverage under such the Company group medical plan and (ii) an individual dental insurance policy that provides coverage that is not materially less than coverage under the Company's group dental plan in effect on the Effective Time, (iii) an individual life insurance policy that provides coverage that is not materially less than the Company Executive's coverage under the Company's life insurance plan in effect on the Effective Time, plus (iv) an additional amount equal to the Federal, State and any other income, employment and other taxes (calculated at the highest rates applicable to the Company Executive) such Company Executive will owe on such amounts (including on the tax gross-up payment itself), it being intended that the individual retain (on an after-tax basis) an amount equal to the monthly premium, which sum of the amounts set forth in clauses (i) to (iv) will be included as a Liability in the calculation of Net Cash (pursuant to and with such adjustments as may be permitted pursuant to *Section 2.2(a)(vii)(A)*). If within the Applicable Period following the Effective Time, the Company and all its Affiliates cease to provide any group medical, dental and/or life insurance plan to employees such that the Company cannot otherwise honor the provisions in the employment agreement relating to group

medical, dental and life insurance coverage during the remainder of the "continuation period" under each Company Executive's employment agreement, then the Company will provide each such Company Executive with the monthly cash payments for the remainder of the continuation period as provided for in such Executive's employment agreement with the Company and the Company's Officer Severance Policy, as applicable. As used herein, "**Applicable Period**" means as to a Company Executive, the required continuation period as provided for in such Executive's employment agreement with the Company or the Company's Officer Severance Policy, as applicable.

(c) On and after the Effective Time, the Company will honor the terms of the employment agreements with each ANI employee or officer listed on *Section 5.17(c)* of the ANI Disclosure Schedule (individually and collectively referred to herein as the "**ANI Executives**") and the terms of the Company's Officer Severance Policy as it applies to Company employees terminated on or prior to the Closing Date.

(d) Set forth on *Section 5.17(d)* of the Company Disclosure Schedule is a calculation by the Company of the severance amounts owed in connection with the Merger that the Company Executives included on such list may not receive until six (6) months following the date they terminate employment with the Company in order to comply with Code Section 409A (the "**Delayed Severance Amounts**"). During the Interim Period, the Company will (i) adopt a grantor trust (substantially in the form of a trust agreement already provided to ANI), of which the Company is the grantor, within the meaning of subpart E, Part I, subchapter J, chapter 1, subtitle A of the Code (the "**Rabbi Trust**") and (ii) deposit an amount equal to the Delayed Severance Amounts in such Rabbi Trust. The Rabbi Trust will be revocable during the Interim Period and will become irrevocable at the Effective Time. The principal of the Rabbi Trust, and any earnings thereon, will be held separate and apart from other funds of the Company and used exclusively for the purpose of making payments to the Company Executives of the Delayed Severance Amounts at the end of the six (6) month suspension period and in accordance with the terms of their employment agreements and will be included as a Liability in the calculation of Net Cash; *provided, however*, that any assets held by the Rabbi Trust will be subject to the claims of the Company's general creditors under federal and state law in the event of the Company's insolvency (as defined under such Rabbi Trust agreement).

(e) The Company will cease contributions to and terminate each Company Plan qualified under Code Section 401(k) (the "**Company 401(k) Plan**"), and adopt written resolutions and a plan amendment terminating the Company Plan, such cessation of contributions and termination to be effective no later than one (1) Business Day preceding the Effective Time; *provided, however*, that such Company 401(k) Plan termination may be made contingent upon the consummation of the transactions contemplated by this Agreement.

(f) Subject to the obligations set forth in *Section 5.17(d)* and *Section 5.7(e)*, nothing in this *Section 5.17* will (i) constitute or be treated as an amendment of any Company Benefit Plan or ANI Benefit Plan (or an undertaking to amend any such plan), (ii) prohibit ANI or the Company from amending, modifying or terminating any ANI Benefit Plan or Company Benefit Plan pursuant to, and in accordance with, the terms thereof, or (iii) confer any rights or benefits on any Person other than ANI and the Company. Notwithstanding the foregoing, the Company will honor, in accordance with the terms as in effect immediately prior to the Effective Time, the employment agreements between the Company and the Company Executives and between ANI and the ANI Executives, as well as the Company's Officer Severance Policy for the individuals set forth in *Section 5.17(f)* of the Company Disclosure Schedule who are entitled to severance in accordance therewith.

(g) Immediately prior to the Effective Time, the Company will terminate all of its employees, except those as to whom ANI has delivered written notice that they should not be terminated, if any.

(h) Following the Effective Time, the Surviving Corporation will use commercially reasonable efforts to provide retiree group medical and dental coverage to the individuals listed on *Section 4.9(j)* of the Company Disclosure Schedule and the Company Executives listed on *Section 5.17(b)* of the Company Disclosure Schedule, in accordance with the group medical and dental plans of the Surviving Corporation in effect from time to time. The premiums for any such retiree group medical and dental coverage, if not required to be paid by the Company pursuant to the terms of an employment agreement of an employee or officer listed on *Section 5.17(b)* of the Disclosure Schedule, will be payable by the covered individual.

**5.18 Takeover Statutes.** At all times prior to the Effective Time, each of the Company and ANI will: (i) take all reasonable action necessary to ensure that no Takeover Statute is or becomes applicable to this Agreement or the transactions contemplated hereby, including the Merger; and (ii) if any Takeover Statute becomes applicable to this Agreement or the transactions contemplated hereby, including the Merger, take all reasonable action necessary to ensure that the transactions contemplated by this Agreement, including the Merger, may be consummated as promptly as practicable on the terms contemplated by this Agreement and otherwise to minimize the effect of such Takeover Statute on this Agreement or the transactions contemplated hereby, including the Merger.

**5.19 Further Assurances.** At and after the Effective Time, the officers and directors of the Company will be authorized to execute and deliver, in the name and on behalf of ANI, any deeds, bills of sale, assignments or assurances and to take and do, in the name and on behalf of ANI, any other actions and things to vest, perfect or confirm of record or otherwise in the Surviving Corporation any and all right, title and interest in, to and under any of the rights, properties or assets of ANI acquired or to be acquired by the Company as a result of, or in connection with, the Merger.

**5.20 Stockholder Litigation.** The Company will give ANI the opportunity to participate in, and the Company and ANI will reasonably cooperate with respect to, the defense or settlement of any stockholder litigation against the Company and/or its directors or executive officers relating to the Merger, this Agreement or any transaction contemplated by this Agreement, whether commenced prior to or after the execution and delivery of this Agreement, will provide ANI with copies of all applicable pleadings, motions and other filings (as well as transcripts of depositions) and give ANI the reasonable opportunity to comment thereon, together with copies of any underlying documents relevant thereto and will not settle or offer to settle any such litigation without the prior written consent of ANI.

**5.21 Net Cash.** The Company will deliver to ANI a calculation of Net Cash (in the form previously delivered as *Section 4.4(d)* of the Company Disclosure Schedule) as follows: (a) no less than ten (10) days after the end of each calendar month, with respect to Net Cash as of the last day of the preceding month, (b) at least (3) calendar days prior to the mailing of the Joint Proxy Statement/Prospectus, with respect to estimated Net Cash as of the date of such mailing, and (c) at least (3) calendar days prior to the Closing Date, with respect to estimated Net Cash as of Closing Date. For purposes of determining Net Cash as of the Closing Date, the Parties agree that if ANI shall dispute such calculation as of the Closing Date and assert that the Minimum Net Cash condition to Closing set forth in *Section 6.2(f)* of the Agreement will not be satisfied, then the process set forth in *Section 2.2(c)* above will be followed in order to determine whether or not the Minimum Net Cash condition to Closing in *Section 6.2(f)* has been satisfied, subject to the timing set forth in clause (c) above. In the event a final determination of the Net Cash has not been made on the scheduled Closing Date, the Parties agree that the Closing Date will be adjourned to the second (2<sup>nd</sup>) Business Day following final determination of the Net Cash in accordance with *Section 2.2(c)(vi)* of the Agreement (assuming the

above referenced Minimum Net Cash covenant referenced above has either been satisfied or waived by ANI).

5.22 **Amending Party.** The Company agrees to use commercially reasonable efforts to enter into an amendment to the Company Contract with the party (the "**Amending Party**") set forth in *Section 5.2* of the Company Disclosure Schedule prior to the Closing Date, in substantially the form provided to ANI prior to the date hereof. In the event that such amendment, in substantially the form presented to ANI prior to the date hereof, is entered into and is in full force and effect (without default thereunder) on the Determination Date, then ANI agrees that any amounts received by the Company pursuant to paragraph 2 of such amendment and Section 7(c)(i) as added by such amended agreement on December 31, 2012, may be included as "Net Cash" for purposes of the calculation of Net Cash as of the Determination Date under *Section 2.2(a)(vii)* of the Agreement, even if the Determination Date occurs prior to December 31, 2012.

5.23 **Asset Letter of Intent.** The Parties agree that the Company may enter into negotiations relating to the sale of the assets referred to in the non-binding letter of intent dated as of October 5, 2012 in the form provided to ANI prior to the date hereof and may execute such letter of intent (as executed, the "**Letter of Intent**") and a definitive agreement related thereto; *provided, however*, that ANI shall have the right to review the execution copy of the Letter of Intent and the right to approve any material changes therein from the form previously provided to ANI and to review the definitive agreement in respect thereto and to the extent any provision of that definitive agreement was not specifically set forth in the Letter of Intent, ANI shall have the right to approve such provision, which approval is not to be unreasonably withheld. ANI agrees that any amounts received by the Company prior to the Determination Date pursuant to such definitive agreement may be included as Net Cash for purposes of the calculation of Net Cash under *Section 2.2(a)(vii)*.

5.24 **Hart-Scott-Rodino.** If the Parties mutually determine that any filing is required by the Hart Scott Rodino Antitrust Improvements Act of 1976, as amended (the "**HSR Act**"), then each of the Parties agrees to file as promptly as practicable with the Federal Trade Commission and the Antitrust Division of the Department of Justice all requisite documents and notifications relating to this Agreement and the transactions contemplated hereby, including the Merger and supply any additional information that may be required or requested in connection therewith as promptly as practicable. The Parties further agree that any filing fee payable in connection therewith will be paid by the Company, however, only 50% thereof will be include in the calculation of Net Cash.

5.25 **ANI Warrants.** ANI agrees to use commercially reasonable efforts to obtain cancellation and termination agreements from all holders of the ANI Warrants prior to the Effective Time, pursuant to which each such holder will agree that all ANI Warrants held by such holder immediately prior to the Effective Time and that have not been validly exercised prior thereto will be cancelled and terminated as of the Effective Time without any consideration therefor.

## **ARTICLE VI. Conditions Precedent**

6.1 **Conditions to Each Party's Obligation to Effect the Merger.** The respective obligation of each of the Parties to this Agreement to effect the Merger will be subject to the satisfaction before the Closing of the following conditions, any one or more of which may be waived in writing by all of the Parties:

(a) **Company Stockholder Approval.** The Company Stockholder Approval has been obtained at the Company Special Meeting (or at any adjournment or postponement thereof).

(b) **ANI Stockholder Approval.** The ANI Stockholder Approval has been obtained at the ANI Special Meeting (or at any adjournment or postponement thereof).

(c) **HSR Clearance.** All applicable waiting periods (including any extensions thereof) under any filing required to be made by the Company and ANI under the HSR Act have expired or been terminated, if applicable.

(d) **Statute or Decree.** No Applicable Law or Order has been enacted, entered, promulgated or enforced by any Government Authority, which remains in effect and which prohibits the consummation of the Merger or otherwise makes the Merger illegal.

(e) **Effectiveness of Registration Statement.** The Registration Statement has become effective in accordance with the provisions of the Securities Act, no stop order has been issued by the SEC and remains in effect with respect to the Registration Statement and no proceeding seeking such a stop order has been initiated by the SEC and remains pending or is threatened by the SEC.

(f) **Listing of Shares.** The existing shares of Company Common Stock have been continually listed on NASDAQ during the Interim Period, and the shares of Company Common Stock issued in connection with the Merger have been approved for listing (subject only to notice of issuance) on The NASDAQ Global Market or The NASDAQ Capital Market, effective at the Effective Time.

(g) **Tax Opinions.** ANI has received the written opinion of SNR Denton US LLP and the Company has received the written opinion of Oppenheimer Wolff & Donnelly LLP, each dated as of the Effective Time and each to the effect that the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code. The issuance of such opinions will be conditioned upon the receipt by such counsel of customary representation letters from each of the Company and ANI, in each case, in form and substance reasonably satisfactory to such counsel. Each such representation letter has been dated on or before the date of such opinion and has not been withdrawn or modified in any material respect.

**6.2 Conditions to Obligations of ANI.** The obligation of ANI to effect the Merger is subject to the satisfaction before the Closing of the following additional conditions, any one or more of which may be waived in writing by ANI:

(a) The representations and warranties of the Company set forth in *Article IV* are true and correct in all material respects at and as of the date of this Agreement and as of the Closing Date as if made on and as of the Closing Date (or, in the case of those representations and warranties that are made as of a particular date or period, as of such date or period) (except for any representations or warranties that are qualified or limited as to "materiality," "Material Adverse Effect" or words of similar import set forth therein shall be true and correct in all respects).

(b) The Company has performed and complied in all material respects with all agreements and obligations required by this Agreement to be performed or complied with by them on or prior to the Closing Date.

(c) There has not occurred and is continuing any Material Adverse Effect on the Company between the date of this Agreement and the Closing Date.

(d) ANI has received a certificate executed by the principal executive officer of the Company certifying that the Company has complied with the conditions set forth in *Section 6.2(a)*, *Section 6.2(b)* and *Section 6.2(c)* of this Agreement.

(e) ANI has received a true, correct and complete copy of the notice required to be delivered under Section 9.6 of the Indenture to the holders of the Company Convertible Notes and any other notice required under the Indenture.

(f) The Company has Net Cash as determined pursuant to *Section 5.21* of no less than \$17 million (which minimum amount will be increased by one-half of the amount of any cash received from the Amending Party pursuant to and as permitted by in *Section 5.22* (the "**Minimum Net Cash**").

(g) No new Actions have been instituted against the Company by or on behalf of any stockholder or holder of Company Convertible Notes other than those which have been settled prior to the Closing Date.

**6.3 Conditions to Obligations of the Company.** The obligation of the Company to effect the Merger is subject to the satisfaction before the Closing of the following additional conditions, any one or more of which may be waived in writing by the Company:

(a) The representations and warranties of ANI set forth in *Article III* are true and correct at and as of the date of this Agreement and as of the Closing Date as if made on and as of the Closing Date (or, in the case of those representations and warranties that are made as of a particular date or period, as of such date or period) (except for any representations or warranties that are qualified or limited as to "materiality," "Material Adverse Effect" or words of similar import set forth therein shall be true and correct in all respects).

(b) ANI has performed and complied in all material respects with all agreements and obligations required by this Agreement to be performed or complied with by it on or prior to the Closing Date.

(c) There has not occurred and is continuing any Material Adverse Effect on ANI between the date of this Agreement and the Closing Date.

(d) The Company has received a certificate executed by the principal executive officer of ANI certifying that ANI has complied with the conditions set forth in *Section 6.3(a)*, *Section 6.3(b)* and *Section 6.3(c)* of this Agreement.

(e) ANI has delivered evidence reasonably satisfactory to the Company that the terminations of (i) the Third Amended and Restated Stockholders' Agreement, dated as of January 28, 2011, by and among ANI and the stockholders name therein and (ii) ANI's obligation to pay the annual monitoring and advisory fees pursuant to the Note Purchase Agreement, dated as of January 28, 2011, as amended, by and among ANI and the other parties named therein, previously delivered to the Company remain in effect.

## **ARTICLE VII. Termination**

**7.1 Termination.** This Agreement may be terminated at any time prior to the Effective Time, whether before or after Company Stockholder Approval or ANI Stockholder Approval is obtained (except as otherwise set forth below):

(a) by mutual written consent of the Company and ANI;

(b) by either the Company or ANI if the Merger has not been consummated by May 31, 2013 (the "**Outside Date**"); *provided, however*, that in the event the Registration Statement is not filed with SEC prior to or on November 30, 2012, the Outside Date will be extended for one day for each day after November 30, 2012 that the Registration Statement has not been filed with the SEC, but will not, in any event, extend past July 31, 2013; *provided further, however*, that the right to terminate this Agreement under this *Section 7.1(b)* will not be available to any Party whose action or failure to act has been a principal cause of or resulted in the failure of the Merger to occur on or before such date and such action or failure to act constitutes a material breach of this Agreement;



(c) by the Company or ANI if any Applicable Law irrevocably prohibits or makes the Merger illegal, or if an Order has been entered by a Government Authority of competent jurisdiction permanently restraining, enjoining or otherwise prohibiting the Merger and such Order has become final and non-appealable, provided in each case that the Party seeking to terminate this Agreement pursuant to this *Section 7.1(c)* has performed its obligations under *Section 5.9* to resist, resolve or remove such Applicable Law or Order;

(d) by the Company or ANI if the Company Special Meeting has been held and completed (including any adjournments or postponements thereof), the Company's stockholders have taken a final vote on a proposal to adopt the Company Charter Amendments and this Agreement and to approve the transactions contemplated by this Agreement, including the Merger, and Company Stockholder Approval has not been obtained; *provided, however*, that a Party will not be permitted to terminate this Agreement pursuant to this *Section 7.1(d)* if the failure to obtain Company Stockholder Approval is attributable to a failure on the part of such Party seeking to terminate this Agreement to perform any material obligation required to be performed by such Party at or prior to the date of such vote;

(e) by the Company or ANI if the ANI Special Meeting has been held and completed (including any adjournments or postponements thereof), ANI's stockholders have taken a final vote on a proposal to adopt this Agreement and approve the transactions contemplated hereby, including the Merger, and the ANI Stockholder Approval has not been obtained; *provided, however*, that a Party will not be permitted to terminate this Agreement pursuant to this *Section 7.1(e)* if the failure to obtain the ANI Stockholder Approval is attributable to a failure on the part of such Party seeking to terminate this Agreement to perform any material obligation required to be performed by such Party at or prior to the date of such vote;

(f) by ANI, if the Company fails to include the Company Board Recommendation in the Registration Statement containing the Joint Proxy/Prospectus or take any of the actions described in *Section 5.3(e)* or *(f)*, even if permitted thereby;

(g) by the Company, pursuant to *Section 5.4(d)(ii)*;

(h) by the Company, upon a breach of any representation, warranty, covenant or obligation on the part of ANI set forth in this Agreement, or if any representation or warranty of ANI has become untrue, in either case such that the conditions set forth in *Section 6.3(a)* or *Section 6.3(b)* would not be satisfied as of the time of such breach or as of the time such representation or warranty has become untrue, provided that such breach by ANI or inaccuracy in ANI's representations and warranties cannot be cured by ANI or, if capable of being cured, has not been cured by ANI, in each case within thirty (30) days following receipt by ANI of written notice of such breach or inaccuracy from the Company (it being understood that the Company may not terminate this Agreement pursuant to this *Section 7.1(f)* if it has materially breached this Agreement and remains in breach of this Agreement as of the date of such proposed termination);

(i) by ANI, upon a breach of any representation, warranty, covenant or obligation on the part of the Company set forth in this Agreement, or if any representation or warranty of the Company has become untrue, in either case such that the conditions set forth in *Section 6.2(a)* or *Section 6.2(b)* would not be satisfied as of the time of such breach or as of the time such representation or warranty has become untrue, provided that such breach by the Company or inaccuracy in the Company's representations and warranties cannot be cured by the Company or, if capable of being cured, has not been cured by the Company, in each case within thirty (30) days following receipt by the Company of written notice of such breach or inaccuracy from ANI (it being understood that ANI may not terminate this Agreement pursuant to this *Section 7.1(e)* if it has materially breached this Agreement and remains in breach of this Agreement as of the date of such proposed termination);

(j) by ANI if, prior to obtaining Company Stockholder Approval, the Company Board has (i) effected any Change in Company Board Recommendation; (ii) failed to publicly reaffirm the Company Board Recommendation within two (2) Business Days of ANI's request; or (iii) failed to recommend against a tender or exchange offer related to an Acquisition Proposal in any position taken pursuant to Rules 14d-9 and 14e-2 under the Exchange Act; or

(k) by ANI if the Company, after receiving an Acquisition Proposal, has materially violated or breached any of its obligations under *Section 5.4(b)* with respect to such Acquisition Proposal.

**7.2 Notice of Termination; Effect of Termination.** A Party desiring to terminate this Agreement pursuant to *Section 7.1* (other than *Section 7.1(a)*) must give written notice of such termination to the other Party in accordance with *Section 8.4*, specifying the provision or provisions hereof pursuant to which such termination is being effected. In the event of the valid termination of this Agreement as provided in *Section 7.1*, except as set forth in this *Section 7.2* or in *Section 7.3*, each of which will survive the termination of this Agreement, this Agreement will forthwith become void and have no effect, without any liability on the part of any Party other than liability for any breach of this Agreement occurring prior to such termination. No termination of this Agreement will affect the obligations of the parties contained in the Confidentiality Agreement, all of which obligations will survive termination of this Agreement in accordance with their terms.

### **7.3 Fees and Expenses.**

(a) Except as set forth in this *Section 7.3*, all fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby, including the Merger, will be paid by the Party incurring such Expenses if the Merger is not consummated; *provided, however*, that the Surviving Corporation will pay the Expenses of each Party if the Merger is consummated. Notwithstanding the foregoing, if this Agreement is terminated (i) by ANI pursuant to *Section 7.1(f)*, *Section 7.1(i)* or *Section 7.1(j)* or (ii) the Company pursuant to *Section 7.1(e)* or *Section 7.1(g)*, then the Company will reimburse ANI for all of ANI's Expenses; *provided, however*, that the amount required to be reimbursed in respect of Expenses by the Company will not exceed five hundred thousand dollars (\$500,000). In addition, in the event of a termination of this Agreement as set forth in clause (i) or (ii) above where another transaction otherwise constituting an Acquisition Proposal (except all references to "15%" in such definition will be deemed to be references to "30%," instead) is consummated within twelve (12) months or, in the case of a termination by the Company pursuant to *Section 7.1(e)*, two (2) months following such termination, an additional termination fee would be paid by the Company to ANI which, when combined with the foregoing Expense reimbursement previously paid to ANI, would equal a total of one million dollars (\$1,000,000) (the "**ANI Termination Fee**"). If the Agreement is terminated by the Company pursuant to *Section 7.1(h)*, then ANI will to pay to the Company a termination fee of seven hundred fifty thousand dollars (\$750,000) (the "**Company Termination Fee**" and, together with the ANI Termination Fee, the "**Termination Fees**"). As used herein "**Expenses**" includes all reasonable out-of-pocket expenses (including all fees and expenses of counsel, accountants, investment bankers, experts and consultants to a Party or its Affiliates) incurred by a Party or on its behalf in connection with, or related to, the authorization, preparation, negotiation and performance of this Agreement and the other documents and agreements required hereby.

(b) Any Expenses or Termination Fee required to be paid by the Company pursuant to this *Section 7.3* will be paid by the Company pursuant to a wire transfer of immediately available funds to an account designated by ANI in writing, concurrently with any notice of termination by the Company, or within two (2) Business Days of any notice of termination given by ANI, in the case of Expenses and concurrently with the consummation of any Acquisition Proposal, in the case of a termination fee.

(c) Any Termination Fee required to be paid by ANI pursuant to this *Section 7.3* will be paid by ANI pursuant to a wire transfer of immediately available funds to an account designated by the Company in writing, concurrently with any notice of termination by the Company.

(d) Subject to the Parties' right to specifically enforce the terms of this Agreement pursuant to *Section 8.7* prior to the valid termination of this Agreement, but notwithstanding any other provision of this Agreement to the contrary, each of ANI and the Company agree that (i) such Party's right to receive the payment of a Termination Fee (and, if applicable, the reimbursement of Expenses), as and when set forth in *Section 7.3(a)*, will be the sole and exclusive remedy of such Party against the other Party, any of such other Party's Subsidiaries or any of their respective former, current or future Representatives, stockholders, general or limited partners, members, managers, directors, officers, employees, agents, assignees or Affiliates (collectively, the "**Other Parties**") for all losses and damages suffered as a result of the failure of the Merger or the other transactions contemplated by this Agreement to be consummated or for any other breach or failure to perform hereunder or otherwise, and (ii) none of the Other Parties will have any liability or obligation, in any such case (clause (i) or (ii)) relating to, arising out of or with respect to this Agreement or any of the transactions contemplated hereby (whether relating to, arising out of or with respect to any matter(s) forming the basis for such termination or otherwise). Without limitation of the foregoing, neither Party nor any of its respective Affiliates or any other Person will be entitled to bring or maintain any proceeding, claim, suit or action against, or seek damages from, any of the Other Parties in contravention of the preceding sentence.

(e) Each of the Parties hereto acknowledges that (i) the agreements contained in this *Section 7.3* are an integral part of the transactions contemplated hereby, (ii) any Termination Fee is not a penalty, but constitutes liquidated damages, in a reasonable amount that will compensate the Company or ANI, as the case may be, in the circumstances in which the Termination Fee is payable for the efforts and resources expended and opportunities foregone while negotiating this Agreement and in reliance on this Agreement and on the expectation of the consummation of the transactions contemplated hereby, which amount would otherwise be impossible to calculate with precision, and (iii) without these agreements, the Parties would not enter into this Agreement. If either the Company or ANI fails to pay a Termination Fee or reimburse Expenses when due, and, in order to obtain such payment, the other Party commences a suit that results in a judgment against the defaulting party for such Termination Fee or Expense reimbursement, the defaulting Party will pay to the other Party its reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with such suit, together with interest on the amount of the Termination Fee or Expense reimbursement from the date such payment was required to be made until the date of payment at the prime rate of Citibank N.A. in effect on the date such payment was required to be made.

## **ARTICLE VIII.**

### **General Provisions**

**8.1 Non-Survival of Representations, Warranties, Covenants and Agreements.** None of the representations, warranties, covenants and agreements in this Agreement or in any instrument delivered pursuant to this Agreement, including any rights arising out of any breach of such representations, warranties, covenants and agreements, will survive the Effective Time, except for (a) those covenants and agreements contained herein that by their terms apply or are to be performed in whole or in part after the Effective Time, and (b) this *Article VIII*.

**8.2 Amendment and Modification.** This Agreement may be amended, modified or supplemented only by the written agreement of the Company and ANI at any time prior to the Effective Time; *provided, however*, that after either Company Stockholder Approval or the ANI Stockholder Approval is obtained no amendment or waiver that, pursuant to Applicable Law, requires further Company

Stockholder Approval or ANI Stockholder Approval, as applicable, will be effective without the receipt of such further Company Stockholder Approval or ANI Stockholder Approval, as applicable.

**8.3 Waiver of Compliance; Consents.** Any failure of the Company or ANI to comply with any obligation, covenant, agreement or condition herein may be waived by ANI (with respect to any failure by the Company) or by the Company (with respect to any failure by ANI), respectively, only by a written instrument signed by the Party granting such waiver, but such waiver or failure to insist upon strict compliance with such obligation, covenant, agreement or condition will not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. Whenever this Agreement requires or permits consent by or on behalf of any Party, such consent will be deemed effective when given in a manner consistent with the requirements for a waiver of compliance as set forth in this *Section 8.3*.

**8.4 Notices.** All notices, requests, demands, claims and other communications that are required to be or may be given under this Agreement must be in writing and will be deemed to have been effectively given: (i) upon personal delivery to the recipient; (ii) when sent by confirmed facsimile, if sent during normal business hours of the recipient; if not, then on the next Business Day; or (iii) one (1) Business Day after deposit with a nationally recognized overnight courier, specifying next-day delivery, with written verification of receipt, in each case to the intended recipient at the following addresses:

(a) if to the Company, to

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, IL 60069  
Attention: Stephen M. Simes  
Facsimile: (847) 478-9260

with a copy to

Oppenheimer Wolff & Donnelly LLP  
222 South Ninth Street, Suite 2000  
Minneapolis, MN 55402-3338  
Attention: Bruce A. Machmeier, Esq.  
Amy E. Culbert, Esq.  
Facsimile No.: (612) 607-7100

and

(b) if to ANI, to

ANIP Acquisition Company  
210 Main Street West  
Baudette, MN 56623  
Attention: Arthur Przybyl  
Facsimile No.: (218) 634-3540

with a copy to

SNR Denton US LLP  
1221 Avenue of the Americas  
New York, NY 10020  
Attention: Paul A. Gajer, Esq.  
Facsimile No.: (212) 768-6800

or to such other address as any Party has furnished to the other by notice given in accordance with this *Section 8.4*.

**8.5 Assignment; Third-Party Beneficiaries.** Neither this Agreement nor any right, interest or obligation hereunder may be assigned by any of the Parties without the prior written consent of the other Party. This Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. This Agreement is not intended to confer any rights or remedies upon any Person other than: (i) the Parties; (ii) the Company Indemnified Persons only after the Effective Time and only with respect to *Section 5.12*; (iii) the ANI Indemnified Persons only after the Effective Time and only with respect to *Section 5.13*; (iv) Company Director Designees only after the Effective Time and only with respect to *Section 5.14* and (v) the Company Executives and other benefit plan participants only after the Effective Time and only with respect to *Section 5.17*.

**8.6 Governing Law.** This Agreement will be governed by the laws of the State of Delaware without reference to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction.

**8.7 Other Remedies; Specific Enforcement; Consent to Jurisdiction.** Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise of any other remedy. The Parties agree that irreparable damage for which monetary damages, even if available, would not be an adequate remedy would occur in the event that the Parties do not perform their obligations pursuant to this Agreement in accordance with its specified terms or otherwise breach such terms. Accordingly, the Parties acknowledge and agree that the Parties will be entitled to an injunction, specific performance and other equitable relief to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, this being in addition to any other remedy to which they are entitled at law or in equity. Each of the Parties agrees that it will not oppose the granting of an injunction, specific performance and other equitable relief as provided herein on the basis that: (i) any Party has an adequate remedy at law; or (ii) an award of specific performance is not an appropriate remedy for any reason at law or in equity. In addition, each of the Parties: (x) consents to submit itself to the personal jurisdiction of any federal court located in the State of Delaware or any state court located in the State of Delaware in the event that any dispute arises out of this Agreement or the transactions contemplated hereby, including the Merger; (y) agrees that it will not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court; and (z) agrees that it will not bring any action relating to this Agreement or the transactions contemplated hereby, including the Merger, in any court other than a federal court located in the State of Delaware or a state court located in the State of Delaware.

**8.8 Counterparts.** This Agreement may be executed in any number of counterparts and by facsimile signatures, any one of which need not contain the signatures of more than one Party and each of which will be an original, but all such counterparts taken together will constitute one and the same instrument. The exchange of copies of this Agreement or amendments thereto and of signature pages by facsimile transmission or by e-mail transmission in portable digital format (or similar format) will constitute effective execution and delivery of such instrument(s) as to the Parties and may be used in lieu of the original Agreement or amendment for all purposes. Signatures of the Parties transmitted by facsimile or by e-mail transmission in portable digital format (or similar format) will be deemed to be their original signatures for all purposes.

**8.9 Severability.** Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction will not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the Parties agree that the court making such determination will have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and

enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement will be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the Parties agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

#### 8.10 Interpretation.

(a) For purposes of this Agreement, whenever the context requires, the singular number will include the plural, and vice versa, the masculine gender will include the feminine and neuter genders, the feminine gender will include the masculine and neuter genders, and the neuter gender will include masculine and feminine genders.

(b) When calculating the time period before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is referenced in calculating such period will be excluded (for example, if an action is to be taken within two (2) days of a triggering event and such event occurs on a Tuesday, then the action must be taken by Thursday). If the last day of such period is a non-Business Day, the period in question will end on the next succeeding Business Day.

(c) As used in this Agreement, the words "include" and "including" and variations thereof, will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation".

(d) Except as otherwise expressly indicated, all references in this Agreement to a "Section", "Article", "Preamble", "Recitals" or "Exhibit" are intended to refer to a Section, Article, the Preamble, the Recitals or an Exhibit of this Agreement, and all references to a "Schedule" are intended to refer to a Section of the ANI Disclosure Schedule or the Company Disclosure Schedule, as applicable.

(e) As used in this Agreement, the terms "hereof", "hereunder", "herein" and words of similar import will refer to this Agreement as a whole and not to any particular provision, Section, Exhibit or Schedule of this Agreement.

(f) The phrases "known" or "**knowledge**" mean, (i) with respect to an individual, that such individual is actually aware of the relevant fact or such individual would reasonably be expected to know such fact in the ordinary course of the performance of the individual's employment or professional responsibility, and (ii) with respect to any Person, that any officer of such Person is actually aware of the relevant fact or such officer would reasonably be expected to know after due inquiry with respect to such officer's areas of primary responsibility.

(g) Each Party has participated in the drafting of this Agreement, which each Party acknowledges is the result of extensive negotiations among the Parties. Consequently, this Agreement will be interpreted without reference to any rule or precept of Applicable Law that states that any ambiguity in a document be construed against the drafter.

(h) Any reference in this Agreement to "\$" or "dollars" will mean U.S. dollars.

(i) All references to any section of any law include any amendment of, and/or successor to, that section.

(j) The table of contents and Article and Section headings contained in this Agreement are for reference purposes only and do not limit or otherwise affect any of the substance of this Agreement.

(k) All terms defined in this Agreement will have such defined meanings when used in the Company Disclosure Schedule or the ANI Disclosure Schedule or any certificate or other document made or delivered pursuant hereto or thereto unless otherwise defined therein.

**8.11 Entire Agreement.** This Agreement and the Confidentiality Agreement, including the exhibits hereto and the documents and instruments referred to herein (including the Company Disclosure Schedule and the ANI Disclosure Schedule), embody the entire agreement and understanding of the Parties in respect of the subject matter contained herein. There are no representations, promises, warranties, covenants, or undertakings, other than those expressly set forth or referred to herein and therein.

**8.12 Deliveries.** Each Party agrees and acknowledges that all documents or other items included in the electronic dataroom used in connection with the Merger or otherwise delivered to the other Party or its representatives (including legal counsel and accountants) will be deemed to be delivered, provided or made available to the other Party for all purposes under this Agreement.

**8.13 Arbitration Concerning Litigation Reserve.** The Parties agree that any dispute arising out of or relating to the determination of the reserve in *Section 2.2(a)(vii)(G)* prior to November 15, 2012 (including any dispute regarding the arbitrability thereof), will be resolved through expedited, binding and confidential arbitration conducted before a single arbitrator pursuant to the then-current Expedited Procedures of the Commercial Arbitration Rules and Mediation Procedures of the American Arbitration Association, unless the parties mutually agree in writing otherwise. Any arbitration hearing will be conducted in Chicago, Illinois. The arbitration hearing will be concluded within thirty (30) days of selection of the arbitrator and the arbitrator will rule within seven (7) days following the closing of the hearing, unless the parties mutually agree in writing otherwise. The arbitrator's award and decision will be limited to a determination of the amount of the litigation reserve to be included in the calculation of Net Cash pursuant to *Section 2.2(a)(vii)(G)*. The Parties mutually waive any and all rights to challenge the arbitration decision in any state or federal court.

**8.14 WAIVER OF JURY TRIAL.** THE COMPANY AND ANI EACH HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY, INCLUDING THE MERGER.

*[signature page follows]*

IN WITNESS WHEREOF, Parties have caused this Agreement to be signed by their respective officers thereunto duly authorized, all as of the date first set forth above.

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ STEPHEN M. SIMES

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Name: Stephen M. Simes  
Title: *Vice Chairman, President and Chief Executive Officer*

ANIP ACQUISITION COMPANY

By: /s/ ARTHUR PRZYBYL

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Name: Arthur Przybyl  
Title: *President and Chief Executive Officer*

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**ANI Stockholders to Sign Voting Agreement**

Meridian Venture Partners II, L.P.

FA Private Equity Fund IV, L.P.

FA Private Equity Fund IV GMBH & Co. Beteiligungs KG

The Productivity Fund IV, L.P.

The Productivity Fund IV Advisors Fund, L.P.

Argentum Capital Partners II, L.P.

**Company Stockholders to Sign Voting Agreement**

Louis W. Sullivan, M.D.

Fred Holubow

Ross Mangano

John T. Potts, Jr., M.D.

Edward C. Rosenow, III, M.D.

Stephen M. Simes

Stephen A. Sherwin, M.D.

Phillip B. Donenberg

Michael C. Snabes, Ph.D., M.D.

JO & Co

Oliver & Co.

**Company Directors and Officers after Effective Time***ANI Director Designees:*

Robert E. Brown, Jr.

Thomas A. Penn

Tracy Marshbanks

Arthur S. Przybyl

Robert Schrepfer

*Company Director Designees (to be two (2) of the following):*

Louis W. Sullivan, M.D.

Fred Holubow

Ross Mangano

John T. Potts, Jr., M.D.

Edward C. Rosenow, III, M.D.

Stephen M. Simes

Stephen A. Sherwin, M.D.

*Officers:*

Robert E. Brown, Jr.—Chairman of the Board

Arthur S. Przybyl—President and Chief Executive Officer

Charlotte Arnold—Secretary, Treasurer and Chief Financial Officer

James Marken—Vice President of Operations

Robert Jamnick—Vice President of Quality and Product Development

**AMENDMENT NO. 1 TO AGREEMENT AND PLAN OF MERGER**

This AMENDMENT NO. 1 TO AGREEMENT AND PLAN OF MERGER (this "**Amendment**") is entered into as of November 13, 2012 by and between BioSante Pharmaceuticals, Inc., a Delaware corporation and ANIP Acquisition Company (d/b/a/ ANI Pharmaceuticals), a Delaware corporation.

**WHEREAS**, the parties are party to that certain Agreement and Plan of Merger dated October 3, 2012 (the "**Agreement**").

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

1. The references to November 15, 2012 set forth in Sections 2.2(a)(vii)(G) and 8.13 of the Agreement are hereby amended to read "November 30, 2012".
2. Except as specifically set forth herein, the Agreement remains in full force and effect.
3. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For purposes of this Agreement, a facsimile or electronic copy of a signature printed by a receiving facsimile machine or printer shall be deemed an original signature.

[Signature page follows]

IN WITNESS WHEREOF, the undersigned have caused this Amendment to be delivered as of the date first above written.

**BIOSANTE PHARMACEUTICALS, INC.**

By: /s/ STEPHEN M. SIMES

Name: Stephen M. Simes

Title: *President & CEO*

**ANIP ACQUISITION COMPANY**

By: /s/ ARTHUR PRZYBYL

Name: Arthur Przybyl

Title: *President and Chief Executive Officer*

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FORM OF VOTING AGREEMENT

This VOTING AGREEMENT (this "**Agreement**"), dated as of October 3, 2012, is by and between, BioSante Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and the undersigned stockholder ("**Stockholder**") of ANIP Acquisition Company, a Delaware corporation ("**ANI**") identified on the signature page hereto.

A. The Company and ANI are entering into an Agreement and Plan of Merger (as amended from time to time, the "**Merger Agreement**"), dated as of the date hereof, providing for, among other things, the merger of ANI with and into the Company, with the Company continuing as the surviving corporation (the "**Merger**");

B. As of the date hereof, Stockholder is the Beneficial Owner (as defined below) of, and has the sole right to vote and dispose of, that number of shares of common stock, Series A Preferred Stock, Series B Preferred Stock, Class C Preferred Stock and Series D Preferred Stock (the "**ANI Shares**") of ANI set forth beside Stockholder's name on *Schedule A* hereto; and

C. Concurrently with the entry by the Company and ANI into the Merger Agreement, and as a condition and inducement to the willingness of the Company to enter into the Merger Agreement and incur the obligations set forth therein, the Company has required that Stockholder enter into this Agreement;

Accordingly, and in consideration of the foregoing and the mutual representations, warranties, covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

**ARTICLE I.**  
**Definitions**

Capitalized terms used but not defined in this Agreement are used in this Agreement with the meanings given to such terms in the Merger Agreement. In addition, for purposes of this Agreement:

"**Affiliate**" means, with respect to any specified person, a person who, at the time of determination, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified person. For purposes of this Agreement, with respect to Stockholder, "**Affiliate**" does not include ANI and the persons that directly, or indirectly through one or more intermediaries, are controlled by ANI. For the avoidance of doubt, no officer or director of ANI will be deemed an Affiliate of another officer or director of ANI by virtue of his or her status as an officer or director of ANI.

"**Beneficially Owned**" or "**Beneficial Ownership**" with respect to any securities means having beneficial ownership of such securities (as determined pursuant to Rule 13d-3 under the Exchange Act, disregarding the phrase "within 60 days" in paragraph (d)(1)(i) thereof), including pursuant to any agreement, arrangement or understanding, whether or not in writing. Without duplicative counting of the same securities, securities Beneficially Owned by a person include securities Beneficially Owned by (i) all Affiliates of such person, and (ii) all other persons with whom such person would constitute a "group" within the meaning of Section 13(d) of the Exchange Act and the rules promulgated thereunder.

"**Beneficial Owner**" with respect to any securities means a person that has Beneficial Ownership of such securities.

"**person**" has the meaning ascribed thereto in the Merger Agreement.

"**Subject Shares**" means, with respect to Stockholder, without duplication, (i) the ANI Shares owned by Stockholder on the date hereof as described on *Schedule A*, and (ii) any additional ANI Shares acquired by Stockholder or over which Stockholder acquires Beneficial Ownership from and after the date hereof, whether pursuant to existing stock option agreements, warrants or otherwise. Without limiting the other provisions of this Agreement, in the event that ANI changes the number of ANI Shares issued and outstanding prior to the Expiration Date as a result of a reclassification, stock split (including a reverse stock split), stock dividend or distribution, combination, recapitalization, subdivision, or other similar transaction, the number of Subject Shares subject to this Agreement will be equitably adjusted to reflect such change.

"**Transfer**" means, with respect to a security, the sale, transfer, pledge, hypothecation, encumbrance, assignment or disposition of such security or the Beneficial Ownership thereof, and each option, agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. As a verb, "**Transfer**" has a correlative meaning.

## ARTICLE II. Covenants of Stockholder

**2.1 Irrevocable Proxy.** Concurrently with the execution of this Agreement, Stockholder agrees to deliver to the Company a proxy in the form attached hereto as *Exhibit A* (the "**Proxy**"), which will be irrevocable to the extent provided in Section 212 of the Delaware General Corporation Law (the "**DGCL**"), with respect to the Subject Shares referred to therein.

### **2.2 Agreement to Vote.**

(a) At any meeting of the stockholders of ANI held prior to the Expiration Date (as defined in *Section 5.14*), however called, and at every adjournment or postponement thereof prior to the Expiration Date, or in connection with any written consent of, or any other action by, the stockholders of the Company given or solicited prior to the Expiration Date, Stockholder will vote, or provide a consent with respect to, all of the Subject Shares entitled to vote or to consent thereon (i) in favor of the adoption of the Merger Agreement, and any actions required in furtherance thereof, and (ii) against any Acquisition Proposal (other than the Merger), against any amendment of ANI's certificate of incorporation or bylaws or any other proposal or transaction involving ANI, the purpose of which amendment or other proposal or transaction is to delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement or change in any manner the voting rights of any capital stock of ANI, and against any other action or agreement that would result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of ANI under the Merger Agreement.

(b) Stockholder will not enter into any agreement with any person (other than the Company) prior to the Expiration Date (with respect to periods prior to or after the Expiration Date) directly or indirectly to vote, grant any proxy or give instructions with respect to the voting of, the Subject Shares in respect of the matters described in *Section 2.2* hereof, or the effect of which would be inconsistent with or violate any provision contained in this *Section 2.2*. Any vote or consent (or withholding of consent) by Stockholder that is not in accordance with this *Section 2.2* will be considered null and void, and the provisions of the Proxy will be deemed to take immediate effect.

### **2.3 Revocation of Proxies; Cooperation.** Stockholder agrees as follows:

(a) Stockholder hereby represents and warrants that any proxies heretofore given in respect of the Subject Shares with respect to the matters described in *Section 2.2(a)* hereof are not irrevocable, and Stockholder hereby revokes any and all prior proxies with respect to such Subject Shares as they relate to such matters. Prior to the Expiration Date, Stockholder will not directly or indirectly grant any proxies or powers of attorney with respect to the matters set forth in

Section 2.2(a) hereof (other than to the Company), deposit any of the Subject Shares or enter into a voting agreement (other than this Agreement) with respect to any of the Subject Shares relating to any matter described in Section 2.2(a).

(b) Stockholder will (i) use all reasonable efforts to cooperate with the Company and ANI in connection with the transactions contemplated by the Merger Agreement, and (ii) provide any information reasonably requested by the Company or ANI for any regulatory application or filing sought for such transactions.

2.4 **No Solicitation.** Stockholder acknowledges that ANI is subject to the non-solicitation prohibitions set forth in Section 5.3 of the Merger Agreement and that the Stockholder has read and understands the terms thereof. Stockholder will not, directly or indirectly, (a) solicit, initiate or knowingly encourage or knowingly facilitate (including by way of furnishing any non-public information relating to ANI or any of its Subsidiaries), or knowingly induce or knowingly take any other action which would reasonably be expected to lead to the making, submission or announcement of, any proposal or inquiry that constitutes, or is reasonably likely to lead to, an Acquisition Proposal; (b) other than informing Persons of the provisions contained in Section 5.3 of the Merger Agreement, enter into, continue or participate in any discussions or any negotiations regarding any Acquisition Proposal or otherwise take any action to knowingly facilitate or knowingly induce any effort or attempt to make or implement an Acquisition Proposal (including any Acquisition Proposal received prior to the date of this Agreement); (iii) approve, endorse or recommend an Acquisition Proposal or any letter of intent, memorandum of understanding or Contract contemplating an Acquisition Proposal or requiring ANI to abandon or terminate its obligations under the Merger Agreement, or enter into any of the foregoing; or (iv) agree, resolve or commit to do any of the foregoing.

2.5 **No Transfer of Subject Shares; Publicity.** Stockholder agrees that:

(a) Stockholder (i) will not Transfer or agree to Transfer any of the Subject Shares or, with respect to any matter described in Section 2.2(a), grant any proxy or power-of-attorney with respect to any of the Subject Shares, (ii) will take all action reasonably necessary to prevent creditors in respect of any pledge of the Subject Shares from exercising their rights under such pledge, and (iii) will not take any action that would make in a material respect any of its representations or warranties contained herein untrue or incorrect or would have the effect of preventing or disabling the Stockholder from performing any of its material obligations hereunder. Notwithstanding the foregoing, Stockholder may Transfer and agree to Transfer any of the Subject Shares provided that each person to which any such Subject Shares are Transferred has (x) executed a counterpart of this Agreement and a Proxy in the form attached hereto as *Exhibit A* (with such modifications as the Company may reasonably request), and (y) agreed in writing to hold such Subject Shares subject to all of the terms and conditions set forth in this Agreement.

(b) Unless required by Applicable Law or permitted by the Merger Agreement, Stockholder will not, and will not authorize or direct any of its Affiliates or Representatives to, make any press release or public announcement with respect to this Agreement or the Merger Agreement or the transactions contemplated hereby or thereby, without the prior written consent of the Company in each instance.

### ARTICLE III.

#### Representations, Warranties and Additional Covenants of Stockholder

Stockholder represents, warrants and covenants to the Company that:

3.1 **Ownership.** Stockholder is the sole Beneficial Owner and the record and legal owner of the Subject Shares identified on *Schedule A* and such shares constitute all of the capital stock of ANI Beneficially Owned by Stockholder. Stockholder has good and valid title to all of the Subject Shares,



free and clear of all Liens, claims, options, proxies, voting agreements and security interests and has the sole right to such Subject Shares and there are no restrictions on rights of disposition or other Liens pertaining to such Subject Shares. Except pursuant to that certain Third Amended and Restated Stockholders' Agreement, dated January 28, 2011, between ANI and certain holders of its capital stock (the "**Stockholders' Agreement**"), none of the Subject Shares is subject to any voting trust or other contract with respect to the voting thereof, and no proxy, power of attorney or other authorization has been granted with respect to any of such Subject Shares.

### 3.2 Authority and Non-Contravention.

(a) [FOR AN INDIVIDUAL:]Stockholder is an individual, and not a corporation, limited liability company, partnership, trust or other such entity. Stockholder has all necessary legal capacity to execute and deliver this Agreement and to perform its obligations hereunder and to consummate the transactions contemplated hereby.[FOR AN ENTITY:]Stockholder is a [ ] duly organized, validly existing and in good standing under the laws of the State of [ ]. Stockholder has all necessary power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Stockholder and the consummation by Stockholder of the transactions contemplated hereby have been duly and validly authorized by all necessary [corporate] action, and no other [corporate] proceedings on the part of Stockholder are necessary to authorize this Agreement or to consummate the transactions contemplated hereby.]

(b) Assuming due authorization, execution and delivery of this Agreement by the Company, this Agreement has been duly and validly executed and delivered by Stockholder and constitutes the legal, valid and binding obligation of Stockholder, enforceable against Stockholder in accordance with its terms except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(c) Stockholder is not nor will it be required to make any filing with or give any notice to, or to obtain any consent from, any person in connection with the execution, delivery or performance of this Agreement or obtain any permit or approval from any Government Authority for any of the transactions contemplated hereby, except to the extent required by Section 13 or Section 16 of the Exchange Act and the rules promulgated thereunder.

(d) Neither the execution and delivery of this Agreement by Stockholder nor the consummation of the transactions contemplated hereby will directly or indirectly (whether with notice or lapse of time or both) (i) conflict with, result in any violation of or constitute a default by Stockholder under any mortgage, bond, indenture, agreement, instrument or obligation to which Stockholder is a party or by which it or any of the Subject Shares are bound, or violate any permit of any Government Authority, or any Applicable Law or Order to which Stockholder, or any of the Subject Shares, may be subject, or (ii) result in the imposition or creation of any Lien upon or with respect to any of the Subject Shares; except, in each case, for conflicts, violations, defaults or Liens that would not individually or in the aggregate be reasonably expected to prevent or materially impair or delay the performance by the Stockholder of its obligations hereunder.

(e) Stockholder has sole voting power and sole power to issue instructions with respect to the matters set forth in Article II hereof and sole power to agree to all of the matters set forth in this Agreement, in each case with respect to all of the Subject Shares, with no limitations, qualifications or restrictions on such rights.

3.3 **Total Shares.** Except as set forth on *Schedule A* or pursuant to the Stockholders' Agreement, Stockholder is not the Beneficial Owner of, and does not have (whether currently, upon

lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing) any right to acquire, and has no other interest in or voting rights with respect to, any ANI Shares or any securities convertible into or exchangeable or exercisable for ANI Shares.

3.4 **Reliance.** Stockholder understands and acknowledges that the Company is entering into the Merger Agreement in reliance upon Stockholder's execution, delivery and performance of this Agreement.

**ARTICLE IV.  
Representations, Warranties and Covenants of the Company**

The Company represents, warrants and covenants to Stockholder that, assuming due authorization, execution and delivery of this Agreement by Stockholder, this Agreement constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. The Company has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution and delivery by the Company of this Agreement and the consummation by the Company of the transactions contemplated hereby have been duly and validly authorized by the Company and no other corporate proceedings on the part of the Company are necessary to authorize this Agreement or to consummate the transactions contemplated hereby. This Agreement has been duly and validly executed and delivered by the Company.

**ARTICLE V.  
Term and Termination**

This Agreement will become effective upon its execution by Stockholder and the Company. This Agreement will terminate upon the earliest of (a) the Effective Time (as defined in the Merger Agreement), (b) a Change in Company Board Recommendation, (c) the Company taking any action permitted under Section 5.4(b) of the Merger Agreement, (d) the termination of the Merger Agreement in accordance with Article VII thereof, or (e) written notice by the Company to Stockholder of the termination of this Agreement (the date of the earliest of the events described in clauses (a), (b), (c) and (d), the "**Expiration Date**"). The Stockholder will not be liable for money damages the Company for any breach of this Agreement and the termination of this Agreement will relieve Stockholder from any liability for any inaccuracy in or breach of any representation, warranty or covenant contained in this Agreement. Notwithstanding the foregoing, Article VI of this Agreement shall survive any termination hereof.

**ARTICLE VI.  
General Provisions**

6.1 **Action in Stockholder Capacity Only.** Stockholder is entering into this Agreement solely in Stockholder's capacity as a record holder and beneficial owner, as applicable, of the Subject Shares and not in Stockholder's capacity as a director or officer of ANI. Nothing herein will limit or affect Stockholder's ability to act as an officer or director of ANI.

**6.2 No Ownership Interest.** Nothing contained in this Agreement will be deemed to vest in the Company or any of its Affiliates any direct or indirect ownership or incidents of ownership of or with respect to the Subject Shares. All rights, ownership and economic benefits of and relating to the Subject Shares will remain and belong to Stockholder, and neither the Company nor any of its Affiliates will have any authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of ANI or exercise any power or authority to direct Stockholder in the voting of any of the Subject Shares, except as otherwise expressly provided herein or in the Merger Agreement.

**6.3 Notices.** All notices, consents, waivers and other communications under this Agreement must be in writing (including facsimile or similar writing) and must be given:

If to the Company, to:

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069  
Attention: Stephen M. Simes  
Facsimile No: (847) 478-9152

with a copy (which will not constitute notice) to:

Oppenheimer Wolff & Donnelly LLP  
222 South Ninth Street, Suite 2000  
Minneapolis, MN 55402-3338  
Attention: Bruce A. Machmeier, Esq.  
Amy E. Culbert, Esq.  
Facsimile No.: (612) 607-7100

If to a Stockholder, to Stockholder's address set forth on *Schedule A*,

or such other address or facsimile number as a party may hereafter specify for the purpose by notice to the other parties hereto. Each notice, consent, waiver or other communication under this Agreement will be effective only (a) if given by facsimile, when the facsimile is transmitted to the facsimile number specified in this Section and the appropriate facsimile confirmation is received or (b) if given by overnight courier or personal delivery when delivered at the address specified in this Section.

**6.4 Further Actions.** Upon the request of any party to this Agreement, the other party will (a) furnish to the requesting party any additional information, (b) execute and deliver, at their own expense, any other documents and (c) take any other actions as the requesting party may reasonably require to more effectively carry out the intent of this Agreement. Stockholder hereby agrees that the Company and ANI may publish and disclose in the Form S-4 Registration Statement and Joint Proxy Statement/Prospectus (including all documents and schedules filed with the SEC) such Stockholder's identity and ownership of Subject Shares and the nature of such Stockholder's commitments, arrangements, and understandings under this Agreement and may further file this Agreement as an exhibit to the Form S-4 Registration Statement or in any other filing made by the Company and/or ANI with the SEC relating to the Merger Agreement or the transactions contemplated thereby. Stockholder agrees to notify the Company promptly of any additional shares of capital stock of ANI of which Stockholder becomes the record or beneficial owner after the date of this Agreement.

**6.5 Entire Agreement and Modification.** This Agreement, the Proxy and any other documents delivered by the parties in connection herewith constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the parties with respect to its subject matter and constitute (along with the documents delivered pursuant to this Agreement) a complete and exclusive statement of the terms of

the agreement between the parties with respect to its subject matter. This Agreement may not be amended, supplemented or otherwise modified except by a written document executed by the party against whose interest the modification will operate. The parties will not enter into any other agreement inconsistent with the terms and conditions of this Agreement and the Proxy, or that addresses any of the subject matters addressed in this Agreement and the Proxy.

**6.6 Drafting and Representation.** The parties agree that the terms and language of this Agreement were the result of negotiations between the parties and, as a result, there will be no presumption that any ambiguities in this Agreement will be resolved against any party. Any controversy over construction of this Agreement will be decided without regard to events of authorship or negotiation.

**6.7 Severability.** Any provision of this Agreement which is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without affecting the validity or enforceability of the remaining provisions hereof. Any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, the provision will be interpreted to be only so broad as is enforceable.

**6.8 No Third-Party Rights.** Stockholder may not assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the Company, except as permitted pursuant to Section 2.5(a). The Company may not assign any of its rights or delegate any of its obligations under this Agreement with respect to Stockholder without the prior written consent of Stockholder. This Agreement will apply to, be binding in all respects upon, and inure to the benefit of each of the respective successors, personal or legal representatives, heirs, distributees, devisees, legatees, executors, administrators and permitted assigns of Stockholder and the successors and permitted assigns of the Company. Nothing expressed or referred to in this Agreement will be construed to give any person, other than the parties to this Agreement, any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement except such rights as may inure to a successor or permitted assignee under this Section.

**6.9 Enforcement of Agreement.** Stockholder acknowledges and agrees that the Company could be damaged irreparably if any of the provisions of this Agreement are not performed in accordance with their specific terms and that any breach of this Agreement by Stockholder could not be adequately compensated by monetary damages. Accordingly, Stockholder agrees that, (a) it will waive, in any action for specific performance, the defense of adequacy of a remedy at law, and (b) in addition to any other right or remedy to which the Company may be entitled, at law or in equity, the Company will be entitled to enforce any provision of this Agreement by a decree of specific performance and to temporary, preliminary and permanent injunctive relief to prevent breaches or threatened breaches of any of the provisions of this Agreement, without posting any bond or other undertaking.

**6.10 Waiver.** The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither any failure nor any delay by a party in exercising any right, power or privilege under this Agreement, the Proxy or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Applicable Law, (a) no claim or right arising out of this Agreement, the Proxy or any of the documents referred to in this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in a written document signed by the other party, (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given, and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of that party or of the right of the party

giving such notice or demand to take further action without notice or demand as provided in this Agreement, the Proxy or the documents referred to in this Agreement.

6.11 **Governing Law.** This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto will be governed by, construed under and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts or choice of law.

6.12 **Consent to Jurisdiction.** Any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement, the Proxy or the transactions contemplated hereby or thereby will be brought exclusively in the United States District Court for the District of Delaware or, if such court does not have jurisdiction over the subject matter of such proceeding or if such jurisdiction is not available, in the Court of Chancery of the State of Delaware, County of New Castle, and each of the parties hereby consents to the exclusive jurisdiction of those courts (and of the appropriate appellate courts therefrom) in any suit, action or proceeding and irrevocably waives, to the fullest extent permitted by Applicable Law, any objection which it may now or hereafter have to the laying of the venue of any suit, action or proceeding in any of those courts or that any suit, action or proceeding which is brought in any of those courts has been brought in an inconvenient forum. Process in any suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any of the named courts. Without limiting the foregoing, each party agrees that service of process on it by notice as provided in Section 5.3 will be deemed effective service of process. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ALL RIGHTS TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY.

6.13 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, but all of which, taken together, will constitute one and the same instrument. This Agreement may be executed by facsimile signature (including signatures in Adobe PDF or similar format).

6.14 **Expenses.** Except as otherwise provided in this Agreement, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby will be paid by the party incurring such expenses.

6.15 **Headings; Construction.** The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. In this Agreement (a) words denoting the singular include the plural and vice versa, (b) "it" or "its" or words denoting any gender include all genders and (c) the word "including" means "including without limitation," whether or not expressed.

*[Signature page follows]*

IN WITNESS WHEREOF, the parties hereto have caused this Voting Agreement to be duly executed as of the day and year first above written.

THE COMPANY:

**BIOSANTE PHARMACEUTICALS, INC.**

By: \_\_\_\_\_

Name:

Title:

STOCKHOLDER:

[NAME]

\_\_\_\_\_  
Name:

Additional Signature (if held jointly):

\_\_\_\_\_  
(If held jointly)

\_\_\_\_\_  
(Printed Full Name)

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**SCHEDULE A**

**NAME AND  
ADDRESS OF STOCKHOLDER**

**ANI SHARES  
BENEFICIALLY OWNED**

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EXHIBIT A

IRREVOCABLE PROXY

From and after the date hereof and until the Expiration Date (as defined below), the undersigned stockholder ("*Stockholder*") of ANIP Acquisition Company, a Delaware corporation ("*ANT*"), hereby irrevocably (to the full extent permitted by Section 212 of the Delaware General Corporation Law) grants to, and appoints, BioSante Pharmaceuticals, Inc., a **Delaware** corporation (the "*Company*"), and any designee of the Company, and each of them individually, as the sole and exclusive attorney and proxy of the undersigned, with full power of substitution and resubstitution, to vote the Subject Shares (as defined in the Voting Agreement) of the Stockholder, or grant a consent or approval in respect of the Subject Shares of the Stockholder, in a manner consistent with Section 2.2 of the Voting Agreement (as defined below). Upon the undersigned's execution of this Proxy, any and all prior proxies given by the undersigned with respect to any Subject Shares relating to the voting rights expressly provided herein are hereby revoked and the undersigned agrees not to grant any subsequent proxies with respect to the Subject Shares relating to such voting rights at any time prior to the Expiration Date.

This Proxy is irrevocable, is coupled with an interest and is granted pursuant to that certain Voting Agreement (as amended from time to time, the "*Voting Agreement*") of even date herewith, by and among the Company and Stockholder, and is granted in consideration of the Company entering into the Merger Agreement (as defined in the Voting Agreement). As used herein, the term "*Expiration Date*," and all capitalized terms used herein and not otherwise defined, will have the meanings set forth in the Voting Agreement. **The Stockholder agrees that this proxy will be irrevocable until the Expiration Date and is coupled with an interest sufficient at law to support an irrevocable proxy and given to the Company as an inducement to enter into the Merger Agreement and, to the extent permitted under applicable law, will be valid and binding on any person to whom Stockholder may transfer any of his, her or its Subject Shares in breach of the Voting Agreement.** The Stockholder hereby ratifies and confirms all that such irrevocable proxy may lawfully do or cause to be done by virtue hereof.

The attorneys and proxies named above, and each of them, are hereby authorized and empowered by the undersigned, at any time prior to the Expiration Date, to act as the undersigned's attorney and proxy to vote the Subject Shares, and to exercise all voting and other rights of the undersigned with respect to the Subject Shares (including, without limitation, the power to execute and deliver written consents pursuant to Section 228 of the Delaware General Corporation Law), at every annual, special or adjourned meeting of the stockholders of the Company and in every written consent in lieu of such meeting in a manner consistent with Section 2.2 of the Voting Agreement.

This Proxy will be binding upon the heirs, estate, executors, personal representatives, successors and assigns of Stockholder (including any transferee of any of the Subject Shares), and all authority herein conferred or agreed to be conferred will survive the death or incapacity of the Stockholder.

If any provision of this Proxy or any part of any such provision is held under any circumstances to be invalid or unenforceable in any jurisdiction, then (a) such provision or part thereof will, with respect to such circumstances and in such jurisdiction, be deemed amended to conform to applicable laws so as to be valid and enforceable to the fullest possible extent, (b) the invalidity or unenforceability of such provision or part thereof under such circumstances and in such jurisdiction will not affect the validity or enforceability of such provision or part thereof under any other circumstances or in any other jurisdiction, and (c) the invalidity or unenforceability of such provision or part thereof will not affect the validity or enforceability of the remainder of such provision or the validity or enforceability of any other provision of this Proxy. Each provision of this Proxy is separable from every other provision of



this Proxy, and each part of each provision of this Proxy is separable from every other part of such provision.

Dated: October , 2012

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(Signature of Stockholder)

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(Print Name of Stockholder)

Number of Subject Shares owned of record or Beneficially  
Owned as of the date of this Proxy:

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VOTING AGREEMENT

This VOTING AGREEMENT (this "**Agreement**"), dated as of October 3, 2012, is by and between, BioSante Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and the undersigned stockholder ("**Stockholder**") of ANIP Acquisition Company, a Delaware corporation ("**ANI**") identified on the signature page hereto.

A. The Company and ANI are entering into an Agreement and Plan of Merger (as amended from time to time, the "**Merger Agreement**"), dated as of the date hereof, providing for, among other things, the merger of ANI with and into the Company, with the Company continuing as the surviving corporation (the "**Merger**");

B. As of the date hereof, Stockholder is the Beneficial Owner (as defined below) of, and has the sole right to vote and dispose of, that number of shares of common stock, Series A Preferred Stock, Series B Preferred Stock, Class C Preferred Stock and Series D Preferred Stock (the "**ANI Shares**") of ANI set forth beside Stockholder's name on *Schedule A* hereto; and

C. Concurrently with the entry by the Company and ANI into the Merger Agreement, and as a condition and inducement to the willingness of the Company to enter into the Merger Agreement and incur the obligations set forth therein, the Company has required that Stockholder enter into this Agreement;

Accordingly, and in consideration of the foregoing and the mutual representations, warranties, covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

**ARTICLE I.**  
**Definitions**

Capitalized terms used but not defined in this Agreement are used in this Agreement with the meanings given to such terms in the Merger Agreement. In addition, for purposes of this Agreement:

"**Affiliate**" means, with respect to any specified person, a person who, at the time of determination, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified person. For purposes of this Agreement, with respect to Stockholder, "**Affiliate**" does not include ANI and the persons that directly, or indirectly through one or more intermediaries, are controlled by ANI. For the avoidance of doubt, no officer or director of ANI will be deemed an Affiliate of another officer or director of ANI by virtue of his or her status as an officer or director of ANI.

"**Beneficially Owned**" or "**Beneficial Ownership**" with respect to any securities means having beneficial ownership of such securities (as determined pursuant to Rule 13d-3 under the Exchange Act, disregarding the phrase "within 60 days" in paragraph (d)(1)(i) thereof), including pursuant to any agreement, arrangement or understanding, whether or not in writing. Without duplicative counting of the same securities, securities Beneficially Owned by a person include securities Beneficially Owned by (i) all Affiliates of such person, and (ii) all other persons with whom such person would constitute a "group" within the meaning of Section 13(d) of the Exchange Act and the rules promulgated thereunder.

"**Beneficial Owner**" with respect to any securities means a person that has Beneficial Ownership of such securities.

"**person**" has the meaning ascribed thereto in the Merger Agreement.

"**Subject Shares**" means, with respect to Stockholder, without duplication, (i) the ANI Shares owned by Stockholder on the date hereof as described on *Schedule A*, and (ii) any additional ANI Shares acquired by Stockholder or over which Stockholder acquires Beneficial Ownership from and after the date hereof, whether pursuant to existing stock option agreements, warrants or otherwise. Without limiting the other provisions of this Agreement, in the event that ANI changes the number of ANI Shares issued and outstanding prior to the Expiration Date as a result of a reclassification, stock split (including a reverse stock split), stock dividend or distribution, combination, recapitalization, subdivision, or other similar transaction, the number of Subject Shares subject to this Agreement will be equitably adjusted to reflect such change.

"**Transfer**" means, with respect to a security, the sale, transfer, pledge, hypothecation, encumbrance, assignment or disposition of such security or the Beneficial Ownership thereof, and each option, agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. As a verb, "**Transfer**" has a correlative meaning.

## ARTICLE II. Covenants of Stockholder

2.1 **Irrevocable Proxy.** Concurrently with the execution of this Agreement, Stockholder agrees to deliver to the Company a proxy in the form attached hereto as *Exhibit A* (the "**Proxy**"), which will be irrevocable to the extent provided in Section 212 of the Delaware General Corporation Law (the "**DGCL**"), with respect to the Subject Shares referred to therein.

### 2.2 **Agreement to Vote.**

(a) At any meeting of the stockholders of ANI held prior to the Expiration Date (as defined in *Section 5.14*), however called, and at every adjournment or postponement thereof prior to the Expiration Date, or in connection with any written consent of, or any other action by, the stockholders of the Company given or solicited prior to the Expiration Date, Stockholder will vote, or provide a consent with respect to, all of the Subject Shares entitled to vote or to consent thereon (i) in favor of the adoption of the Merger Agreement, and any actions required in furtherance thereof, and (ii) against any Acquisition Proposal (other than the Merger), against any amendment of ANI's certificate of incorporation or bylaws or any other proposal or transaction involving ANI, the purpose of which amendment or other proposal or transaction is to delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement or change in any manner the voting rights of any capital stock of ANI, and against any other action or agreement that would result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of ANI under the Merger Agreement.

(b) From the Effective Time until immediately following the first annual meeting of the stockholders of the Company following the consummation of the Merger (the "**Annual Meeting**"), Stockholder agrees that, provided that prior to the Annual Meeting the Company Director Nominees: (1) have nominated Robert E. Brown, Jr. and Thomas A. Penn to the Company Board and (2) have nominated Robert E. Brown, Jr. to be the Chairman of the Board, then it will vote, or cause to be voted, any securities of the Company that entitle holders thereof to vote for members of the Board of Directors of the Company (the "**Company Board**"), including all shares of common stock of the Company, \$0.0001 par value per share (the "**Common Stock**"), received by Stockholder in consideration of its capital stock of ANI, by whatever name called, now owned or subsequently acquired by the Stockholder, however acquired, whether through stock splits, stock dividends, reclassifications, recapitalizations, similar events or otherwise, owned by the Stockholder, or over which the Stockholder has voting control:

(i) in favor of the election of the Company Director Nominees (as defined in the Merger Agreement) to the Company Board at the Annual Meeting or any prior special

meeting of the Company's stockholders at which an election of directors is held or pursuant to any written consent of the stockholders (a "**Prior Election Meeting or Consent**"); and

(ii) against any motion to remove any of the Company Director Nominees from the Company Board.

(c) Stockholder will not enter into any agreement with any person (other than the Company) prior to the Expiration Date (with respect to periods prior to or after the Expiration Date) directly or indirectly to vote, grant any proxy or give instructions with respect to the voting of, the Subject Shares in respect of the matters described in *Section 2.2* hereof, or the effect of which would be inconsistent with or violate any provision contained in this *Section 2.2*. Any vote or consent (or withholding of consent) by Stockholder that is not in accordance with this *Section 2.2* will be considered null and void, and the provisions of the Proxy will be deemed to take immediate effect.

**2.3 Revocation of Proxies; Cooperation.** Stockholder agrees as follows:

(a) Stockholder hereby represents and warrants that any proxies heretofore given in respect of the Subject Shares with respect to the matters described in *Section 2.2(a)* hereof are not irrevocable, and Stockholder hereby revokes any and all prior proxies with respect to such Subject Shares as they relate to such matters. Prior to the Expiration Date, Stockholder will not directly or indirectly grant any proxies or powers of attorney with respect to the matters set forth in *Section 2.2(a)* hereof (other than to the Company), deposit any of the Subject Shares or enter into a voting agreement (other than this Agreement) with respect to any of the Subject Shares relating to any matter described in *Section 2.2(a)*.

(b) Stockholder will (i) use all reasonable efforts to cooperate with the Company and ANI in connection with the transactions contemplated by the Merger Agreement, and (ii) provide any information reasonably requested by the Company or ANI for any regulatory application or filing sought for such transactions.

**2.4 No Solicitation.** Stockholder acknowledges that ANI is subject to the non-solicitation prohibitions set forth in *Section 5.3* of the Merger Agreement and that the Stockholder has read and understands the terms thereof. Stockholder will not, directly or indirectly, (a) solicit, initiate or knowingly encourage or knowingly facilitate (including by way of furnishing any non-public information relating to ANI or any of its Subsidiaries), or knowingly induce or knowingly take any other action which would reasonably be expected to lead to the making, submission or announcement of, any proposal or inquiry that constitutes, or is reasonably likely to lead to, an Acquisition Proposal; (b) other than informing Persons of the provisions contained in *Section 5.3* of the Merger Agreement, enter into, continue or participate in any discussions or any negotiations regarding any Acquisition Proposal or otherwise take any action to knowingly facilitate or knowingly induce any effort or attempt to make or implement an Acquisition Proposal (including any Acquisition Proposal received prior to the date of this Agreement); (iii) approve, endorse or recommend an Acquisition Proposal or any letter of intent, memorandum of understanding or Contract contemplating an Acquisition Proposal or requiring ANI to abandon or terminate its obligations under the Merger Agreement, or enter into any of the foregoing; or (iv) agree, resolve or commit to do any of the foregoing.

**2.5 No Transfer of Subject Shares; Publicity.** Stockholder agrees that:

(a) Stockholder (i) will not Transfer or agree to Transfer any of the Subject Shares or, with respect to any matter described in *Section 2.2(a)*, grant any proxy or power-of-attorney with respect to any of the Subject Shares, (ii) will take all action reasonably necessary to prevent creditors in respect of any pledge of the Subject Shares from exercising their rights under such pledge, and (iii) will not take any action that would make in a material respect any of its representations or warranties contained herein untrue or incorrect or would have the effect of preventing or disabling the Stockholder from performing any of its material obligations hereunder. Notwithstanding the

foregoing, Stockholder may Transfer and agree to Transfer any of the Subject Shares provided that each person to which any such Subject Shares are Transferred has (x) executed a counterpart of this Agreement and a Proxy in the form attached hereto as *Exhibit A* (with such modifications as the Company may reasonably request), and (y) agreed in writing to hold such Subject Shares subject to all of the terms and conditions set forth in this Agreement.

(b) Unless required by Applicable Law or permitted by the Merger Agreement, Stockholder will not, and will not authorize or direct any of its Affiliates or Representatives to, make any press release or public announcement with respect to this Agreement or the Merger Agreement or the transactions contemplated hereby or thereby, without the prior written consent of the Company in each instance.

**2.6 Termination of Warrant.** Stockholder agrees that that certain (i) Common Stock Purchase Warrant No. 1 dated March 29, 2005, for the purchase of 52,490 shares of ANI Common Stock, (ii) Common Stock Purchase Warrant No. 7 dated in July, 2005, for the purchase of 61,740 shares of ANI Common Stock and (iii) Common Stock Purchase Warrant No. 12 dated in March, 2005, for the purchase of 5,280 shares of ANI Common Stock shall terminate immediately prior to the Effective Time (as defined in the Merger Agreement) and thereafter shall be of no further force or effect.

### **ARTICLE III. Representations, Warranties and Additional Covenants of Stockholder**

Stockholder represents, warrants and covenants to the Company that:

**3.1 Ownership.** Stockholder is the sole Beneficial Owner and the record and legal owner of the Subject Shares identified on *Schedule A* and such shares constitute all of the capital stock of ANI Beneficially Owned by Stockholder. Stockholder has good and valid title to all of the Subject Shares, free and clear of all Liens, claims, options, proxies, voting agreements and security interests and has the sole right to such Subject Shares and there are no restrictions on rights of disposition or other Liens pertaining to such Subject Shares. Except pursuant to that certain Third Amended and Restated Stockholders' Agreement, dated January 28, 2011, between ANI and certain holders of its capital stock (the "**Stockholders' Agreement**"), none of the Subject Shares is subject to any voting trust or other contract with respect to the voting thereof, and no proxy, power of attorney or other authorization has been granted with respect to any of such Subject Shares.

**3.2 Authority and Non-Contravention.**

(a) Stockholder is a limited partnership duly organized, validly existing and in good standing under the laws of the State of Delaware. Stockholder has all necessary power and authority to execute and deliver this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement by Stockholder and the consummation by Stockholder of the transactions contemplated hereby have been duly and validly authorized by all necessary limited partnership action, and no other limited partnership proceedings on the part of Stockholder are necessary to authorize this Agreement or to consummate the transactions contemplated hereby.

(b) Assuming due authorization, execution and delivery of this Agreement by the Company, this Agreement has been duly and validly executed and delivered by Stockholder and constitutes the legal, valid and binding obligation of Stockholder, enforceable against Stockholder in accordance with its terms except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(c) Stockholder is not nor will it be required to make any filing with or give any notice to, or to obtain any consent from, any person in connection with the execution, delivery or performance of this Agreement or obtain any permit or approval from any Government Authority for any of the transactions contemplated hereby, except to the extent required by Section 13 or Section 16 of the Exchange Act and the rules promulgated thereunder.

(d) Neither the execution and delivery of this Agreement by Stockholder nor the consummation of the transactions contemplated hereby will directly or indirectly (whether with notice or lapse of time or both) (i) conflict with, result in any violation of or constitute a default by Stockholder under any mortgage, bond, indenture, agreement, instrument or obligation to which Stockholder is a party or by which it or any of the Subject Shares are bound, or violate any permit of any Government Authority, or any Applicable Law or Order to which Stockholder, or any of the Subject Shares, may be subject, or (ii) result in the imposition or creation of any Lien upon or with respect to any of the Subject Shares; except, in each case, for conflicts, violations, defaults or Liens that would not individually or in the aggregate be reasonably expected to prevent or materially impair or delay the performance by the Stockholder of its obligations hereunder.

(e) Stockholder has sole voting power and sole power to issue instructions with respect to the matters set forth in Article II hereof and sole power to agree to all of the matters set forth in this Agreement, in each case with respect to all of the Subject Shares, with no limitations, qualifications or restrictions on such rights.

3.3 **Total Shares.** Except as set forth on *Schedule A* or pursuant to the Stockholders' Agreement, Stockholder is not the Beneficial Owner of, and does not have (whether currently, upon lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing) any right to acquire, and has no other interest in or voting rights with respect to, any ANI Shares or any securities convertible into or exchangeable or exercisable for ANI Shares.

3.4 **Reliance.** Stockholder understands and acknowledges that the Company is entering into the Merger Agreement in reliance upon Stockholder's execution, delivery and performance of this Agreement.

**ARTICLE IV.  
Representations, Warranties and Covenants of the Company**

The Company represents, warrants and covenants to Stockholder that, assuming due authorization, execution and delivery of this Agreement by Stockholder, this Agreement constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. The Company has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution and delivery by the Company of this Agreement and the consummation by the Company of the transactions contemplated hereby have been duly and validly authorized by the Company and no other corporate proceedings on the part of the Company are necessary to authorize this Agreement or to consummate the transactions contemplated hereby. This Agreement has been duly and validly executed and delivered by the Company.

**ARTICLE V.  
Term and Termination**

This Agreement will become effective upon its execution by Stockholder and the Company. This Agreement will terminate upon the earliest of (a) the Effective Time (as defined in the Merger Agreement), (b) a Change in Company Board Recommendation, (c) the Company taking any action permitted under Section 5.4(b) of the Merger Agreement, (d) the termination of the Merger Agreement in accordance with Article VII thereof, or (e) written notice by the Company to Stockholder of the termination of this Agreement (the date of the earliest of the events described in clauses (a), (b), (c) and (d), the "**Expiration Date**"); provided, however, that, in the event this agreement is terminated pursuant to clause (a) above, the obligation of Stockholder under Section 2.2(b) shall survive until immediately following the Annual Meeting, or if earlier, upon the occurrence of a Prior Election or Consent. The Stockholder will not be liable for money damages the Company for any breach of this Agreement and the termination of this Agreement will relieve Stockholder from any liability for any inaccuracy in or breach of any representation, warranty or covenant contained in this Agreement. Notwithstanding the foregoing, Article VI of this Agreement shall survive any termination hereof.

**ARTICLE VI.  
General Provisions**

**6.1 Action in Stockholder Capacity Only.** Stockholder is entering into this Agreement solely in Stockholder's capacity as a record holder and beneficial owner, as applicable, of the Subject Shares and not in Stockholder's capacity as a director or officer of ANI. Nothing herein will limit or affect Stockholder's ability to act as an officer or director of ANI.

**6.2 No Ownership Interest.** Nothing contained in this Agreement will be deemed to vest in the Company or any of its Affiliates any direct or indirect ownership or incidents of ownership of or with respect to the Subject Shares. All rights, ownership and economic benefits of and relating to the Subject Shares will remain and belong to Stockholder, and neither the Company nor any of its Affiliates will have any authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of ANI or exercise any power or authority to direct Stockholder in the voting of any of the Subject Shares, except as otherwise expressly provided herein or in the Merger Agreement.

**6.3 Notices.** All notices, consents, waivers and other communications under this Agreement must be in writing (including facsimile or similar writing) and must be given:

If to the Company, to:

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069  
Attention: Stephen M. Simes  
Facsimile No: (847) 478-9152

with a copy (which will not constitute notice) to:

Oppenheimer Wolff & Donnelly LLP  
222 South Ninth Street, Suite 2000  
Minneapolis, MN 55402-3338  
Attention: Bruce A. Machmeier, Esq.  
Amy E. Culbert, Esq.  
Facsimile No.: (612) 607-7100

If to a Stockholder, to Stockholder's address set forth on *Schedule A*,

or such other address or facsimile number as a party may hereafter specify for the purpose by notice to the other parties hereto. Each notice, consent, waiver or other communication under this Agreement will be effective only (a) if given by facsimile, when the facsimile is transmitted to the facsimile number specified in this Section and the appropriate facsimile confirmation is received or (b) if given by overnight courier or personal delivery when delivered at the address specified in this Section.

**6.4 Further Actions.** Upon the request of any party to this Agreement, the other party will (a) furnish to the requesting party any additional information, (b) execute and deliver, at their own expense, any other documents and (c) take any other actions as the requesting party may reasonably require to more effectively carry out the intent of this Agreement. Stockholder hereby agrees that the Company and ANI may publish and disclose in the Form S-4 Registration Statement and Joint Proxy Statement/Prospectus (including all documents and schedules filed with the SEC) such Stockholder's identity and ownership of Subject Shares and the nature of such Stockholder's commitments, arrangements, and understandings under this Agreement and may further file this Agreement as an exhibit to the Form S-4 Registration Statement or in any other filing made by the Company and/or ANI with the SEC relating to the Merger Agreement or the transactions contemplated thereby. Stockholder agrees to notify the Company promptly of any additional shares of capital stock of ANI of which Stockholder becomes the record or beneficial owner after the date of this Agreement.

**6.5 Entire Agreement and Modification.** This Agreement, the Proxy and any other documents delivered by the parties in connection herewith constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the parties with respect to its subject matter and constitute (along with the documents delivered pursuant to this Agreement) a complete and exclusive statement of the terms of the agreement between the parties with respect to its subject matter. This Agreement may not be amended, supplemented or otherwise modified except by a written document executed by the party against whose interest the modification will operate. The parties will not enter into any other agreement inconsistent with the terms and conditions of this Agreement and the Proxy, or that addresses any of the subject matters addressed in this Agreement and the Proxy.

**6.6 Drafting and Representation.** The parties agree that the terms and language of this Agreement were the result of negotiations between the parties and, as a result, there will be no presumption that any ambiguities in this Agreement will be resolved against any party. Any controversy over construction of this Agreement will be decided without regard to events of authorship or negotiation.

**6.7 Severability.** Any provision of this Agreement which is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without affecting the validity or enforceability of the remaining provisions hereof. Any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, the provision will be interpreted to be only so broad as is enforceable.

**6.8 No Third-Party Rights.** Stockholder may not assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the Company, except as permitted pursuant to Section 2.5(a). The Company may not assign any of its rights or delegate any of its obligations under this Agreement with respect to Stockholder without the prior written consent of Stockholder. This Agreement will apply to, be binding in all respects upon, and inure to the benefit of each of the respective successors, personal or legal representatives, heirs, distributes, devisees, legatees, executors, administrators and permitted assigns of Stockholder and the successors and permitted assigns of the Company. Nothing expressed or referred to in this Agreement will be construed to give any person, other than the parties to this Agreement, any legal or equitable right, remedy or claim under or



with respect to this Agreement or any provision of this Agreement except such rights as may inure to a successor or permitted assignee under this Section.

**6.9 Enforcement of Agreement.** Stockholder acknowledges and agrees that the Company could be damaged irreparably if any of the provisions of this Agreement are not performed in accordance with their specific terms and that any breach of this Agreement by Stockholder could not be adequately compensated by monetary damages. Accordingly, Stockholder agrees that, (a) it will waive, in any action for specific performance, the defense of adequacy of a remedy at law, and (b) in addition to any other right or remedy to which the Company may be entitled, at law or in equity, the Company will be entitled to enforce any provision of this Agreement by a decree of specific performance and to temporary, preliminary and permanent injunctive relief to prevent breaches or threatened breaches of any of the provisions of this Agreement, without posting any bond or other undertaking.

**6.10 Waiver.** The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither any failure nor any delay by a party in exercising any right, power or privilege under this Agreement, the Proxy or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Applicable Law, (a) no claim or right arising out of this Agreement, the Proxy or any of the documents referred to in this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in a written document signed by the other party, (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given, and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of that party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement, the Proxy or the documents referred to in this Agreement.

**6.11 Governing Law.** This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto will be governed by, construed under and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts or choice of law.

**6.12 Consent to Jurisdiction.** Any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement, the Proxy or the transactions contemplated hereby or thereby will be brought exclusively in the United States District Court for the District of Delaware or, if such court does not have jurisdiction over the subject matter of such proceeding or if such jurisdiction is not available, in the Court of Chancery of the State of Delaware, County of New Castle, and each of the parties hereby consents to the exclusive jurisdiction of those courts (and of the appropriate appellate courts therefrom) in any suit, action or proceeding and irrevocably waives, to the fullest extent permitted by Applicable Law, any objection which it may now or hereafter have to the laying of the venue of any suit, action or proceeding in any of those courts or that any suit, action or proceeding which is brought in any of those courts has been brought in an inconvenient forum. Process in any suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any of the named courts. Without limiting the foregoing, each party agrees that service of process on it by notice as provided in *Section 5.3* will be deemed effective service of process. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ALL RIGHTS TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY.

**6.13 Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, but all of which, taken together, will constitute one and the

same instrument. This Agreement may be executed by facsimile signature (including signatures in Adobe PDF or similar format).

6.14 **Expenses.** Except as otherwise provided in this Agreement, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby will be paid by the party incurring such expenses.

6.15 **Headings; Construction.** The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. In this Agreement (a) words denoting the singular include the plural and vice versa, (b) "it" or "its" or words denoting any gender include all genders and (c) the word "including" means "including without limitation," whether or not expressed.

*[Signature page follows]*

IN WITNESS WHEREOF, the parties hereto have caused this Voting Agreement to be duly executed as of the day and year first above written.

THE COMPANY:

**BIOSANTE PHARMACEUTICALS, INC.**

By: /s/ STEPHEN M. SIMES

Name: Stephen M. Simes

Title: President and Chief Executive Officer

STOCKHOLDER:

**MERIDIAN VENTURE PARTNERS II, L.P.**

By: MVP II, G.P., L.P., its General Partner

By: Meridian Venture Partners II Co., its  
General Partner

By: /s/ THOMAS A. PENN

Its: *Vice President*

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**SCHEDULE A**

**NAME AND  
ADDRESS OF STOCKHOLDER**  
Meridian Venture Partners II, L.P.  
259 N. Radnor-Chester Road, Suite 130  
Radnor, PA 19087

**ANI SHARES  
BENEFICIALLY OWNED**  
67,599 shares of Series A Preferred Stock  
13,638 shares of Series B Preferred Stock  
11,364 shares of Series C Preferred Stock  
1,376,596 shares of Series D Preferred Stock  
12,477 Shares of Common Stock

## EXHIBIT A

### IRREVOCABLE PROXY

From and after the date hereof and until the Expiration Date (as defined below), the undersigned stockholder ("*Stockholder*") of ANIP Acquisition Company, a Delaware corporation ("*ANT*"), hereby irrevocably (to the full extent permitted by Section 212 of the Delaware General Corporation Law) grants to, and appoints, BioSante Pharmaceuticals, Inc., a **Delaware** corporation (the "*Company*"), and any designee of the Company, and each of them individually, as the sole and exclusive attorney and proxy of the undersigned, with full power of substitution and resubstitution, to vote the Subject Shares (as defined in the Voting Agreement) of the Stockholder, or grant a consent or approval in respect of the Subject Shares of the Stockholder, in a manner consistent with Section 2.2 of the Voting Agreement (as defined below). Upon the undersigned's execution of this Proxy, any and all prior proxies given by the undersigned with respect to any Subject Shares relating to the voting rights expressly provided herein are hereby revoked and the undersigned agrees not to grant any subsequent proxies with respect to the Subject Shares relating to such voting rights at any time prior to the Expiration Date.

This Proxy is irrevocable, is coupled with an interest and is granted pursuant to that certain Voting Agreement (as amended from time to time, the "*Voting Agreement*") of even date herewith, by and among the Company and Stockholder, and is granted in consideration of the Company entering into the Merger Agreement (as defined in the Voting Agreement). As used herein, the term "*Expiration Date*," and all capitalized terms used herein and not otherwise defined, will have the meanings set forth in the Voting Agreement. **The Stockholder agrees that this proxy will be irrevocable until the Expiration Date and is coupled with an interest sufficient at law to support an irrevocable proxy and given to the Company as an inducement to enter into the Merger Agreement and, to the extent permitted under applicable law, will be valid and binding on any person to whom Stockholder may transfer any of his, her or its Subject Shares in breach of the Voting Agreement.** The Stockholder hereby ratifies and confirms all that such irrevocable proxy may lawfully do or cause to be done by virtue hereof.

The attorneys and proxies named above, and each of them, are hereby authorized and empowered by the undersigned, at any time prior to the Expiration Date, to act as the undersigned's attorney and proxy to vote the Subject Shares, and to exercise all voting and other rights of the undersigned with respect to the Subject Shares (including, without limitation, the power to execute and deliver written consents pursuant to Section 228 of the Delaware General Corporation Law), at every annual, special or adjourned meeting of the stockholders of the Company and in every written consent in lieu of such meeting in a manner consistent with Section 2.2 of the Voting Agreement.

This Proxy will be binding upon the heirs, estate, executors, personal representatives, successors and assigns of Stockholder (including any transferee of any of the Subject Shares), and all authority herein conferred or agreed to be conferred will survive the death or incapacity of the Stockholder.

If any provision of this Proxy or any part of any such provision is held under any circumstances to be invalid or unenforceable in any jurisdiction, then (a) such provision or part thereof will, with respect to such circumstances and in such jurisdiction, be deemed amended to conform to applicable laws so as to be valid and enforceable to the fullest possible extent, (b) the invalidity or unenforceability of such provision or part thereof under such circumstances and in such jurisdiction will not affect the validity or enforceability of such provision or part thereof under any other circumstances or in any other jurisdiction, and (c) the invalidity or unenforceability of such provision or part thereof will not affect the validity or enforceability of the remainder of such provision or the validity or enforceability of any other provision of this Proxy. Each provision of this Proxy is separable from every other provision of

this Proxy, and each part of each provision of this Proxy is separable from every other part of such provision.

Dated: October 3, 2012

**MERIDIAN VENTURE PARTNERS II, L.P.**

By: MVP II, G.P., L.P., its General Partner

By: MERIDIAN VENTURE PARTNERS II CO., its  
General Partner

By: /s/ THOAMS A. PENN

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Name: Thomas A. Penn  
Title: *Vice President*

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VOTING AGREEMENT

This VOTING AGREEMENT (this "**Agreement**"), dated as of October , 2012, is by and between ANIP Acquisition Company, a Delaware corporation ("**ANI**"), and the undersigned stockholder ("**Stockholder**") of BioSante Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), identified on the signature page hereto.

A. The Company and ANI are entering into an Agreement and Plan of Merger (as amended from time to time, the "**Merger Agreement**"), dated as of the date hereof, providing for, among other things, the merger of ANI with and into the Company, with the Company continuing as the surviving corporation (the "**Merger**");

B. As of the date hereof, Stockholder is the Beneficial Owner (as defined below) of, and has the sole right to vote and dispose of, that number of shares of common stock and Class C Special Shares (the "**Company Shares**") of the Company set forth beside Stockholder's name on *Schedule A* hereto; and

C. Concurrently with the entry by the Company and ANI into the Merger Agreement, and as a condition and inducement to the willingness of ANI to enter into the Merger Agreement and incur the obligations set forth therein, ANI has required that Stockholder enter into this Agreement;

Accordingly, and in consideration of the foregoing and the mutual representations, warranties, covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

**ARTICLE I.**

**Definitions**

Capitalized terms used but not defined in this Agreement are used in this Agreement with the meanings given to such terms in the Merger Agreement. In addition, for purposes of this Agreement:

"**Affiliate**" means, with respect to any specified person, a person who, at the time of determination, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such specified person. For purposes of this Agreement, with respect to Stockholder, "**Affiliate**" does not include the Company and the persons that directly, or indirectly through one or more intermediaries, are controlled by the Company. For the avoidance of doubt, no officer or director of the Company will be deemed an Affiliate of another officer or director of the Company by virtue of his or her status as an officer or director of the Company.

"**Beneficially Owned**" or "**Beneficial Ownership**" with respect to any securities means having beneficial ownership of such securities (as determined pursuant to Rule 13d-3 under the Exchange Act, disregarding the phrase "within 60 days" in paragraph (d)(1)(i) thereof), including pursuant to any agreement, arrangement or understanding, whether or not in writing. Without duplicative counting of the same securities, securities Beneficially Owned by a person include securities Beneficially Owned by (i) all Affiliates of such person, and (ii) all other persons with whom such person would constitute a "group" within the meaning of Section 13(d) of the Exchange Act and the rules promulgated thereunder.

"**Beneficial Owner**" with respect to any securities means a person that has Beneficial Ownership of such securities.

"**person**" has the meaning ascribed thereto in the Merger Agreement.

"**Subject Shares**" means, with respect to Stockholder, without duplication, (i) the Company Shares owned by Stockholder on the date hereof as described on *Schedule A*, and (ii) any additional Company

Shares acquired by Stockholder or over which Stockholder acquires Beneficial Ownership from and after the date hereof, whether pursuant to existing stock option agreements or otherwise. Without limiting the other provisions of this Agreement, in the event that the Company changes the number of Company Shares issued and outstanding prior to the Expiration Date as a result of a reclassification, stock split (including a reverse stock split), stock dividend or distribution, combination, recapitalization, subdivision, or other similar transaction, the number of Subject Shares subject to this Agreement will be equitably adjusted to reflect such change.

"**Transfer**" means, with respect to a security, the sale, transfer, pledge, hypothecation, encumbrance, assignment or disposition of such security or the Beneficial Ownership thereof, and each option, agreement, arrangement or understanding, whether or not in writing, to effect any of the foregoing. As a verb, "**Transfer**" has a correlative meaning.

## ARTICLE II. Covenants of Stockholder

**2.1 Irrevocable Proxy.** Concurrently with the execution of this Agreement, Stockholder agrees to deliver to ANI a proxy in the form attached hereto as *Exhibit A* (the "**Proxy**"), which will be irrevocable to the extent provided in Section 212 of the Delaware General Corporation Law (the "**DGCL**"), with respect to the Subject Shares referred to therein.

### **2.2 Agreement to Vote.**

(a) At any meeting of the stockholders of the Company held prior to the Expiration Date (as defined in *Section 5.14*), however called, and at every adjournment or postponement thereof prior to the Expiration Date, or in connection with any written consent of, or any other action by, the stockholders of the Company given or solicited prior to the Expiration Date, Stockholder will vote, or provide a consent with respect to, all of the Subject Shares entitled to vote or to consent thereon (i) in favor of the adoption of the Merger Agreement and approval of the issuance of shares of common stock of the Company to the stockholders of ANI pursuant to the Merger Agreement, and any actions required in furtherance thereof, including the BioSante Charter Amendment, and (ii) against any Acquisition Proposal (other than the Merger), against any amendment of the Company's certificate of incorporation or bylaws or any other proposal or transaction involving the Company, the purpose of which amendment or other proposal or transaction is to delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement or change in any manner the voting rights of any capital stock of the Company, and against any other action or agreement that would result in a breach in any material respect of any covenant, representation or warranty or any other obligation or agreement of the Company under the Merger Agreement.

(b) Stockholder will not enter into any agreement with any person (other than ANI) prior to the Expiration Date (with respect to periods prior to or after the Expiration Date) directly or indirectly to vote, grant any proxy or give instructions with respect to the voting of, the Subject Shares in respect of the matters described in *Section 2.2* hereof, or the effect of which would be inconsistent with or violate any provision contained in this *Section 2.2*. Any vote or consent (or withholding of consent) by Stockholder that is not in accordance with this *Section 2.2* will be considered null and void, and the provisions of the Proxy will be deemed to take immediate effect.

### **2.3 Revocation of Proxies; Cooperation.** Stockholder agrees as follows:

(a) Stockholder hereby represents and warrants that any proxies heretofore given in respect of the Subject Shares with respect to the matters described in *Section 2.2(a)* hereof are not irrevocable, and Stockholder hereby revokes any and all prior proxies with respect to such Subject Shares as they relate to such matters. Prior to the Expiration Date, Stockholder will not directly or



indirectly grant any proxies or powers of attorney with respect to the matters set forth in *Section 2.2(a)* hereof (other than to ANI), deposit any of the Subject Shares or enter into a voting agreement (other than this Agreement) with respect to any of the Subject Shares relating to any matter described in *Section 2.2(a)*.

(b) Stockholder will (i) use all reasonable efforts to cooperate with the Company and ANI in connection with the transactions contemplated by the Merger Agreement, and (ii) provide any information reasonably requested by the Company or ANI for any regulatory application or filing sought for such transactions.

**2.4 No Solicitation.** Stockholder acknowledges that the Company is subject to the non-solicitation prohibitions set forth in *Section 5.4* of the Merger Agreement and that the Stockholder has read and understands the terms thereof. Stockholder will not, directly or indirectly, (a) solicit, initiate or knowingly encourage or knowingly facilitate (including by way of furnishing any non-public information relating to the Company or any of its Subsidiaries), or knowingly induce or knowingly take any other action which would reasonably be expected to lead to the making, submission or announcement of, any proposal or inquiry that constitutes, or is reasonably likely to lead to, an Acquisition Proposal; (b) other than informing Persons of the provisions contained in *Section 5.4* of the Merger Agreement, enter into, continue or participate in any discussions or any negotiations regarding any Acquisition Proposal or otherwise take any action to knowingly facilitate or knowingly induce any effort or attempt to make or implement an Acquisition Proposal (including any Acquisition Proposal received prior to the date of this Agreement); (iii) approve, endorse or recommend an Acquisition Proposal or any letter of intent, memorandum of understanding or Contract contemplating an Acquisition Proposal or requiring the Company to abandon or terminate its obligations under the Merger Agreement, or enter into any of the foregoing; or (iv) agree, resolve or commit to do any of the foregoing.

**2.5 No Transfer of Subject Shares; Publicity.** Stockholder agrees that:

(a) Stockholder (i) will not Transfer or agree to Transfer any of the Subject Shares or, with respect to any matter described in *Section 2.2(a)*, grant any proxy or power-of-attorney with respect to any of the Subject Shares, (ii) will take all action reasonably necessary to prevent creditors in respect of any pledge of the Subject Shares from exercising their rights under such pledge, and (iii) will not take any action that would make in a material respect any of its representations or warranties contained herein untrue or incorrect or would have the effect of preventing or disabling the Stockholder from performing any of its material obligations hereunder. Notwithstanding the foregoing, Stockholder may Transfer and agree to Transfer any of the Subject Shares provided that each person to which any such Subject Shares are Transferred has (x) executed a counterpart of this Agreement and a Proxy in the form attached hereto as *Exhibit A* (with such modifications as ANI may reasonably request), and (y) agreed in writing to hold such Subject Shares subject to all of the terms and conditions set forth in this Agreement.

(b) Unless required by Applicable Law or permitted by the Merger Agreement, Stockholder will not, and will not authorize or direct any of its Affiliates or Representatives to, make any press release or public announcement with respect to this Agreement or the Merger Agreement or the transactions contemplated hereby or thereby, without the prior written consent of ANI in each instance.

**ARTICLE III.  
Representations, Warranties and Additional Covenants of Stockholder**

Stockholder represents, warrants and covenants to ANI that:

3.1 **Ownership.** Stockholder is the sole Beneficial Owner and the record and legal owner of the Subject Shares identified on *Schedule A* and such shares constitute all of the capital stock of the Company Beneficially Owned by Stockholder. Stockholder has good and valid title to all of the Subject Shares, free and clear of all Liens, claims, options, proxies, voting agreements and security interests and has the sole right to such Subject Shares and there are no restrictions on rights of disposition or other Liens pertaining to such Subject Shares. None of the Subject Shares is subject to any voting trust or other contract with respect to the voting thereof, and no proxy, power of attorney or other authorization has been granted with respect to any of such Subject Shares.

3.2 **Authority and Non-Contravention.**

(a) Stockholder is an individual acting in such capacity and in Stockholder's capacity as trustee of a trust or other custodial capacity, and not a corporation, limited liability company, partnership or other such entity. Stockholder has all necessary legal capacity to execute and deliver this Agreement and to perform its obligations hereunder and to consummate the transactions contemplated hereby.

(b) Assuming due authorization, execution and delivery of this Agreement by ANI, this Agreement has been duly and validly executed and delivered by Stockholder and constitutes the legal, valid and binding obligation of Stockholder, enforceable against Stockholder in accordance with its terms except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

(c) Stockholder is not nor will it be required to make any filing with or give any notice to, or to obtain any consent from, any person in connection with the execution, delivery or performance of this Agreement or obtain any permit or approval from any Government Authority for any of the transactions contemplated hereby, except to the extent required by Section 13 or Section 16 of the Exchange Act and the rules promulgated thereunder.

(d) Neither the execution and delivery of this Agreement by Stockholder nor the consummation of the transactions contemplated hereby will directly or indirectly (whether with notice or lapse of time or both) (i) conflict with, result in any violation of or constitute a default by Stockholder under any mortgage, bond, indenture, agreement, instrument or obligation to which Stockholder is a party or by which it or any of the Subject Shares are bound, or violate any permit of any Government Authority, or any Applicable Law or Order to which Stockholder, or any of the Subject Shares, may be subject, or (ii) result in the imposition or creation of any Lien upon or with respect to any of the Subject Shares; except, in each case, for conflicts, violations, defaults or Liens that would not individually or in the aggregate be reasonably expected to prevent or materially impair or delay the performance by the Stockholder of its obligations hereunder.

(e) Stockholder has sole voting power and sole power to issue instructions with respect to the matters set forth in Article II hereof and sole power to agree to all of the matters set forth in this Agreement, in each case with respect to all of the Subject Shares, with no limitations, qualifications or restrictions on such rights.

3.3 **Total Shares.** Except as set forth on *Schedule A*, Stockholder is not the Beneficial Owner of, and does not have (whether currently, upon lapse of time, following the satisfaction of any conditions, upon the occurrence of any event or any combination of the foregoing) any right to acquire, and has

no other interest in or voting rights with respect to, any Company Shares or any securities convertible into or exchangeable or exercisable for Company Shares.

3.4 **Reliance.** Stockholder understands and acknowledges that ANI is entering into the Merger Agreement in reliance upon Stockholder's execution, delivery and performance of this Agreement.

**ARTICLE IV.  
Representations, Warranties and Covenants of ANI**

ANI represents, warrants and covenants to Stockholder that, assuming due authorization, execution and delivery of this Agreement by Stockholder, this Agreement constitutes the legal, valid and binding obligation of ANI, enforceable against ANI in accordance with its terms, except (i) to the extent limited by applicable bankruptcy, insolvency or similar laws affecting creditors' rights and (ii) the remedy of specific performance and injunctive and other forms of equitable relief may be subject to equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. ANI has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder. The execution and delivery by ANI of this Agreement and the consummation by ANI of the transactions contemplated hereby have been duly and validly authorized by ANI and no other corporate proceedings on the part of ANI are necessary to authorize this Agreement or to consummate the transactions contemplated hereby. This Agreement has been duly and validly executed and delivered by ANI.

**ARTICLE V.  
Term and Termination**

This Agreement will become effective upon its execution by Stockholder and ANI. This Agreement will terminate upon the earliest of (a) the Effective Time (as defined in the Merger Agreement), (b) the termination of the Merger Agreement in accordance with Article VII thereof, or (c) written notice by ANI to Stockholder of the termination of this Agreement (the date of the earliest of the events described in clauses (a), (b) and (c), the "**Expiration Date**"). The Stockholder will not be liable for money damages to ANI for any breach of this Agreement and the termination of this Agreement will relieve Stockholder from any liability for any inaccuracy in or breach of any representation, warranty or covenant contained in this Agreement. Notwithstanding the foregoing, Article VI of this Agreement shall survive any termination hereof.

**ARTICLE VI.  
General Provisions**

6.1 **Action in Stockholder Capacity Only.** Stockholder is entering into this Agreement solely in Stockholder's capacity as a record holder and beneficial owner, as applicable, of the Subject Shares and not in Stockholder's capacity as a director or officer of the Company. Nothing herein will limit or affect Stockholder's ability to act as an officer or director of the Company.

6.2 **No Ownership Interest.** Nothing contained in this Agreement will be deemed to vest in ANI or any of its Affiliates any direct or indirect ownership or incidents of ownership of or with respect to the Subject Shares. All rights, ownership and economic benefits of and relating to the Subject Shares will remain and belong to Stockholder, and neither ANI nor any of its Affiliates will have any authority to manage, direct, superintend, restrict, regulate, govern or administer any of the policies or operations of the Company or exercise any power or authority to direct Stockholder in the voting of any of the Subject Shares, except as otherwise expressly provided herein or in the Merger Agreement.

6.3 **Notices.** All notices, consents, waivers and other communications under this Agreement must be in writing (including facsimile or similar writing) and must be given:

If to ANI, to:

ANIP Acquisition Company  
210 Main Street West  
Baudette, MN 56623  
Attention: Arthur Przybyl  
Facsimile No: (218) 634-3540

with a copy (which will not constitute notice) to:

SNR Denton US LLP  
1221 Avenue of the Americas  
New York, NY 10020  
Attention: Paul A. Gajer, Esq.  
Facsimile No: (212) 768-6800

If to a Stockholder, to Stockholder's address set forth on *Schedule A*,

or such other address or facsimile number as a party may hereafter specify for the purpose by notice to the other parties hereto. Each notice, consent, waiver or other communication under this Agreement will be effective only (a) if given by facsimile, when the facsimile is transmitted to the facsimile number specified in this Section and the appropriate facsimile confirmation is received or (b) if given by overnight courier or personal delivery when delivered at the address specified in this Section.

6.4 **Further Actions.** Upon the request of any party to this Agreement, the other party will (a) furnish to the requesting party any additional information, (b) execute and deliver, at their own expense, any other documents and (c) take any other actions as the requesting party may reasonably require to more effectively carry out the intent of this Agreement. Stockholder hereby agrees that the Company and ANI may publish and disclose in the Form S-4 Registration Statement and Joint Proxy Statement/Prospectus (including all documents and schedules filed with the SEC) such Stockholder's identity and ownership of Subject Shares and the nature of such Stockholder's commitments, arrangements, and understandings under this Agreement and may further file this Agreement as an exhibit to the Form S-4 Registration Statement or in any other filing made by the Company with the SEC relating to the Merger Agreement or the transactions contemplated thereby. Stockholder agrees to notify ANI promptly of any additional shares of capital stock of the Company of which Stockholder becomes the record or beneficial owner after the date of this Agreement.

6.5 **Entire Agreement and Modification.** This Agreement, the Proxy and any other documents delivered by the parties in connection herewith constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements and understandings, both written and oral, between the parties with respect to its subject matter and constitute (along with the documents delivered pursuant to this Agreement) a complete and exclusive statement of the terms of the agreement between the parties with respect to its subject matter. This Agreement may not be amended, supplemented or otherwise modified except by a written document executed by the party against whose interest the modification will operate. The parties will not enter into any other agreement inconsistent with the terms and conditions of this Agreement and the Proxy, or that addresses any of the subject matters addressed in this Agreement and the Proxy.

**6.6 Drafting and Representation.** The parties agree that the terms and language of this Agreement were the result of negotiations between the parties and, as a result, there will be no presumption that any ambiguities in this Agreement will be resolved against any party. Any controversy over construction of this Agreement will be decided without regard to events of authorship or negotiation.

**6.7 Severability.** Any provision of this Agreement which is prohibited or unenforceable in any jurisdiction will, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without affecting the validity or enforceability of the remaining provisions hereof. Any such prohibition or unenforceability in any jurisdiction will not invalidate or render unenforceable such provision in any other jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, the provision will be interpreted to be only so broad as is enforceable.

**6.8 No Third-Party Rights.** Stockholder may not assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of ANI. ANI may not assign any of its rights or delegate any of its obligations under this Agreement with respect to Stockholder without the prior written consent of Stockholder. This Agreement will apply to, be binding in all respects upon, and inure to the benefit of each of the respective successors, personal or legal representatives, heirs, distributees, devisees, legatees, executors, administrators and permitted assigns of Stockholder and the successors and permitted assigns of ANI. Nothing expressed or referred to in this Agreement will be construed to give any person, other than the parties to this Agreement, any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement except such rights as may inure to a successor or permitted assignee under this Section.

**6.9 Enforcement of Agreement.** Stockholder acknowledges and agrees that ANI could be damaged irreparably if any of the provisions of this Agreement are not performed in accordance with their specific terms and that any breach of this Agreement by Stockholder could not be adequately compensated by monetary damages. Accordingly, Stockholder agrees that, (a) it will waive, in any action for specific performance, the defense of adequacy of a remedy at law, and (b) in addition to any other right or remedy to which ANI may be entitled, at law or in equity, ANI will be entitled to enforce any provision of this Agreement by a decree of specific performance and to temporary, preliminary and permanent injunctive relief to prevent breaches or threatened breaches of any of the provisions of this Agreement, without posting any bond or other undertaking.

**6.10 Waiver.** The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither any failure nor any delay by a party in exercising any right, power or privilege under this Agreement, the Proxy or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Applicable Law, (a) no claim or right arising out of this Agreement, the Proxy or any of the documents referred to in this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in a written document signed by the other party, (b) no waiver that may be given by a party will be applicable except in the specific instance for which it is given, and (c) no notice to or demand on one party will be deemed to be a waiver of any obligation of that party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement, the Proxy or the documents referred to in this Agreement.

**6.11 Governing Law.** This Agreement and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto will be governed by, construed under and interpreted in accordance with the laws of the State of Delaware, without giving effect to principles of conflicts or choice of law.

**6.12 Consent to Jurisdiction.** Any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement, the Proxy or the transactions contemplated hereby or thereby will be brought exclusively in the United States District Court for the District of Delaware or, if such court does not have jurisdiction over the subject matter of such proceeding or if such jurisdiction is not available, in the Court of Chancery of the State of Delaware, County of New Castle, and each of the parties hereby consents to the exclusive jurisdiction of those courts (and of the appropriate appellate courts therefrom) in any suit, action or proceeding and irrevocably waives, to the fullest extent permitted by Applicable Law, any objection which it may now or hereafter have to the laying of the venue of any suit, action or proceeding in any of those courts or that any suit, action or proceeding which is brought in any of those courts has been brought in an inconvenient forum. Process in any suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any of the named courts. Without limiting the foregoing, each party agrees that service of process on it by notice as provided in *Section 5.3* will be deemed effective service of process. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ALL RIGHTS TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY.

**6.13 Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, but all of which, taken together, will constitute one and the same instrument. This Agreement may be executed by facsimile signature (including signatures in Adobe PDF or similar format).

**6.14 Expenses.** Except as otherwise provided in this Agreement, all costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby will be paid by the party incurring such expenses.

**6.15 Headings; Construction.** The headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement. In this Agreement (a) words denoting the singular include the plural and vice versa, (b) "it" or "its" or words denoting any gender include all genders and (c) the word "including" means "including without limitation," whether or not expressed.

*[Signature page follows]*

IN WITNESS WHEREOF, the parties hereto have caused this Voting Agreement to be duly executed as of the day and year first above written.

ANI:

**ANIP ACQUISITION COMPANY**

By: \_\_\_\_\_

Name:

Title:

STOCKHOLDER:

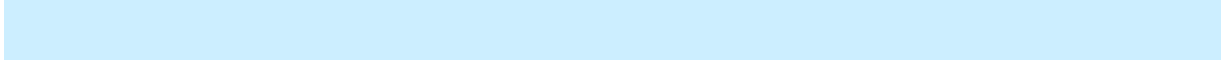
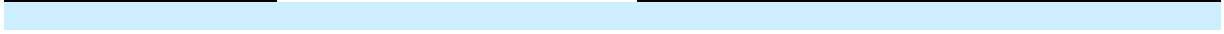
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**SCHEDULE A**

**NAME AND  
ADDRESS OF STOCKHOLDER**

**COMPANY SHARES  
BENEFICIALLY OWNED**





**EXHIBIT A**

**IRREVOCABLE PROXY**

Dated: October , 2012

From and after the date hereof and until the Expiration Date (as defined below), the undersigned stockholder ("*Stockholder*") of BioSante Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), hereby irrevocably (to the full extent permitted by Section 212 of the Delaware General Corporation Law) grants to, and appoints, ANIP Acquisition Company, a Delaware corporation ("*ANI*"), and any designee of ANI, and each of them individually, as the sole and exclusive attorney and proxy of the undersigned, with full power of substitution and resubstitution, to vote the Subject Shares (as defined in the Voting Agreement) of the Stockholder, or grant a consent or approval in respect of the Subject Shares of the Stockholder, in a manner consistent with Section 2.2 of the Voting Agreement (as defined below). Upon the undersigned's execution of this Proxy, any and all prior proxies given by the undersigned with respect to any Subject Shares relating to the voting rights expressly provided herein are hereby revoked and the undersigned agrees not to grant any subsequent proxies with respect to the Subject Shares relating to such voting rights at any time prior to the Expiration Date.

This Proxy is irrevocable, is coupled with an interest and is granted pursuant to that certain Voting Agreement (as amended from time to time, the "*Voting Agreement*") of even date herewith, by and among ANI and Stockholder, and is granted in consideration of ANI entering into the Merger Agreement (as defined in the Voting Agreement). As used herein, the term "*Expiration Date*," and all capitalized terms used herein and not otherwise defined, will have the meanings set forth in the Voting Agreement. **The Stockholder agrees that this proxy will be irrevocable until the Expiration Date and is coupled with an interest sufficient at law to support an irrevocable proxy and given to ANI as an inducement to enter into the Merger Agreement and, to the extent permitted under applicable law, will be valid and binding on any person to whom Stockholder may transfer any of his, her or its Subject Shares in breach of the Voting Agreement.** The Stockholder hereby ratifies and confirms all that such irrevocable proxy may lawfully do or cause to be done by virtue hereof.

The attorneys and proxies named above, and each of them, are hereby authorized and empowered by the undersigned, at any time prior to the Expiration Date, to act as the undersigned's attorney and proxy to vote the Subject Shares, and to exercise all voting and other rights of the undersigned with respect to the Subject Shares (including, without limitation, the power to execute and deliver written consents pursuant to Section 228 of the Delaware General Corporation Law), at every annual, special or adjourned meeting of the stockholders of the Company and in every written consent in lieu of such meeting in a manner consistent with Section 2.2 of the Voting Agreement.

This Proxy will be binding upon the heirs, estate, executors, personal representatives, successors and assigns of Stockholder (including any transferee of any of the Subject Shares), and all authority herein conferred or agreed to be conferred will survive the death or incapacity of the Stockholder.

If any provision of this Proxy or any part of any such provision is held under any circumstances to be invalid or unenforceable in any jurisdiction, then (a) such provision or part thereof will, with respect to such circumstances and in such jurisdiction, be deemed amended to conform to applicable laws so as to be valid and enforceable to the fullest possible extent, (b) the invalidity or unenforceability of such provision or part thereof under such circumstances and in such jurisdiction will not affect the validity or enforceability of such provision or part thereof under any other circumstances or in any other jurisdiction, and (c) the invalidity or unenforceability of such provision or part thereof will not affect the validity or enforceability of the remainder of such provision or the validity or enforceability of any other provision of this Proxy. Each provision of this Proxy is separable from every other provision of

this Proxy, and each part of each provision of this Proxy is separable from every other part of such provision.

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(Signature of Stockholder)

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(Print Name of Stockholder)

Number of Subject Shares owned of record or Beneficially  
Owned as of the date of this Proxy:

**FORM OF LOCK-UP AGREEMENT**

October 3, 2012

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, Illinois 60069

Ladies and Gentlemen:

Reference is made to the Agreement and Plan of Merger (the "*Merger Agreement*"), by and between BioSante Pharmaceuticals, Inc., a Delaware corporation ("*BioSante*"), and ANIP Acquisition Company (d/b/a ANI Pharmaceuticals, Inc.), a Delaware corporation ("*ANI*"), dated as of the date hereof. Pursuant to the Merger Agreement, BioSante and ANI plan to effect a merger (the "*Merger*") in which ANI will be merging with and into BioSante, with BioSante being the surviving corporation. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Merger Agreement.

To induce both parties to continue their efforts in connection with the Merger contemplated by the Merger Agreement, the undersigned agrees that, without BioSante's prior written consent, the undersigned will not, for a period commencing on the closing date of the Merger and ending 180 days after such date (the "*Lock-Up Period*"), directly or indirectly, or publicly announce an intention to (a) offer, sell, contract to sell, grant any option or contract to purchase, purchase any option or contract to sell, or otherwise dispose of any shares of BioSante's common stock, par value \$0.0001 per share, to be received by the undersigned in the Merger (the "*Common Stock*"), (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing restriction (i) shall not limit the right of the undersigned during the Lock-Up Period to make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any securities convertible into, exercisable for, or exchangeable for shares of Common Stock so long as there are no sales of such shares of Common Stock during the Lock-Up Period and (ii) shall include, without limitation, any securities issued to the undersigned in the Merger in exchange for securities of ANI.

Any Common Stock acquired by the undersigned in the open market on or after the closing of the Merger will not be subject to this agreement. A transfer of Common Stock to an immediate family member or a trust for the benefit of the undersigned or an immediate family member (including by will or intestacy) or a distribution to partners, members or shareholders of the undersigned may be made, provided that the transferee agrees in writing prior to such transfer to be bound by the terms of this agreement as if it were a party hereto. For purposes of this agreement, "immediate family" means any relationship by blood, marriage or adoption, not more remote than first cousin (including lineal descendants, stepchildren, father, mother, brother or sister of the undersigned or the undersigned's spouse).

The foregoing restriction shall not apply: (1) to bona fide gifts by the undersigned, provided that (a) each resulting transferee of Common Stock executes and delivers to BioSante an agreement certifying that such transferee is bound by the terms of this agreement and has been in compliance with the terms hereof since the date first above written as if it had been an original party hereto and (b) to the extent any interest in Common Stock is retained by the undersigned (or such spouse or family member), such Common Stock shall remain subject to the restrictions contained in this agreement or (2) to sale, transfer or other transaction in or relating to shares of Common Stock in connection with any merger of BioSante with or into any other entity or tender offer by BioSante or any other entity

for the Common Stock, in each case which transaction has been approved by at least a majority of BioSante's Board of Directors.

The undersigned agrees and consents to the entry of stop transfer instructions with BioSante's transfer agent and registrar relating to the transfer of the undersigned's shares of Common Stock except in compliance with the restrictions described above and authorizes BioSante, during the Lock-Up Period, to cause BioSante's transfer agent to place a notation on book-entry notations representing the Common Stock.

The undersigned represents and warrants that the undersigned has full power and authority to enter into this agreement, and that, upon request, the undersigned will execute any additional documents reasonably necessary to carry out the transactions contemplated hereby. Any obligations created by this agreement shall be binding upon the heirs, devisees, personal representatives, successors and assigns of the undersigned.

The undersigned agrees that in the event of any breach or threatened breach by the undersigned of any covenant, obligation or other provision contained in this agreement, then BioSante shall be entitled (in addition to any other remedy that may be available to BioSante) to (a) a decree or order of specific performance to enforce the observance and performance of such covenant, obligation or other provision and (b) an injunction restraining such breach or threatened breach.

Any term or provision of this agreement that is invalid or unenforceable under applicable law, such provision shall be excluded from this agreement and the balance of this agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

The provisions of this agreement may not be amended or waived by the undersigned party without the prior written consent of BioSante.

This agreement shall be governed by and construed in accordance with the laws of the State of Delaware without regard to such State's principles of conflict of laws. Delivery of a signed copy of this letter by facsimile transmission shall be effective as delivery of the original hereof.

Very truly yours,

By:

\_\_\_\_\_  
Name:  
Title:

## CONTINGENT VALUE RIGHTS AGREEMENT

THIS CONTINGENT VALUE RIGHTS AGREEMENT, dated as of [ ], 2013 (this "**Agreement**"), is entered into by and among BioSante Pharmaceuticals, Inc., a Delaware corporation ("**BioSante**"), ANIP Acquisition Company, a Delaware corporation ("**ANI**"), Computershare Inc., a Delaware corporation, and its fully owned subsidiary Computershare Trust Company, N.A., a federally chartered trust company (collectively, the "**Rights Agent**" or individually, "**Computershare**" and the "**Trust Company**", respectively) and as initial CVR Registrar (as defined herein), and [ ], acting solely in his capacity as representative of the Holders (the "**Holder Representative**").

A. BioSante and ANI have entered into an Agreement and Plan of Merger dated as of October 3, 2012 (the "**Merger Agreement**"), pursuant to which ANI will merge with and into BioSante (the "**Merger**") (the surviving entity of the Merger is referred to in this Agreement as the "**Company**").

B. Prior to the effectiveness of the Merger, BioSante wishes to create and issue contingent value rights relating to the LibiGel Assets (as defined below) to the record holders of BioSante Common Stock (as hereinafter defined) as of a record date prior to the effectiveness of the Merger.

C. On [ ], 2013 the Board of Directors of BioSante authorized and declared a dividend of one CVR (as hereinafter defined) for each share of Common Stock outstanding at the Close of Business (as hereinafter defined) on the Record Date (as hereinafter defined).

D. BioSante has done all things necessary to make the CVRs, when issued hereunder, the valid obligations of the Company in accordance with their terms.

Accordingly, and in consideration of the premises and the consummation of the transactions referred to above, it is mutually covenanted and agreed, for the benefit of the Holders (as hereinafter defined), as follows:

### ARTICLE I. Definitions

#### 1.1 Definitions.

(a) For all purposes of this Agreement, except as otherwise expressly provided or unless the context otherwise requires:

(i) all accounting terms used herein and not expressly defined herein have the meanings assigned to such terms in accordance with United States generally accepted accounting principles, as in effect on the date hereof;

(ii) unless the context otherwise requires, words describing the singular number include the plural and vice versa, words denoting any gender include all genders and words denoting natural Persons include corporations, partnerships and other Persons and vice versa;

(iii) the words "include" and "including" and variations thereof will not be deemed to be terms of limitation, but rather will be deemed to be followed by the words "without limitation";

(iv) the terms "hereof", "hereunder", "herein" and words of similar import refer to this Agreement as a whole and not to any particular Article, Section or provision of this Agreement; and

(v) the Article and Section headings contained in this Agreement are for reference purposes only and do not limit or otherwise affect any of the substance of this Agreement.

(b) The following terms have the meanings ascribed to them as follows:

"**Achievement Certificate**" has the meaning set forth in *Section 2.4(a)*.

"**Affiliates**" means, with respect to any Person, any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Person.

"**Board of Directors**" means the board of directors of the Company.

"**Board Resolution**" means a copy of a resolution certified by the secretary or an assistant secretary of the Company to have been duly adopted by the Board of Directors and to be in full force and effect on the date of such certification, and delivered to the Rights Agent and the Holder Representative.

"**Business Day**" means each day other than a Saturday, Sunday or any other day on which commercial banks in New York, New York are authorized or required by law to close.

"**Change of Control**" means (x) (i) any consolidation or merger of the Company with or into any other corporation or entity or Person or (ii) any other corporate reorganization, in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, own less than 50% of the voting power of the surviving entity immediately after such consolidation, merger or reorganization, or (y) any sale of all or substantially all of the assets of the Company.

"**Close of Business**" on any given date means 5:00 p.m., Central Time, on such date; *provided, however*, that if such date is not a Business Day it will mean 5:00 p.m., Central Time, on the next succeeding Business Day.

"**Common Stock**" means the common stock, \$0.0001 par value, of BioSante.

"**CVR Payment Amount**" means an amount equal to sixty-six percent (66%) of the Net Proceeds actually received by the Company (or any of its Subsidiaries) in connection with a LibiGel Transaction occurring after the date of the Merger Agreement and prior to the Outside Date; *provided, however*, that in no event will the aggregate amount of CVR Payment Amounts paid to the Holders pursuant to this Agreement exceed \$40,000,000. All payments of any CVR Payment Amount to any Holders pursuant to this Agreement must be made in cash, and for that purpose any property other than cash received as Net Proceeds will be either, as determined by the board of directors of the Company in its discretion within sixty (60) days of the receipt of such property, (i) valued in good faith by the board of directors of the Company and the value so determined will be treated as Net Proceeds as of the date such non-cash property was received by the Company or (ii) the non-cash property will be excluded from Net Proceeds until converted into or exchanged for or disposed of by the Company for cash.

"**CVR Payment Date**" means the date (if any and if ever) that a CVR Payment Amount is payable by the Company to the Holders, which date will be established pursuant to *Section 2.4*.

"**CVR Register**" has the meaning set forth in *Section 2.3(b)*.

"**CVR Registrar**" has the meaning set forth in *Section 2.3(b)*.

"**CVRs**" means the contingent value rights issued by BioSante pursuant to this Agreement.

"**Effective Time**" means the effective time of the Merger, pursuant to the Merger Agreement. Company shall notify the Rights Agent of the Effective Time promptly after the occurrence thereof.

"**Holder**" means a Person in whose name a CVR is registered in the CVR Register.

"**Holder Representative**" means the Holder Representative named in the first paragraph of this Agreement, until a successor Holder Representative has become such pursuant to the applicable provisions of this Agreement, and thereafter "**Holder Representative**" will mean such successor Holder Representative.

"**LibiGel Assets**" means the intellectual property rights and know-how and related assets, that currently are or have been used in the research, development and manufacture of BioSante's LibiGel® product, a proprietary transdermal testosterone formulation subject to a license agreement with Antares Pharma Inc., including all BioSante generated regulatory filings, clinical and non-clinical safety, efficacy and pharmacokinetic data, compiled by or on behalf of BioSante in connection with the development of the LibiGel product.

"**LibiGel Transaction**" means the full or partial sale, license, transfer or other disposition entered into by the Company or any Subsidiary prior to Outside Date with any Person (other than any of the Company's Subsidiaries) with respect to the LibiGel Assets. For purposes of clarity, more than one transaction can constitute a LibiGel Transaction pursuant to this Agreement.

"**Net Proceeds**" means the aggregate payments received after the Effective Time in connection with a LibiGel Transaction, less (i) all transaction costs and expenses, such as legal and investment banker fees, incurred or payable by the Company (or any of its stockholders or Affiliates) after the Effective Time in connection with the LibiGel Transaction, (ii) all applicable sales, income and other taxes in respect of the LibiGel Transaction that are incurred or payable after the Effective Time (net of any Company tax benefits resulting from the payment of any CVR Payment Amount to Holders pursuant to this Agreement), (iii) all out-of-pocket costs incurred or payable after the Effective Time in connection with or relating to the CVRs, including the Rights Agent Fee and legal fees, reimbursement of expenses or indemnity payments payable in respect of the CVRs or the administration thereof or calculation of Net Proceeds, but excluding any fees or expenses related to the Company's internal accounting for the CVRs, (iv) all of the Company's remaining costs or liabilities (whether incurred before or after the completion of the Merger) related to the development of the LibiGel Assets or the conduct, completion or termination of any clinical trials, safety studies or other research studies associated with the LibiGel Assets (in each case, to the extent not paid prior to completion of the Merger or included pursuant to Section 2.2(a)(vii)(E) of the Merger Agreement in the calculation of Net Cash as of the Determination Date), and (v) in the case of Net Proceeds received by a Subsidiary which is not wholly owned by the Company, a percentage of such Net Proceeds equal to the percentage of the equity of such Subsidiary not owned by the Company or its wholly owned Subsidiaries. Amounts placed in escrow or earnout or other contingent payments in connection with a LibiGel Transaction will not be considered Net Proceeds unless and until (and only to the extent that) such amounts are released from escrow or otherwise paid to the Company (or any of its stockholders or Affiliates) in cash. With respect to any LibiGel Transaction that occurs prior to the Outside Date, any such escrow, earnout or other contingent payments released or paid after the Outside Date will be deemed to be Net Proceeds, so long as such amount is actually received within three years of the Outside Date. For purposes of determining any income taxes relating to a LibiGel Transaction, the tax rate used will be the highest marginal rate that would be paid by the Company in connection with similar types of income for the year in which such LibiGel Transaction occurs (taking into account all tax benefits, including net operating losses, of the Company for such period).

"**Non-Achievement Certificate**" has the meaning set forth in *Section 2.4(b)*.

"**Notice of Objection**" has the meaning set forth in *Section 2.4(c)*.

"**Objection Period**" has the meaning set forth in *Section 2.4(c)*.

"**Officer's Certificate**" means a certificate signed by the chief executive officer, president, chief financial officer or secretary of the Company, in his or her capacity as such an officer, and delivered to the Rights Agent and the Holder Representative.

"**Outside Date**" means the date that is ten (10) years after the date hereof.

"**Permitted Transfer**" means: (i) the transfer of any or all of the CVRs (upon the death of the Holder) by will or intestacy; (ii) transfer by instrument to an inter vivos or testamentary trust in which

the CVRs are to be passed to beneficiaries upon the death of the trustee; (iii) transfers made pursuant to a court order of a court of competent jurisdiction (such as in connection with divorce, bankruptcy or liquidation); (iv) if the Holder is a partnership or limited liability company, a pro-rata distribution by the transferring partnership or limited liability company to its partners or members, as applicable; (v) a transfer made by operation of law (including a consolidation or merger) or in connection with the dissolution, liquidation or termination of any corporation, limited liability company, partnership or other entity; (vi) a transfer from a participant's account in a tax-qualified employee benefit plan to the participant or to such participant's account in a different tax-qualified employee benefit plan or to a tax-qualified individual retirement account for the benefit of such participant; or (vii) a transfer from a participant in a tax-qualified employee benefit plan, who received the CVRs from such participant's account in such tax-qualified employee benefit plan, to such participant's account in a different tax-qualified employee benefit plan or to a tax-qualified individual retirement account for the benefit of such participant.

"**Person**" means an individual, a corporation, a limited liability company, a partnership, an association, a trust or any other entity or organization, including a government or political subdivision or any agency or instrumentality thereof.

"**Record Date**" means [                      ].

"**Rights Agent**" means the Rights Agent named in the first paragraph of this Agreement, until a successor Rights Agent has become such pursuant to the applicable provisions of this Agreement, and thereafter "Rights Agent" will mean such successor Rights Agent.

"**Rights Agent Fee**" means the agreed-upon fee of the Rights Agent to act in such capacity pursuant to the terms of this Agreement.

"**Subsidiary**" means any corporation or other entity in which the Company owns at least a majority of the stock or other equity interests.

"**Surviving Person**" has the meaning set forth in *Section 6.1(a)(i)*.

## **ARTICLE II. Contingent Value Rights**

### **2.1 Authority; Issuance of CVRs; Appointment of Rights Agent.**

(a) BioSante has all requisite corporate power and authority to execute and deliver this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of BioSante and no other corporate proceedings on the part of BioSante are necessary to authorize this Agreement or to consummate the transactions contemplated hereby. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will, (i) result in any Violation (as defined in the Merger Agreement) pursuant to any provision of the Certificate of Incorporation or By-laws of BioSante, or (ii) result in any Violation of any loan or credit agreement, note, mortgage, indenture, lease, Company Benefit Plan (as defined in the Merger Agreement) or other agreement, obligation, instrument, permit, concession, franchise, license, judgment, order, decree, statute, law, ordinance, rule or regulation applicable to BioSante or its properties or assets which Violation, in the case of clause (ii), individually or in the aggregate, would reasonably be expected to be material to BioSante. No consent, approval, order or authorization of, or registration, declaration or filing with, any Government Authority (as defined in the Merger Agreement) is required by or with respect to BioSante in connection with the execution and delivery of this Agreement by BioSante or the consummation by BioSante of the transactions contemplated hereby.



(b) One CVR will be issued with respect to each share of Common Stock that is outstanding as of the Close of Business on the Record Date.

(c) The Company hereby appoints the Trust Company as the Rights Agent to act as rights agent for the Company in accordance with the instructions hereinafter set forth in this Agreement, and Computershare as the service provider to the Trust Company and as processor of all payments received or made by or on behalf of Company under this Agreement, and the Trust Company and Computershare hereby accept such appointment.

## 2.2 Nontransferable.

The CVRs may not be sold, assigned, transferred, pledged, encumbered or in any other manner transferred or disposed of, in whole or in part, other than through a Permitted Transfer.

## 2.3 No Certificate; Registration; Registration of Transfer; Change of Address.

(a) The CVRs will be issued in book-entry form only and will not be evidenced by a certificate or other instrument.

(b) The Rights Agent will keep a register (the "**CVR Register**") for the registration of CVRs. The Rights Agent is hereby initially appointed "**CVR Registrar**" for the purpose of registering CVRs and transfers of CVRs as herein provided. Upon any change in the identity of the Rights Agent, the successor Rights Agent will automatically also become the successor CVR Registrar.

(c) Subject to the restrictions on transferability set forth in *Section 2.2*, every request made to transfer a CVR must be in writing and accompanied by a written instrument or instruments of transfer and any other requested documentation in a form reasonably satisfactory to the Company and the CVR Registrar, duly executed by the registered Holder or Holders thereof or by the duly appointed legal representative thereof or by a duly authorized attorney, including the evidence of authority of the party presenting the CVR for transfer which authority may include, if applicable, a signature guarantee from an eligible guarantor institution participating in a signature guarantee program approved by the Securities Transfer Association. A request for a transfer of a CVR must be accompanied by such documentation establishing that the transfer is a Permitted Transfer as may be reasonably requested by the Company and/or the CVR Registrar, if appropriate. Upon receipt of such written request and materials, the CVR Registrar will, subject to its reasonable determination that the transfer instrument is in proper form and the transfer otherwise complies with the other terms and conditions herein, register the transfer of the CVRs in the CVR Register. All duly transferred CVRs registered in the CVR Register will be the valid obligations of the Company, evidencing the same right and will entitle the transferee to the same benefits and rights under this Agreement, as those previously held by the transferor. No transfer of a CVR will be valid until registered in the CVR Register, and any transfer not duly registered in the CVR Register will be void and invalid. All costs and expenses related to any transfer or assignment of the CVRs (including the cost of any transfer tax) will be the responsibility of the transferor.

(d) A Holder (or an authorized representative thereof) may make a request to the CVR Registrar to change such Holder's address of record in the CVR Register. Upon receipt of such request, the CVR Registrar will promptly record the change of address in the CVR Register.

## 2.4 Payment Procedures.

(a) Promptly following the occurrence of a LibiGel Transaction as to which the Holders are entitled to receive a CVR Payment Amount, but in no event later than thirty (30) days after the occurrence of such a LibiGel Transaction, the Company will deliver to the Holder Representative and the Rights Agent a certificate (the "**Achievement Certificate**"), certifying that the Holders are entitled to receive a CVR Payment Amount (and setting forth the calculation of the CVR Payment Amount).

No transaction described in *Section 6.1(a)* hereof will give the Holders the right to receive a CVR Payment Amount.

(b) If no LibiGel Transaction has occurred on or before the Outside Date, then, as soon as reasonably practicable after the Outside Date, but in no event later than thirty (30) days after the Outside Date, the Company will deliver to the Holder Representative and the Rights Agent a certificate (the "**Non-Achievement Certificate**"), stating that no LibiGel Transaction occurred.

(c) Within sixty (60) calendar days after distribution by the Rights Agent of a Non-Achievement Certificate (the "**Objection Period**"), the Holder Representative may deliver a written notice to the Company specifying that the Holder Representative objects to the determination of the Company that no LibiGel Transaction occurred (a "**Notice of Objection**") and stating the reason upon which the Holder Representative has determined that a LibiGel Transaction has occurred on or before the Outside Date. Any dispute arising from a Notice of Objection will be resolved in accordance with the procedure set forth in *Section 8.10*, which decision will be binding on the parties hereto and every Holder.

(d) If a Notice of Objection has not been delivered to the Company within the Objection Period, then the Holders will have no right to receive the CVR Payment Amount, and the Company and the Rights Agent will have no further obligations with respect to the CVR Payment Amount.

(e) If the Company delivers an Achievement Certificate to the Holder Representative and the Rights Agent or if the CVR Payment Amount is determined to be payable pursuant to *Section 2.4(c)* above, the Company will establish a CVR Payment Date that is the earlier of (i) one hundred (100) days after the end of the Company's fiscal year (or, if the applicable CVR Payment Date is greater than twelve million five hundred thousand dollars (\$12,500,000), fifty (50) days after the end of the Company's fiscal quarter) during which the Achievement Certificate is delivered or (ii) thirty (30) days after the date of final determination pursuant to *Section 2.4(c)* above, as applicable. At least five (5) Business Days before such CVR Payment Date, the Company will cause the CVR Payment Amount in cash to be delivered to the Rights Agent, and in turn, on the CVR Payment Date, Computershare will distribute the CVR Payment Amount to the Holders (each Holder being entitled to receive its pro rata share of the CVR Payment Amount based on the number of CVRs held (as of the date of the Achievement Certificate or the date of final determination pursuant to *Section 2.4(c)* above, as applicable) by such Holder as reflected on the CVR Register) (i) by check mailed to the address of each such respective Holder as reflected in the CVR Register as of the Close of Business on the last Business Day before such CVR Payment Date, or, (ii) with respect to any Holder who has provided the Rights Agent with wire transfer instructions meeting the Rights Agent's requirements, by wire transfer of immediately available funds to such account.

(f) The Company will be entitled to deduct and withhold, or cause to be deducted or withheld, from each CVR Payment Amount otherwise payable pursuant to this Agreement, such amounts as the Company or the applicable Affiliate of the Company is required to deduct and withhold with respect to the making of such payment under the Internal Revenue Code, or any provision of state, local or foreign tax law. To the extent that amounts are so withheld or paid over to or deposited with the relevant governmental entity, such withheld amounts will be treated for all purposes of this Agreement as having been paid to the Holder in respect of which such deduction and withholding was made.

(g) Subject to prior execution and delivery by the Holder Representative of a reasonable and customary confidentiality agreement, the Company will promptly furnish to the Holder Representative all information and documentation in connection with this Agreement and the CVRs that the Holder Representative may reasonably request in connection with the determination of whether the LibiGel Transaction has occurred. The Company will promptly furnish to the Rights Agent all information and documentation in connection with this Agreement and the CVRs that the Rights Agent may reasonably request in order to perform under this Agreement.

(h) The Company acknowledges that the bank accounts maintained by Computershare in connection with the services provided under this Agreement will be in Computershare's name and that Computershare may receive investment earnings in connection with the investment at Computershare's risk and for its benefit of funds held in those accounts from time to time.

**2.5 No Voting, Dividends or Interest; No Equity or Ownership Interest in the Company.**

- (a) The CVRs will not have any voting or dividend rights, and interest will not accrue on any amounts payable on the CVRs to any Holder.
- (b) The CVRs will not represent any equity or ownership interest in the Company.

**2.6 No Obligation on Company.**

Notwithstanding anything else in this Agreement to the contrary, the Company's only obligation in connection with (a) any continued operation of, development of or investment in the LibiGel Assets, (b) pursuing, negotiating or entering into one or more LibiGel Transactions, and (c) the terms and conditions of any LibiGel Transaction will be to act or forbear from acting in good faith; *provided, however*, that to the extent that the Company makes a decision to pursue, engage in, negotiate or enter into a LibiGel Transaction, the Company will use commercially reasonable efforts to seek to ensure that the consideration from such LibiGel Transaction is paid to the Company in cash and prior to the Outside Date.

**ARTICLE III.  
The Rights Agent**

**3.1 Certain Duties and Responsibilities.**

(a) The Rights Agent will not have any liability for any actions taken or not taken in connection with this Agreement, except to the extent of its willful misconduct, bad faith or gross negligence. No provision of this Agreement will require the Rights Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties hereunder or in the exercise of any of its rights or powers. Notwithstanding anything contained herein to the contrary, the Rights Agent's aggregate liability under this Agreement, or from all services provided or omitted to be provided under this Agreement, whether in contract, or in tort, or otherwise, is limited to, and shall not exceed, the amounts paid hereunder by the Company to the Rights Agent as fees and charges, but not including reimbursable expenses.

(b) The Holder Representative may direct the Rights Agent to act on behalf of the Holders in enforcing any of its or their rights hereunder, including the delivery of any Notice of Objection and negotiation or arbitration pursuant to *Section 8.10*. The Rights Agent will be under no obligation to institute any action, suit or legal proceeding or to take any other action likely to involve material expense unless the Holder Representative will furnish the Rights Agent with reasonable security and indemnity for any costs and expenses that may be incurred. All rights of action under this Agreement may be enforced by the Rights Agent, and any action, suit or proceeding instituted by the Rights Agent will be brought in its name as Rights Agent, and any recovery of judgment will be for the ratable benefit of all the Holders, as their respective rights or interests may appear.

**3.2 Certain Rights of Rights Agent.**

The Rights Agent undertakes to perform such duties and only such duties as are specifically set forth in this Agreement, and no implied covenants or obligations will be read into this Agreement against the Rights Agent. In addition:

- (a) the Rights Agent may rely and will be protected in acting or refraining from acting upon any resolution, certificate, statement, instrument, opinion, report, notice, request, direction, consent, order

or other paper or document believed by it to be genuine and to have been signed or presented by the proper party or parties;

(b) whenever the Rights Agent will deem it desirable that a matter be proved or established before taking, suffering or omitting any action hereunder, the Rights Agent may, in the absence of willful misconduct, bad faith or gross negligence on its part, rely upon an Officer's Certificate;

(c) the Rights Agent may engage and consult with counsel of its selection and the written advice of such counsel or any opinion of counsel will be full and complete authorization and protection in respect of any action taken, suffered or omitted by it hereunder in good faith and in reliance thereon;

(d) in the event of arbitration, the Rights Agent may engage and consult with tax experts, valuation firms and other experts and third parties that it, in its sole and absolute discretion, deems appropriate or necessary to enable it to discharge its duties hereunder;

(e) the permissive rights of the Rights Agent to do things enumerated in this Agreement will not be construed as a duty;

(f) the Rights Agent will not be required to give any note or surety in respect of the execution of such powers or otherwise in respect of the premises;

(g) the Company agrees to indemnify the Rights Agent for, and hold the Rights Agent harmless against, any loss, liability, claim, demands, suits or expense (in each case pertaining to the Rights Agent's own account only) arising out of or in connection with the Rights Agent's duties under this Agreement, including the costs and expenses of defending the Rights Agent against any claims, charges, demands, suits or loss, unless such loss has been determined by a court of competent jurisdiction to be a result of the Rights Agent's willful misconduct, bad faith or gross negligence; and

(h) the Company agrees (i) to pay the fees and expenses of the Rights Agent in connection with this Agreement, as set forth on *Schedule 1* hereto, and (ii) to reimburse the Rights Agent for all taxes and governmental charges, reasonable expenses and other charges of any kind and nature incurred by the Rights Agent in the execution of this Agreement (other than taxes measured by the Rights Agent's net income). The Rights Agent will also be entitled to reimbursement from the Company for all reasonable and necessary out-of-pocket expenses (including reasonable fees and expenses of the Rights Agent's counsel and agent) paid or incurred by it in connection with the administration by the Rights Agent of its duties hereunder. An invoice for the Rights Agent Fee will be rendered a reasonable time before, and paid on, the effective date of the applicable transaction. An invoice for any out-of-pocket expenses and per item fees realized will be rendered and payable within thirty (30) calendar days after receipt by the Company. The Company agrees to pay to Rights Agent any amounts, including fees and expenses, payable in favor of the Rights Agent in connection with any dispute, resolution or arbitration arising under or in connection with the Agreement; and any fees and expenses, payable by the Company in favor of the Rights Agent or payable in favor of the Company related to such dispute, resolution or arbitration will be offset against the CVR Payment Amount, if any, or any payment to be made thereafter under this Agreement.

### **3.3 Resignation and Removal; Appointment of Successor.**

(a) The Rights Agent may resign at any time by giving written notice thereof to the Company specifying a date when such resignation will take effect, which notice will be sent at least thirty (30) days before the date so specified.

(b) If the Rights Agent will resign, be removed or become incapable of acting, the Company, by way of a Board Resolution, will promptly appoint a qualified successor Rights Agent who may (but need not) be a Holder but will not be an officer of the Company. The successor Rights Agent so appointed will, forthwith upon its acceptance of such appointment in accordance with this *Section 3.3(b)*, become the successor Rights Agent.

(c) The Company will give notice of each resignation and each removal of a Rights Agent and each appointment of a successor Rights Agent by mailing written notice of such event by first-class mail, postage prepaid, to the Holders as their names and addresses appear in the CVR Register and by delivering notice to the Holder Representative. Each notice will include the name and address of the successor Rights Agent. If the Company fails to send such notice within five (5) Business Days after acceptance of appointment by a successor Rights Agent, upon Company's request the successor Rights Agent will cause such notice to be mailed at the expense of the Company.

#### **3.4 Acceptance of Appointment by Successor.**

Every successor Rights Agent appointed hereunder will execute, acknowledge and deliver to the Company and to the retiring Rights Agent an instrument accepting such appointment and a counterpart of this Agreement, and thereupon such successor Rights Agent, without any further act, deed or conveyance, will become vested with all the rights, powers, trusts and duties of the retiring Rights Agent; *provided, however*, that upon the request of the Company or the successor Rights Agent, such retiring Rights Agent will cooperate in the transfer of all relevant data, including the CVR Register, to the successor Rights Agent.

### **ARTICLE IV. Covenants**

#### **4.1 List of Holders.**

The Company will furnish or cause to be furnished to the Holder Representative and the Rights Agent in such form as the Company receives from its transfer agent (or other agent performing similar services for the Company), the names, addresses and shareholdings of registered holders of Common Stock as of the Close of Business on the Record Date. The Company will promptly furnish an electronic copy of the CVR Register to the Holder Representative upon written request from the Holder Representative.

#### **4.2 Payment of CVR Payment Amount.**

The Company will duly and promptly pay the CVR Payment Amount, if any, in immediately available funds, to the Rights Agent to be distributed to the Holders in the manner provided for in *Section 2.4* and in accordance with the terms of this Agreement.

### **ARTICLE V. Amendments**

#### **5.1 Amendments Without Consent of Holder Representative.**

(a) Without the consent of the Holder Representative or the Rights Agent, the Company, when authorized by a Board Resolution, at any time and from time to time, may enter into one or more amendments hereto, for any of the following purposes:

(i) to evidence the succession of another Person to the Company and the assumption by any such successor of the covenants of the Company herein in a transaction contemplated by *Section 6.1* hereof; or

(ii) to evidence the termination of the CVR Registrar and the succession of another Person as a successor CVR Registrar and the assumption by any successor of the obligations of the CVR Registrar herein.

(b) Without the consent of the Holder Representative, the Company, when authorized by a Board Resolution, together with the Rights Agent, in the Rights Agent's sole and absolute discretion, may at any time and from time to time, enter into one or more amendments hereto:

(i) to evidence the succession of another Person as a successor Rights Agent and the assumption by any successor of the covenants and obligations of the Rights Agent herein;

(ii) to add to the covenants of the Company such further covenants, restrictions, conditions or provisions as the Board of Directors and the Rights Agent will consider to be for the protection of the Holders;

(iii) to cure any ambiguity, to correct or supplement any provision herein that may be defective or inconsistent with any other provision herein; *provided, however*, that in each case, such provisions will not materially adversely affect the interests of the Holders; or

(iv) to add, eliminate or change any provision of this Agreement unless such addition, elimination or change is adverse to the interests of the Holders.

(c) Promptly after the execution by the Company and the Rights Agent of any amendment pursuant to the provisions of this *Section 5.1*, the Company will deliver a notice thereof to the Holder Representative, setting forth in general terms the substance of such amendment.

## **5.2 Amendments with Consent of Holder Representative.**

Subject to *Section 5.1* (which amendments pursuant to *Section 5.1* may be made without the consent of the Holder Representative), the Company, when authorized by a Board Resolution, and the Rights Agent and the Holder Representative may enter into one or more amendments hereto for the purpose of adding, eliminating or changing any or all provisions of this Agreement.

## **5.3 Execution of Amendments.**

In executing any amendment permitted by this *Article V*, the Rights Agent will be entitled to receive, and will be fully protected in relying upon, an opinion of counsel of the Company, at Company's sole expense, stating that the execution of such amendment is authorized or permitted by this Agreement. The Rights Agent may, but is not obligated to, enter into any such amendment that affects the Rights Agent's own rights, privileges, covenants or duties under this Agreement or otherwise.

## **5.4 Effect of Amendments.**

Upon the execution of any amendment under this *Article V*, this Agreement will be modified in accordance therewith, such amendment will form a part of this Agreement for all purposes and every Holder will be bound thereby.

## **5.5 Amendment Prior to Effective Time.**

This Agreement may not be amended prior to the Effective Time without the prior written consent of ANI.

**ARTICLE VI.**  
**Consolidation, Merger, Sale or Conveyance**

**6.1 The Company May Consolidate, Etc.**

(a) Except as contemplated by the Merger, the Company will not consolidate with or merge into any other Person or convey, transfer or lease its properties and assets substantially as an entirety to any Person, unless:

(i) the Person formed by such consolidation or into which the Company is merged or the Person that acquires by conveyance or transfer, or that leases, the properties and assets of the Company substantially as an entirety (the "**Surviving Person**") will expressly assume payment (if and to the extent required hereunder) of amounts on all the CVRs and the performance of every duty and covenant of this Agreement on the part of the Company to be performed or observed; and

(ii) the Company has delivered to the Holder Representative and the Rights Agent an Officer's Certificate, stating that such consolidation, merger, conveyance, transfer or lease complies with this Article VI and that all conditions precedent herein provided for relating to such transaction have been complied with.

(b) In the event the Company conveys, transfers or leases its properties and assets substantially as an entirety in accordance with the terms and conditions of this *Section 6.1*, the Surviving Person will be liable for the payment of the CVR Payment Amount and the performance of every duty and covenant of this Agreement on the part of the Company to be performed or observed.

(c) Notwithstanding the foregoing, in the event the Company conveys, transfers or leases its properties and assets substantially as an entirety in accordance with the terms and conditions of this *Section 6.1* or a Change of Control shall occur, then the Company will have the right to purchase all, but not less than all, of the outstanding CVRs for an amount equal to their then fair market value as determined in good faith by an independent third party appraisal firm retained by the Company; provided, however, that such right may not be exercised by the Company or the Surviving Person prior to the fifth anniversary of the Effective Time. Within sixty (60) calendar days after distribution by the Rights Agent of the purchase price for the CVRs as determined in accordance with the terms of this *Section 6.1(c)*, the Holder Representative may deliver a written notice to the Company specifying that the Holder Representative objects to the determination of the purchase price for the CVRs as determined in accordance with the terms of this *Section 6.1(c)*. Any dispute arising from such an objection will be resolved in accordance with the procedure set forth in *Section 8.10*, which decision will be binding on the parties hereto and every Holder (including the Holders not participating therein).

**6.2 Successor Substituted.**

Upon any consolidation of or merger by the Company with or into any other Person, or any conveyance, transfer or lease of the properties and assets substantially as an entirety to any Person in accordance with *Section 6.1*, the Surviving Person will succeed to, and be substituted for, and may exercise every right and power of, the Company under this Agreement with the same effect as if the Surviving Person had been named as the Company herein, and thereafter the predecessor Person will be relieved of all obligations and covenants under this Agreement and the CVRs.

**ARTICLE VII.**  
**The Holder Representative**

**7.1 Appointment.**

Effective upon the issuance of the CVRs under this terms of this Agreement, and without any further act of any of Holders, the Holder Representative is appointed as the representative of the Holders and as the attorney-in-fact and agent for and on behalf of each Holder for purposes of this Agreement and will take such actions to be taken by the Holder Representative under this Agreement and such other actions on behalf of such Holders as it may deem necessary or appropriate in connection with or to consummate the transactions contemplated hereby, including (i) executing and delivering this Agreement and any other ancillary documents and negotiating and executing any amendments, modifications, waivers or changes thereto as to which the Holder Representative, in its sole discretion, has consented (provided that any waiver or amendment that adversely and disproportionately affects the rights or obligations of one or more Holders as compared to other Holders will require the prior written consent of a majority in interest of the disproportionately affected Holders), (ii) agreeing to, negotiating, entering into settlements and compromises of, complying with orders of courts with respect to, and otherwise administering and handling any claims under this Agreement on behalf of such Holders, and (iii) taking all other actions that are either necessary or appropriate in the judgment of the Holder Representative for the accomplishment of the foregoing or contemplated by the terms of this Agreement. The Holder Representative hereby accepts such appointment and agrees to serve as such without compensation. The appointment of the Holder Representative as each Holder's attorney-in-fact revokes any power of attorney heretofore granted that authorized any other Person to represent such Holder with regard to this Agreement and any other agreements or documents executed or delivered in connection with this Agreement. The Holder Representative is the sole and exclusive representative of each of the Holders for any purpose provided for by this Agreement.

**7.2 Actions of Holder Representative.**

(a) A decision, act, consent or instruction of the Holder Representative hereunder will constitute a decision, act, consent or instruction of all Holders and will be final, binding and conclusive upon each such Holder, and the Company and the Rights Agent may rely upon any such decision, act, consent or instruction of the Holder Representative as being the decision, act, consent or instruction of each and every such Holder. The Company and the Rights Agent will be relieved from any liability to any Person for any acts done by them in accordance with such decision, act, consent or instruction of the Holder Representative.

(b) The Holder Representative will incur no liability with respect to any action taken or suffered by any Holder in reliance upon any notice, direction, instruction, consent, statement or other document believed by such Holder Representative to be genuine and to have been signed by such Holder (and will have no responsibility to determine the authenticity thereof), nor for any other action or inaction, except the gross negligence, bad faith or willful misconduct of the Holder Representative. In all questions arising under this Agreement, the Holder Representative may rely on the advice of outside counsel, and the Holder Representative will not be liable to any Holder for anything done, omitted or suffered in good faith by Holder Representative based on such advice.

(c) The Holders will severally (on a pro rata basis, based on the number of CVRs held by each Holder) but not jointly indemnify the Holder Representative and hold the Holder Representative harmless against any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Holder Representative and arising out of or in connection with the acceptance or administration of the Holder Representative's duties hereunder, including the reasonable fees and expenses of any legal counsel or other advisors reasonably retained by the Holder Representative.



(d) In connection with providing services under this Agreement, the Holder Representative (i) will be compensated by the Company at the rate of \$[ ] per hour for such services and (ii) will be reimbursed by the Company for all reasonable fees and expenses incurred in providing such services. Any such compensation and fees and expenses will be paid by the Company within thirty (30) days of the receipt of an invoice from the Holder Representative and will be offset against the CVR Payment Amount, if any.

**7.3 Removal; Appointment of Successor.**

(a) At any time Holders representing at least a majority of the outstanding CVRs may, by written consent, appoint another Person as Holder Representative. Notice together with a copy of the written consent appointing such Person and bearing the signatures of Holders of at least a majority of the outstanding CVRs must be delivered to the Company and the Rights Agent not less than ten (10) days prior to such appointment. Such appointment will be effective upon the later of the date indicated in the consent or the date ten (10) days after such consent is received by the Company and the Rights Agent.

(b) If the Holder Representative becomes unable or unwilling to continue in his or its capacity as the Holder Representative, or if the Holder Representative resigns as a Holder Representative, the Holder Representative may appoint a new representative as the Holder Representative. If the Holder Representative is unable or unwilling to appoint a successor Holder Representative, then [ ] will serve as the Holder Representative. Notice and a copy of the written consent appointing such new representative must be delivered to the Company and the Rights Agent. Such appointment will be effective upon the later of the date indicated in the consent or the date ten (10) days after such consent is received by the Company and the Rights Agent.

**7.4 Grant of Authority.**

The grant of authority provided for in this Article VII (i) is coupled with an interest and will be irrevocable and survive the death, incompetency, bankruptcy or liquidation of any Holder, and (ii) will survive the consummation of the Merger. The provisions of this Article III will be binding upon the executors, heirs, legal representatives, successors and assigns of each Holder, and any references in this Agreement to any Holder or the Holders will mean and include the successors to such Holder's rights hereunder, whether pursuant to testamentary disposition, the laws of descent and distribution or otherwise.



any case where notice to Holders is given by mail, neither the failure to mail such notice, nor any defect in any notice so mailed, to any particular Holder will affect the sufficiency of such notice with respect to other Holders.

### **8.3 Assignment; Third Party Beneficiaries.**

Neither this Agreement nor any right, interest or obligation hereunder may be assigned by any of the parties hereto without the prior written consent of the other parties hereto; *provided, however*, that the Rights Agent may, without further consent of the other parties hereto, assign any of its rights and obligations hereunder to any affiliated transfer agent registered under Rule 17Ac2-1 promulgated under the Securities Exchange Act of 1934, as amended. This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Nothing in this Agreement, express or implied, will give to any Person (other than the parties hereto, the Holders and their permitted successors and assigns hereunder) any benefit or any legal or equitable right, remedy or claim under this Agreement or under any covenant or provision herein contained, all such covenants and provisions being for the sole benefit of the parties hereto, the Holders and their permitted successors and assigns. The Holders will not have any rights or remedies with respect to the CVRs except as expressly set forth herein.

### **8.4 Governing Law.**

This Agreement and the CVRs will be governed by the laws of the State of Delaware without reference to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction.

### **8.5 Legal Holidays.**

If a CVR Payment Date is not a Business Day, then, notwithstanding any provision of this Agreement to the contrary, any payment required to be made in respect of the CVRs on such date need not be made on such date, but may be made on the next succeeding Business Day with the same force and effect as if made on the CVR Payment Date.

### **8.6 Severability Clause.**

Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction will not affect the validity or enforceability of the remaining terms and provisions of this Agreement or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If a final judgment of a court of competent jurisdiction declares that any term or provision of this Agreement is invalid or unenforceable, the parties hereto agree that the court making such determination will have the power to limit such term or provision, to delete specific words or phrases or to replace such term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement will be valid and enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable term or provision.

### **8.7 Counterparts.**

This Agreement may be executed in any number of counterparts and by facsimile signatures, any one of which need not contain the signatures of more than one party and each of which will be an original, but all such counterparts taken together will constitute one and the same instrument. The exchange of copies of this Agreement or amendments thereto and of signature pages by facsimile transmission or by e-mail transmission in portable digital format (or similar format) will constitute effective execution and delivery of such instrument(s) as to the parties and may be used in lieu of the

original Agreement or amendment for all purposes. Signatures of the parties transmitted by facsimile or by e-mail transmission in portable digital format (or similar format) will be deemed to be their original signatures for all purposes.

#### **8.8 Termination.**

This Agreement will terminate and be of no further force or effect, and the parties hereto will have no liability hereunder, upon the earliest to occur of (a) the payment of the last possible CVR Payment Amount due hereunder, (b) if a Notice of Objection is not delivered within the Objection Period, the expiration of the Objection Period or (c) in the event of the delivery of a Notice of Objection, either (i) the final determination in accordance with this Agreement that no LibiGel Transaction has been achieved or (ii) the fulfillment of any payment obligation required pursuant to a final determination made in accordance with this Agreement.

#### **8.9 Entire Agreement.**

This Agreement represents the entire understanding of the parties hereto with reference to the CVRs and this Agreement supersedes any and all other oral or written agreements made with respect to the CVRs.

#### **8.10 Arbitration.**

(a) Before any arbitration pursuant to *Section 8.10(b)*, the Company, the Rights Agent and the Holder Representative will negotiate in good faith for a period of thirty (30) days to resolve any controversy or claim arising out of or relating to this Agreement or the breach thereof.

(b) Any claim which the Holders have the right to assert hereunder (including any claims brought by the Holder Representative on behalf of the Holders) will be settled by arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules, and judgment on the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The Company, the Rights Agent and/or the Holder Representative may initiate an arbitration for any matter relating to this Agreement. However, in the event of a dispute arising from the delivery of a Notice of Objection, the sole matter to be settled by arbitration will be whether a LibiGel Transaction has occurred on or before the Outside Date. The number of arbitrators will be one, and such arbitrator will be selected by the American Arbitration Association. The place of the arbitration will be Chicago, Illinois. The arbitrator will be a lawyer or retired judge or accountant with experience in the pharmaceutical industry and with mergers and acquisitions. Except as may be required by law, neither a party nor the arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of the other parties (provided that the Holder Representative may disclose to the Holders any such information without the consent of the Company). Any award payable in favor of the Holders or the Rights Agent as a result of arbitration will be distributed to the Holders on a pro rata basis, based on the number of CVRs held by each Holder. The Company will pay all fees and expenses of the arbitration, including the costs and expenses billed by the arbitrator in connection with the performance of its duties described herein; *provided, however*, that if the arbitrator rules in favor of the Company, the arbitrator's fees and expenses will be offset against the CVR Payment Amount, if any, or any payment to be made thereafter hereunder. Each party will be responsible for its own attorney fees, expenses and costs of investigation.

#### **8.11 Survival.**

Notwithstanding anything in this Agreement to the contrary, all provisions regarding indemnification, warranty, liability and limits thereon, and confidentiality and protection of proprietary rights and trade secrets shall survive the termination or expiration of this Agreement.

## 8.12 Force Majeure.

Notwithstanding anything to the contrary contained herein, the Rights Agent shall not be liable for any delays or failures in performance resulting from acts beyond its reasonable control including, without limitation, acts of God, terrorist acts, shortage of supply, breakdowns or malfunctions, interruptions or malfunctions of computer facilities, or loss of data due to power failures or mechanical difficulties with information storage or retrieval systems, labor difficulties, war or civil unrest.

## 8.13 Confidentiality

(a) *Definition.* "**Confidential Information**" shall mean any and all technical or business information relating to a party, including, without limitation, financial, marketing and product development information, stockholder information (including any non-public information of such stockholder), and proprietary information that is disclosed or otherwise becomes known to the other party or its affiliates, agents or representatives before or during the term of this Agreement. Confidential Information constitutes trade secrets and is of great value to the owner (or its affiliates). Confidential Information shall not include any information that is: (a) already known to the other party or its affiliates at the time of the disclosure, provided that such prior knowledge can be substantiated by the written records of such party; (b) publicly known at the time of the disclosure or becomes publicly known through no wrongful act or failure of the other party; (c) subsequently disclosed to the other party or its affiliates on a non-confidential basis by a third party not having a confidential relationship with the owner and which rightfully acquired such information; or (d) independently developed by one party without access to the Confidential Information of the other, provided that such independent development can be substantiated by the written records of such party. This Agreement, including all of its terms and conditions, will not be deemed to be Confidential Information and may be publicly disclosed by BioSante and ANI.

(b) *Use and Disclosure.* All Confidential Information of a party will be held in confidence by the other party with at least the same degree of care as such party protects its own confidential or proprietary information of like kind and import, but not less than a reasonable degree of care. Neither party will disclose in any manner Confidential Information of the other party in any form to any person or entity without the other party's prior consent. However, each party may disclose relevant aspects of the other party's Confidential Information to its officers, affiliates, agents, subcontractors and employees to the extent reasonably necessary to perform its duties and obligations under this Agreement. Without limiting the foregoing, each party will implement such physical and other security measures and controls as are necessary to protect (a) the security and confidentiality of Confidential Information; (b) against any threats or hazards to the security and integrity of Confidential Information; and (c) against any unauthorized access to or use of Confidential Information. To the extent that a party delegates any duties and responsibilities under this Agreement to an agent or other subcontractor, the party ensures that such agent and subcontractor are contractually bound to confidentiality terms consistent with the terms of this Section 8.13.

(c) *Required or Permitted Disclosure.* In the event that any requests or demands are made for the disclosure of Confidential Information, other than requests to Rights Agent for stockholder records pursuant to standard subpoenas from state or federal government authorities (e.g., divorce and criminal actions), the party receiving such request will promptly notify the other party to secure instructions from an authorized officer of such party as to such request and to enable the other party the opportunity to obtain a protective order or other confidential treatment, unless such notification is otherwise prohibited by law or court order. Each party expressly reserves the right, however, to disclose Confidential Information to any person whenever it is advised by counsel that it may be held liable for the failure to disclose such Confidential Information or if required by law or court order.

(d) *Unauthorized Disclosure.* As may be required by law and without limiting any party's rights in respect of a breach of this *Section 8.13*, each party will promptly:

(i) notify the other party in writing of any unauthorized possession, use or disclosure of the other party's Confidential Information by any person or entity that may become known to such party;

(ii) furnish to the other party full details of the unauthorized possession, use or disclosure; and

(iii) use commercially reasonable efforts to prevent a recurrence of any such unauthorized possession, use or disclosure of Confidential Information.

(e) *Costs.* Each party will bear the costs it incurs as a result of compliance with this *Section 8.13*.

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IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized officers as of the day and year first above written.

**BIOSANTE PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**ANIP ACQUISITION COMPANY**

By: \_\_\_\_\_  
Name:  
Title:

**COMPUTERSHARE TRUST COMPANY, N.A. AND  
COMPUTERSHARE INC.  
(ON BEHALF OF BOTH ENTITIES)**

By: \_\_\_\_\_  
Name:  
Title:

**[HOLDER REPRESENTATIVE]**

By: \_\_\_\_\_  
Name:  
Title:

October 3, 2012

The Board of Directors  
BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, IL 60069

Members of the Board:

You have asked Oppenheimer & Co. Inc. ("*Oppenheimer*") to render a written opinion ("*Opinion*") to the Board of Directors of BioSante Pharmaceuticals, Inc. (the "*Company*") as to the fairness, from a financial point of view, to the Company, of the Exchange Ratios, as defined in the draft of the Agreement and Plan of Merger, dated as of October 2, 2012 (the "*Agreement*"), to be entered into between the Company and ANIP Acquisition Company ("*ANI*"). The Agreement provides for, among other things, the merger of ANI with and into the Company (the "*Merger*"), pursuant to which each outstanding share of the series D convertible preferred stock, par value \$0.10 per share, of ANI ("*ANI Series D Preferred Stock*") will be converted into the right to receive the number of shares of common stock, par value \$0.0001 per share, of the Company (the "*Company Common Stock*") equal to the Series D Exchange Ratio (as defined in the Agreement). Further, pursuant to the Agreement under certain circumstances, holders of (i) series C convertible preferred stock, par value \$0.10 per share, of ANI, (ii) series B convertible preferred stock, par value \$0.10 per share, of ANI and (iii) series A convertible preferred stock, par value \$0.10 per share, of ANI may receive shares of Company Common Stock equal to the applicable Exchange Ratio (as defined in the Agreement).

In arriving at our Opinion, we:

- (a) reviewed the draft, dated October 2, 2012, of the Agreement;
- (b) reviewed publicly available financial statements of the Company for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of the Company for the six months ended June 30, 2012;
- (c) reviewed audited financial statements of ANI for the fiscal years ended December 31, 2010 and 2011, and unaudited financial statements of ANI for the eight months ended August 31, 2012, and other relevant financial and operating data furnished to Oppenheimer by ANI;
- (d) reviewed financial forecasts and estimates relating to the Company prepared by the management of the Company;
- (e) reviewed financial forecasts and estimates relating to ANI prepared by the management of ANI;
- (f) held discussions with the senior managements of the Company and ANI with respect to the businesses and prospects of the Company and ANI, respectively;
- (g) reviewed the historical market prices and trading volumes of Company Common Stock;
- (h) reviewed and analyzed certain publicly available financial data for companies we deemed relevant in evaluating ANI;
- (i) analyzed the estimated present value of the future cash flows of ANI based on financial forecasts and estimates prepared by the management of ANI;
- (j) reviewed other public information concerning the Company; and
- (k) performed such other analyses, reviewed such other information and considered such other factors as we deemed appropriate.



In rendering our Opinion, we relied upon and assumed, without independent verification or investigation, the accuracy and completeness of all of the financial and other information publicly available or provided to or discussed with us by the Company and ANI and their respective employees, representatives and affiliates or otherwise reviewed by us. With respect to the respective financial forecasts and estimates relating to the Company and ANI referred to above, we have assumed, at the direction of the respective management of each of the Company and ANI and with the Company's consent, without independent verification or investigation, that such forecasts and estimates were reasonably prepared on bases reflecting the best available information, estimates and judgments of the respective managements of the Company and ANI as to the future financial condition and operating results of the Company and ANI and the other matters covered thereby and that the financial results reflected in such forecasts and estimates will be achieved at the times and in the amounts projected. At the direction of representatives of the Company, we also assumed that the final terms of the Agreement will not vary materially from those set forth in the draft reviewed by us. We have assumed, with the consent of the Company, that the Merger will qualify for federal income tax purposes as a reorganization under Section 368(a) of the Internal Revenue Code of 1986, as amended. We also have assumed, with the consent of the Company, that the Merger will be consummated in accordance with its terms without waiver, modification or amendment of any material term, condition or agreement and in compliance with all applicable laws and other requirements and that, in the course of obtaining the necessary regulatory or third party approvals, consents and releases with respect to the Merger, no delay, limitation, restriction or condition will be imposed that would have an adverse effect on the Company or the contemplated benefits of the Merger. We have neither made nor obtained any independent evaluations or appraisals of the assets or liabilities, contingent or otherwise, of the Company or ANI.

We are not expressing any opinion as to the underlying valuation, future performance or long term viability of the Company or ANI, the actual value of Company Common Stock when issued in the Merger or the price at which Company Common Stock will trade at any time. We express no view as to, and our Opinion does not address, any terms or other aspects or implications of the Merger (other than the Exchange Ratios to the extent expressly specified herein) or any aspect or implication of any other agreement, arrangement or understanding entered into in connection with the Merger or otherwise, including, without limitation, the fairness of the amount or nature of the compensation resulting from the Merger to any individual officers, directors or employees of the Company, or class of such persons, relative to the Exchange Ratios. Notably, we express no view as to, and our Opinion does not address, the right of the Company to issue to the holders of Company Common Stock a dividend prior to the consummation of the Merger of contingent value rights with respect to certain payments arising from the sale, transfer, license or a similar transaction relating to the Company's LibiGel program in accordance with the terms of a form of Contingent Value Rights Agreement in the form agreed to by the Company and ANI.

In addition, we express no view as to, and our Opinion does not address, the underlying business decision of the Company to proceed with or effect the Merger nor does our Opinion address the relative merits of the Merger as compared to any alternative business strategies that might exist for the Company or the effect of any other transaction in which the Company might engage. Our Opinion is necessarily based on the information available to us and general economic, financial and stock market conditions and circumstances as they exist and can be evaluated by us on the date hereof. It should be understood that, although subsequent developments may affect this Opinion, we do not have any obligation to update, revise or reaffirm the Opinion.

We are not legal, tax, regulatory or accounting advisors and have relied on the assessments made by the Company and its advisors with respect to such issues. This Opinion does not address any legal, tax, regulatory or accounting matters. In addition, this Opinion does not constitute a solvency opinion

or a fair value opinion, and we have not evaluated the solvency or fair value of the Company under any federal or state laws relating to bankruptcy, insolvency or similar matters.

The issuance of this Opinion was approved by an authorized committee of Oppenheimer. As part of our investment banking business, we are regularly engaged in valuations of businesses and securities in connection with acquisitions and mergers, underwritings, secondary distributions of securities, private placements and valuations for other purposes.

We have acted as financial advisor to the Company in connection with the Merger and will receive a fee for our services, a portion of which will be payable upon delivery of this Opinion and a portion of which is contingent upon consummation of the Merger. In the two years prior to the date hereof, we have provided financial advisory services for the Company unrelated to the Merger and have received fees from the Company in connection with certain of such services. During the same period, we provided certain private placement and/or arranger services for ANI unrelated to the Merger; however, the proposed transaction was not consummated and we did not receive any compensation therefor. We may also seek to provide financial advisory services to the Company in the future and expect to receive fees for the rendering of these services. In the ordinary course of business, we and our affiliates may actively trade securities of the Company for our and our affiliates' own accounts and for the accounts of customers and, accordingly, may at any time hold a long or short position in such securities. In addition, a senior member of the Oppenheimer Investment Banking team assisting the Company in connection with the Merger currently owns approximately 1,400 shares of Company Common Stock, which were acquired in 2009.

Based upon and subject to the foregoing, and such other factors as we deemed relevant, it is our opinion that, as of the date hereof, the Exchange Ratios provided for in the Agreement are fair, from a financial point of view, to the Company. This Opinion is for the use of the Board of Directors of the Company in its evaluation of the Merger and may not be used for any other purpose without our prior written consent, except that a copy of this Opinion may be included in its entirety in any filing that the Company is required to make with the Securities and Exchange Commission in connection with the Merger if such inclusion is required by law. In addition, this Opinion does not constitute a recommendation to any stockholder as to how such stockholder should vote or act with respect to any matters relating to the Merger.

Very truly yours,

OPPENHEIMER & CO. INC.

SECTION 262 OF THE DELAWARE GENERAL CORPORATION LAW

§ 262. Appraisal rights.

(a) Any stockholder of a corporation of this State who holds shares of stock on the date of the making of a demand pursuant to subsection (d) of this section with respect to such shares, who continuously holds such shares through the effective date of the merger or consolidation, who has otherwise complied with subsection (d) of this section and who has neither voted in favor of the merger or consolidation nor consented thereto in writing pursuant to § 228 of this title shall be entitled to an appraisal by the Court of Chancery of the fair value of the stockholder's shares of stock under the circumstances described in subsections (b) and (c) of this section. As used in this section, the word "stockholder" means a holder of record of stock in a corporation; the words "stock" and "share" mean and include what is ordinarily meant by those words; and the words "depository receipt" mean a receipt or other instrument issued by a depository representing an interest in 1 or more shares, or fractions thereof, solely of stock of a corporation, which stock is deposited with the depository.

(b) Appraisal rights shall be available for the shares of any class or series of stock of a constituent corporation in a merger or consolidation to be effected pursuant to § 251 (other than a merger effected pursuant to § 251(g) of this title), § 252, § 254, § 255, § 256, § 257, § 258, § 263 or § 264 of this title:

(1) Provided, however, that no appraisal rights under this section shall be available for the shares of any class or series of stock, which stock, or depository receipts in respect thereof, at the record date fixed to determine the stockholders entitled to receive notice of the meeting of stockholders to act upon the agreement of merger or consolidation, were either (i) listed on a national securities exchange or (ii) held of record by more than 2,000 holders; and further provided that no appraisal rights shall be available for any shares of stock of the constituent corporation surviving a merger if the merger did not require for its approval the vote of the stockholders of the surviving corporation as provided in § 251(f) of this title.

(2) Notwithstanding paragraph (b)(1) of this section, appraisal rights under this section shall be available for the shares of any class or series of stock of a constituent corporation if the holders thereof are required by the terms of an agreement of merger or consolidation pursuant to §§ 251, 252, 254, 255, 256, 257, 258, 263 and 264 of this title to accept for such stock anything except:

- a. Shares of stock of the corporation surviving or resulting from such merger or consolidation, or depository receipts in respect thereof;
- b. Shares of stock of any other corporation, or depository receipts in respect thereof, which shares of stock (or depository receipts in respect thereof) or depository receipts at the effective date of the merger or consolidation will be either listed on a national securities exchange or held of record by more than 2,000 holders;
- c. Cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a. and b. of this section; or
- d. Any combination of the shares of stock, depository receipts and cash in lieu of fractional shares or fractional depository receipts described in the foregoing paragraphs (b)(2)a., b. and c. of this section.

(3) In the event all of the stock of a subsidiary Delaware corporation party to a merger effected under § 253 or § 267 of this title is not owned by the parent immediately prior to the merger, appraisal rights shall be available for the shares of the subsidiary Delaware corporation.

(c) Any corporation may provide in its certificate of incorporation that appraisal rights under this section shall be available for the shares of any class or series of its stock as a result of an amendment to its certificate of incorporation, any merger or consolidation in which the corporation is a constituent corporation or the sale of all or substantially all of the assets of the corporation. If the certificate of incorporation contains such a provision, the procedures of this section, including those set forth in subsections (d) and (e) of this section, shall apply as nearly as is practicable.

(d) Appraisal rights shall be perfected as follows:

(1) If a proposed merger or consolidation for which appraisal rights are provided under this section is to be submitted for approval at a meeting of stockholders, the corporation, not less than 20 days prior to the meeting, shall notify each of its stockholders who was such on the record date for notice of such meeting (or such members who received notice in accordance with § 255(c) of this title) with respect to shares for which appraisal rights are available pursuant to subsection (b) or (c) of this section that appraisal rights are available for any or all of the shares of the constituent corporations, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Each stockholder electing to demand the appraisal of such stockholder's shares shall deliver to the corporation, before the taking of the vote on the merger or consolidation, a written demand for appraisal of such stockholder's shares. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such stockholder's shares. A proxy or vote against the merger or consolidation shall not constitute such a demand. A stockholder electing to take such action must do so by a separate written demand as herein provided. Within 10 days after the effective date of such merger or consolidation, the surviving or resulting corporation shall notify each stockholder of each constituent corporation who has complied with this subsection and has not voted in favor of or consented to the merger or consolidation of the date that the merger or consolidation has become effective; or

(2) If the merger or consolidation was approved pursuant to § 228, § 253, or § 267 of this title, then either a constituent corporation before the effective date of the merger or consolidation or the surviving or resulting corporation within 10 days thereafter shall notify each of the holders of any class or series of stock of such constituent corporation who are entitled to appraisal rights of the approval of the merger or consolidation and that appraisal rights are available for any or all shares of such class or series of stock of such constituent corporation, and shall include in such notice a copy of this section and, if 1 of the constituent corporations is a nonstock corporation, a copy of § 114 of this title. Such notice may, and, if given on or after the effective date of the merger or consolidation, shall, also notify such stockholders of the effective date of the merger or consolidation. Any stockholder entitled to appraisal rights may, within 20 days after the date of mailing of such notice, demand in writing from the surviving or resulting corporation the appraisal of such holder's shares. Such demand will be sufficient if it reasonably informs the corporation of the identity of the stockholder and that the stockholder intends thereby to demand the appraisal of such holder's shares. If such notice did not notify stockholders of the effective date of the merger or consolidation, either (i) each such constituent corporation shall send a second notice before the effective date of the merger or consolidation notifying each of the holders of any class or series of stock of such constituent corporation that are entitled to appraisal rights of the effective date of the merger or consolidation or (ii) the surviving or resulting corporation shall send such a second notice to all such holders on or within 10 days after such effective date; provided, however, that if such second notice is sent more than 20 days following the sending of the first notice, such second notice need only be sent to each stockholder who is entitled to appraisal rights and who has demanded appraisal of such holder's shares in accordance with this subsection. An affidavit of the secretary or assistant secretary or of the transfer agent of the corporation that is required to give

either notice that such notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of determining the stockholders entitled to receive either notice, each constituent corporation may fix, in advance, a record date that shall be not more than 10 days prior to the date the notice is given, provided, that if the notice is given on or after the effective date of the merger or consolidation, the record date shall be such effective date. If no record date is fixed and the notice is given prior to the effective date, the record date shall be the close of business on the day next preceding the day on which the notice is given.

(e) Within 120 days after the effective date of the merger or consolidation, the surviving or resulting corporation or any stockholder who has complied with subsections (a) and (d) of this section hereof and who is otherwise entitled to appraisal rights, may commence an appraisal proceeding by filing a petition in the Court of Chancery demanding a determination of the value of the stock of all such stockholders. Notwithstanding the foregoing, at any time within 60 days after the effective date of the merger or consolidation, any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party shall have the right to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation. Within 120 days after the effective date of the merger or consolidation, any stockholder who has complied with the requirements of subsections (a) and (d) of this section hereof, upon written request, shall be entitled to receive from the corporation surviving the merger or resulting from the consolidation a statement setting forth the aggregate number of shares not voted in favor of the merger or consolidation and with respect to which demands for appraisal have been received and the aggregate number of holders of such shares. Such written statement shall be mailed to the stockholder within 10 days after such stockholder's written request for such a statement is received by the surviving or resulting corporation or within 10 days after expiration of the period for delivery of demands for appraisal under subsection (d) of this section hereof, whichever is later. Notwithstanding subsection (a) of this section, a person who is the beneficial owner of shares of such stock held either in a voting trust or by a nominee on behalf of such person may, in such person's own name, file a petition or request from the corporation the statement described in this subsection.

(f) Upon the filing of any such petition by a stockholder, service of a copy thereof shall be made upon the surviving or resulting corporation, which shall within 20 days after such service file in the office of the Register in Chancery in which the petition was filed a duly verified list containing the names and addresses of all stockholders who have demanded payment for their shares and with whom agreements as to the value of their shares have not been reached by the surviving or resulting corporation. If the petition shall be filed by the surviving or resulting corporation, the petition shall be accompanied by such a duly verified list. The Register in Chancery, if so ordered by the Court, shall give notice of the time and place fixed for the hearing of such petition by registered or certified mail to the surviving or resulting corporation and to the stockholders shown on the list at the addresses therein stated. Such notice shall also be given by 1 or more publications at least 1 week before the day of the hearing, in a newspaper of general circulation published in the City of Wilmington, Delaware or such publication as the Court deems advisable. The forms of the notices by mail and by publication shall be approved by the Court, and the costs thereof shall be borne by the surviving or resulting corporation.

(g) At the hearing on such petition, the Court shall determine the stockholders who have complied with this section and who have become entitled to appraisal rights. The Court may require the stockholders who have demanded an appraisal for their shares and who hold stock represented by certificates to submit their certificates of stock to the Register in Chancery for notation thereon of the pendency of the appraisal proceedings; and if any stockholder fails to comply with such direction, the Court may dismiss the proceedings as to such stockholder.

(h) After the Court determines the stockholders entitled to an appraisal, the appraisal proceeding shall be conducted in accordance with the rules of the Court of Chancery, including any rules specifically governing appraisal proceedings. Through such proceeding the Court shall determine the

fair value of the shares exclusive of any element of value arising from the accomplishment or expectation of the merger or consolidation, together with interest, if any, to be paid upon the amount determined to be the fair value. In determining such fair value, the Court shall take into account all relevant factors. Unless the Court in its discretion determines otherwise for good cause shown, interest from the effective date of the merger through the date of payment of the judgment shall be compounded quarterly and shall accrue at 5% over the Federal Reserve discount rate (including any surcharge) as established from time to time during the period between the effective date of the merger and the date of payment of the judgment. Upon application by the surviving or resulting corporation or by any stockholder entitled to participate in the appraisal proceeding, the Court may, in its discretion, proceed to trial upon the appraisal prior to the final determination of the stockholders entitled to an appraisal. Any stockholder whose name appears on the list filed by the surviving or resulting corporation pursuant to subsection (f) of this section and who has submitted such stockholder's certificates of stock to the Register in Chancery, if such is required, may participate fully in all proceedings until it is finally determined that such stockholder is not entitled to appraisal rights under this section.

(i) The Court shall direct the payment of the fair value of the shares, together with interest, if any, by the surviving or resulting corporation to the stockholders entitled thereto. Payment shall be so made to each such stockholder, in the case of holders of uncertificated stock forthwith, and in the case of holders of shares represented by certificates upon the surrender to the corporation of the certificates representing such stock. The Court's decree may be enforced as other decrees in the Court of Chancery may be enforced, whether such surviving or resulting corporation be a corporation of this State or of any state.

(j) The costs of the proceeding may be determined by the Court and taxed upon the parties as the Court deems equitable in the circumstances. Upon application of a stockholder, the Court may order all or a portion of the expenses incurred by any stockholder in connection with the appraisal proceeding, including, without limitation, reasonable attorney's fees and the fees and expenses of experts, to be charged pro rata against the value of all the shares entitled to an appraisal.

(k) From and after the effective date of the merger or consolidation, no stockholder who has demanded appraisal rights as provided in subsection (d) of this section shall be entitled to vote such stock for any purpose or to receive payment of dividends or other distributions on the stock (except dividends or other distributions payable to stockholders of record at a date which is prior to the effective date of the merger or consolidation); provided, however, that if no petition for an appraisal shall be filed within the time provided in subsection (e) of this section, or if such stockholder shall deliver to the surviving or resulting corporation a written withdrawal of such stockholder's demand for an appraisal and an acceptance of the merger or consolidation, either within 60 days after the effective date of the merger or consolidation as provided in subsection (e) of this section or thereafter with the written approval of the corporation, then the right of such stockholder to an appraisal shall cease. Notwithstanding the foregoing, no appraisal proceeding in the Court of Chancery shall be dismissed as to any stockholder without the approval of the Court, and such approval may be conditioned upon such terms as the Court deems just; provided, however that this provision shall not affect the right of any stockholder who has not commenced an appraisal proceeding or joined that proceeding as a named party to withdraw such stockholder's demand for appraisal and to accept the terms offered upon the merger or consolidation within 60 days after the effective date of the merger or consolidation, as set forth in subsection (e) of this section.

(l) The shares of the surviving or resulting corporation to which the shares of such objecting stockholders would have been converted had they assented to the merger or consolidation shall have the status of authorized and unissued shares of the surviving or resulting corporation.

**FORM OF  
CERTIFICATE OF AMENDMENT  
OF THE  
RESTATED CERTIFICATE OF INCORPORATION  
OF BIOSANTE PHARMACEUTICALS, INC.**

BioSante Pharmaceuticals, Inc., a corporation organized and existing under and by virtue of the laws of the State of Delaware (the "Corporation"), pursuant to the provisions of the General Corporation Law of the State of Delaware (the "DGCL"), DOES HEREBY CERTIFY that:

FIRST: The Board of Directors of the Corporation (the "Board of Directors"), at meetings held on [ ], 201[ ] and [ ], duly adopted resolutions setting forth proposed amendments of the Restated Certificate of Incorporation of the Corporation, as amended, declaring said amendments to be advisable and proposing that said amendments be submitted to the stockholders of the Corporation for their consideration and approval. The resolutions setting forth the proposed amendments are substantially as follows:

RESOLVED, that the Board of Directors declares that it is advisable to amend Article IV of the Restated Certificate of Incorporation of the Corporation, as amended, as follows:

Amend Article IV by adding the following at the end of the second paragraph of Article IV:

Effective upon the later of (i) the filing with the Secretary of State of the State of Delaware of this Certificate of Amendment or (ii) [ ], Eastern Time, on [ ] (the "Effective Date"), each [ ] ([ ]) [to be filled in prior to filing with the appropriate split number, between two and five] shares of Common Stock of the Corporation issued and outstanding immediately prior to the Effective Date, shall automatically be reclassified, without any action on the part of the holder thereof, into one fully paid and nonassessable share of Common Stock, and each [ ] ([ ]) [to be filled in prior to filing with the appropriate split number, between two and five] shares of Class C Special Stock of the Corporation issued and outstanding immediately prior to the Effective Date, shall automatically be reclassified, without any action on the part of the holder thereof, into one fully paid and nonassessable share of Class C Special Stock (the "Reverse Split"). The Corporation shall not issue fractional shares to the stockholders entitled to a fractional interest in a share of Common Stock or Class C Special Stock issued pursuant to the Reverse Split. In lieu of any fractional share of Common Stock to which a stockholder otherwise would be entitled as a result of the Reverse Split, the Corporation shall pay a cash amount equal to the fair value of the fractional share of Common Stock as of the Effective Date of the Reverse Split which shall be equal to a proportionate interest of the value of a whole share based on the closing sale price of the Common Stock on the NASDAQ Stock Market on the Effective Date. In lieu of any fractional share of Class C Special Stock to which a stockholder otherwise would be entitled as a result of the Reverse Split, the Corporation shall pay a cash amount equal to the fair value of the fractional share of Class C Special Stock as of the Effective Date of the Reverse Split which shall be equal to a proportionate interest of the value of a whole share based on the closing sale price of a share of Common Stock on the NASDAQ Stock Market on the Effective Date minus \$15.00.

RESOLVED FURTHER, that the Board of Directors declares that it is advisable to amend Article IV(3)(a) of the Restated Certificate of Incorporation of the Corporation, as amended, as follows:

Amend Article IV(3)(a) in its entirety to state as follows:

A holder of Class C Special Stock shall be entitled, in accordance with the provisions hereof, to acquire Common Stock of the Corporation as the same may then be constituted by tendering any of the Class C Special Stock held and registered in such holder's name together with \$[ ] [to be filled in prior to filing with a number equal to the product of (i) 15.00, multiplied by (ii) the appropriate split ratio, between two and five] per share as a result of the Reverse Split (the "Common Stock Purchase Price") on the basis of one share of Common Stock for each share of Class C Special Stock and \$[ ] [to be filled in prior to filing with a number equal to the product of (i) 15.00, multiplied by (ii) the appropriate split ratio, between two and five] as a result of the Reverse Split. The purchase right herein provided shall be exercised by notice in writing given to the Corporation which notice shall specify the number of shares of Class C Special Stock that the holder desires to have applied to the purchase price of Common Stock. If any shares of Class C Special Stock are applied to the purchase of Common Stock pursuant to this paragraph, the holder of such shares of Class C Special Stock shall surrender the certificate or certificates representing the shares of Class C Special Stock so applied to the registered office of the Corporation, or to the transfer agent of the Corporation at the time of purchase together with cash or a certified cheque in the amount of \$[ ] [to be filled in prior to filing with a number equal to the product of (i) 15.00, multiplied by (ii) the appropriate split ratio, between two and five] per share of Common Stock being acquired, and the Corporation shall thereupon issue to such holder certificates representing the number of shares of Common Stock to which the holder became entitled upon such purchase.

SECOND: The stockholders of the Corporation duly approved and adopted such amendments in accordance with the provisions of Section 242 of the DGCL.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by Stephen M. Simes, its Vice Chairman, President and Chief Executive Officer, thereunto duly authorized, this [ ] day of [ ].

BIOSANTE PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Stephen M. Simes  
*Vice Chairman, President and Chief Executive Officer*



**FORM OF  
CERTIFICATE OF AMENDMENT  
OF THE  
RESTATED CERTIFICATE OF INCORPORATION  
OF BIOSANTE PHARMACEUTICALS, INC.**

BioSante Pharmaceuticals, Inc., a corporation organized and existing under and by virtue of the laws of the State of Delaware (the "Corporation"), pursuant to the provisions of the General Corporation Law of the State of Delaware (the "DGCL"), DOES HEREBY CERTIFY that:

FIRST: The Board of Directors of the Corporation (the "Board of Directors"), at meetings held on [ ], 201[ ] and [ ], duly adopted resolutions setting forth a proposed amendment of the Restated Certificate of Incorporation of the Corporation, as amended, declaring said amendment to be advisable and proposing that said amendment be submitted to the stockholders of the Corporation for their consideration and approval. The resolution setting forth the proposed amendment is substantially as follows:

RESOLVED, that the Board of Directors declares that it is advisable to amend Article I of the Restated Certificate of Incorporation of the Corporation, as amended, in its entirety to state as follows:

The name of the Corporation is ANI Pharmaceuticals, Inc.

SECOND: The stockholders of the Corporation duly approved and adopted such amendment in accordance with the provisions of Section 242 of the DGCL.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by Stephen M. Simes, its Vice Chairman, President and Chief Executive Officer, thereunto duly authorized, this [ ] day of [ ].

BIOSANTE PHARMACEUTICALS, INC.

By:

\_\_\_\_\_  
Stephen M. Simes  
*Vice Chairman, President and  
Chief Executive Officer*

**PART II**  
**INFORMATION NOT REQUIRED IN JOINT PROXY STATEMENT/PROSPECTUS**

**Item 20. Indemnification of Directors and Officers**

BioSante's certificate of incorporation limits the liability of its directors to the fullest extent permitted by the Delaware General Corporation Law. Specifically, Article VII of BioSante's certificate of incorporation provides that no director of BioSante shall be personally liable to BioSante or its stockholders for monetary damages for any breach of fiduciary duty by such a director as a director, except to the extent provided by applicable law (i) for any breach of the director's duty of loyalty to BioSante or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which such director derived an improper personal benefit. If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of BioSante shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law as so amended. No amendment to or repeal of Article VII shall apply to or have any effect on the liability or alleged liability of any director of BioSante for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal.

BioSante's certificate of incorporation provides for indemnification of BioSante's directors and officers. Specifically, Article VI provides that BioSante shall indemnify, to the fullest extent authorized or permitted by law, as the same exists or may thereafter be amended, any person who was or is made or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of BioSante), by reason of the fact that such person is or was a director or officer of BioSante, or is or was serving at the request of BioSante as a director, officer, employee or agent of any other company, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise; provided, however, that BioSante shall not indemnify any director or officer in connection with any action by such director or officer against BioSante unless BioSante shall have consented to such action. BioSante may, to the extent authorized from time to time by the BioSante board of directors, provide rights to indemnification to employees and agents of BioSante similar to those conferred in Article VI to directors and officers of BioSante. No amendment or repeal of Article VI shall apply to or have any effect on any right to indemnification provided thereunder with respect to any acts or omission occurring prior to such amendment or repeal.

The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director or officer of BioSante, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, including advancing expenses, to the fullest extent permitted under applicable law and BioSante's certificate of incorporation or bylaws. The merger agreement also provides that the combined company will honor all indemnification agreements in place with each present and former director or officer of BioSante. The merger agreement provides that the combined company will continue to indemnify and hold harmless each present and former director, officer, or employee of ANI, with respect to acts or omissions occurring or alleged to have occurred at or prior to completion of the merger, including advancing expenses, to the fullest extent allowed by applicable law. In addition, all rights to indemnification with respect to acts or omissions occurring at or prior to completion of the merger existing in favor of each present and former director, officer, or employee of ANI as provided in ANI's certificate of incorporation, ANI's bylaws, or indemnification agreements will remain in effect. The merger agreement also provides that, prior to completion of the merger, BioSante will purchase and maintain for a period of six years following completion of the merger, a directors' and officers' liability "tail" insurance policy covering the present and former directors and officers of BioSante and ANI for events

occurring prior to completion of the merger. Such policy must contain terms no less favorable than the policies maintained by BioSante and ANI prior to completion of the merger.

BioSante has entered into agreements with its directors and officers regarding indemnification, in addition to indemnification provided for in BioSante's certificate of incorporation, bylaws and the Delaware General Corporation Law and intends to enter into indemnification agreements with any new directors and officers in the future. Under these agreements, BioSante is required to indemnify its current and former directors and officers against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of BioSante's directors or officers. BioSante will be obligated to pay these amounts only if the director or officer acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to BioSante's best interests. With respect to any criminal proceeding, BioSante will be obligated to pay these amounts only if the director or officer had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

BioSante maintains an insurance policy for its directors and officers pursuant to which its directors and officers are insured against liability for certain actions in their capacity as directors and officers of BioSante.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to BioSante's directors, officers or persons controlling BioSante pursuant to the foregoing provisions, BioSante is aware that in the opinion of the Securities and Exchange Commission that this indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable.

#### **Item 21. Exhibits and Financial Statement Schedules**

(a) *Exhibits Index.*

See exhibit index which is incorporated herein by reference.

(b) *Financial Statement Schedules.*

Not applicable.

#### **Item 22. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more

than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
  - (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
  - (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference into the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) The undersigned registrant undertakes as follows:
- (1) that prior to any public reoffering of the securities registered hereunder through use of a prospectus which is a part of this registration statement, by any person or party who is deemed to be an underwriter within the meaning of Rule 145(c), the issuer undertakes that such reoffering prospectus will contain the information called for by the applicable registration form with respect to reofferings by persons who may be deemed underwriters, in addition to the information called for by the other items of the applicable form.
  - (2) that every prospectus (i) that is filed pursuant to paragraph (1) immediately preceding, or (ii) that purports to meet the requirements of Section 10(a)(3) of the Securities Act of 1933 and is used in connection with an offering of securities subject to Rule 415, will be filed as a part of an amendment to the registration statement and will not be used until such amendment is effective, and that, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (d) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

- (e) The undersigned registrant hereby undertakes to respond to requests for information that is incorporated by reference into the prospectus pursuant to Items 4, 10(b), 11 or 13 of this form, within one business day of receipt of such request, and to send the incorporated documents by first-class mail or other equally prompt means. This includes information contained in documents filed subsequent to the effective date of the registration statement through the date of responding to the request.
- (f) The undersigned registrant hereby undertakes to supply by means of a post-effective amendment all information concerning a transaction, and the company being acquired involved therein, that was not the subject of and included in the registration statement when it became effective.



<u>Name and Signature</u>	<u>Title</u>	<u>Date</u>
* _____ John T. Potts, Jr., M.D.	Director	January 18, 2013
* _____ Edward C. Rosenow, III, M.D.	Director	January 18, 2013
* _____ Stephen A. Sherwin, M.D.	Director	January 18, 2013
*By:        /s/ STEPHEN M. SIMES _____ Stephen M. Simes	Attorney-in-Fact	January 18, 2013

**BIOSANTE PHARMACEUTICALS, INC.**  
**EXHIBIT INDEX TO REGISTRATION STATEMENT ON FORM S-4**  
**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
1.1	Placement Agent Agreement dated as of August 13, 2009 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
1.2	Placement Agent Agreement dated as of March 4, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
1.3	Placement Agent Agreement dated as of June 20, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
1.4	Placement Agent Agreement dated as of December 27, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
1.5	Placement Agent Agreement dated March 3, 2011 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
1.6	Underwriting Agreement, dated July 28, 2011 by and between BioSante Pharmaceuticals, Inc. and Jefferies & Company, Inc., as Representative of the Several Underwriters Named in Schedule A Thereto	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 28, 2011 (File No. 001-31812)
1.7	Placement Agent Agreement dated August 16, 2012 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)
2.1	Agreement and Plan of Merger dated as of October 3, 2012 by and between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.(1)	Incorporated by reference to Exhibit 2.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)



<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
2.2	Amendment No. 1 to Agreement and Plan of Merger dated as of November 13, 2012 by and between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.(1)	Previously filed
2.3	Agreement and Plan of Merger dated as of June 29, 2009 by and between BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc.(1)	Incorporated by reference to Exhibit 2.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812)
3.1	Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
3.2	Amendment to Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
3.3	Form of Proposed Amendment to Restated Certificate of Incorporation to Effect Reverse Stock Split	Included as Annex I to the joint proxy statement/prospectus forming part of this Registration Statement and incorporated herein by reference
3.4	Form of Proposed Amendment to Restated Certificate of Incorporation to Effect Name Change	Included as Annex J to the joint proxy statement/prospectus forming part of this Registration Statement and incorporated herein by reference
3.5	Amended and Restated Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
4.1	Indenture, dated as of June 24, 2009, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to Cell Genesys's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-19986)
4.2	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of June 24, 2009, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2013	Incorporated by reference to Exhibit 4.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
4.3	Warrant dated December 15, 2008 issued by BioSante Pharmaceuticals, Inc. to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
4.4	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the August 2009 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
4.5	Form of Replacement Warrant issued to Investors in Cell Genesys, Inc.'s April 2007 Registered Direct Offering	Incorporated by reference to Exhibit 4.9 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
4.6	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the March 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
4.7	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the June 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
4.8	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the December 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
4.9	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placement Agent in the March 2011 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
4.10	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors in the August 2012 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)
5.1	Opinion of Oppenheimer Wolff & Donnelly LLP regarding validity of the shares of BioSante common stock registered hereunder	Previously filed
8.1	Opinion of Oppenheimer Wolff & Donnelly LLP regarding certain federal income tax matters	Previously filed

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
8.2	Opinion of SNR Denton US LLP regarding certain federal income tax matters	Previously filed
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes(4)	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg(4)	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.3	Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc.(4)	Incorporated by reference to Exhibit 10.3 contained in BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.4	Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes(4)	Incorporated by reference to Exhibit 10.4 contained in BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.5	BioSante Pharmaceuticals, Inc. Officer Severance Policy(4)	Incorporated by reference to Exhibit 10.5 contained in BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011 (File No. 001-31812)
10.6	BioSante Pharmaceuticals, Inc. Performance Incentive Plan(4)	Incorporated (by reference to Exhibit 10.4 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)
10.7	BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan(4)	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.8	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan(4)	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.9	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan(4)	Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.10	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan(4)	Incorporated by reference to Exhibit 10.4 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)
10.11	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan(4)	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.12	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan(4)	Incorporated by reference to Exhibit 10.5 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.13	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan(4)	Incorporated by reference to Exhibit 10.30 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.14	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's Directors Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan(4)	Incorporated by reference to Exhibit 10.31 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.15	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its Directors and Executive Officers(4)	Incorporated by reference to Exhibit 10.30 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
10.16	Description of Non-Employee Director Compensation Arrangements(4)	Incorporated by reference to Exhibit 10.16 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 (File No. 001-31812)
10.17	Cell Genesys, Inc. 2005 Equity Incentive Plan, as amended(4)	Incorporated by reference to Exhibit 10.3 to Cell Genesys's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-19986)

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.18	Cell Genesys, Inc. Amended and Restated 1998 Incentive Stock Plan(4)	Incorporated by reference to Exhibit 10.2 to Cell Genesys's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-19986)
10.19	Office Lease, dated December 19, 2003, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.29 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.20	First Amendment to Lease, dated February 26, 2004, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2004 (File No. 001-31812)
10.21	Second Amendment to Lease dated as of January 4, 2005, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 6, 2005 (File No. 001-31812)
10.22	Third Amendment to Lease dated as of January 27, 2006 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 1, 2006 (File No. 001-31812)
10.23	Fourth Amendment to Lease dated as of March 7, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2007 (File No. 001-31812)
10.24	Fifth Amendment to Lease dated as of November 2, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago.	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 6, 2007 (File No. 001-31812)
10.25	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 21, 2008 (File No. 001-31812)

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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.26	Seventh Amendment to Lease dated as of November 17, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.22 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.27	Eighth Amendment to Lease dated as of September 8, 2009 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.23 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.28	Ninth Amendment to Lease dated as of January 19, 2011 by and between 111 Barclay Associates, the sole beneficiary under Chicago Title Land Trust Company, as successor trustee to LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 27, 2011 (File No. 001-31812)
10.29	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.27 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.30	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.28 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.31	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.19 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.32	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.30 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.33	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.31 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)

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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.34	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.32 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.35	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.33 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.36	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited(2)	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.37	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited(2)	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.38	Development and License Agreement dated December 27, 2002 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.39	First Amendment to Development and License Agreement dated March 13, 2003 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.2 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.40	Letter Agreement dated June 4, 2007 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. Regarding Development and License Agreement dated December 27, 2002 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.3 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.41	Third Amendment to Development and License Agreement dated as of October 17, 2012 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.4 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)

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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.42	Registration Rights Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.43	Amendment to Registration Rights Agreement dated as of dated as of June 26, 2009 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.3 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2009 (File No. 001-31812)
10.44	Form of Securities Purchase Agreement, dated August 13, 2009, between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
10.45	Form of Securities Purchase Agreement, dated March 4, 2010, between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
10.46	Form of Securities Purchase Agreement, dated June 20, 2010, between BioSante Pharmaceuticals, Inc. and each of the investors in the June 2010 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
10.47	Form of Securities Purchase Agreement, dated December 27, 2010, between BioSante Pharmaceuticals, Inc. and each of the investors in the December 2010 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
10.48	Form of Securities Purchase Agreement, dated March 3, 2011, between BioSante Pharmaceuticals, Inc. and each of the investors in the March 2011 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2012 (File No. 001-31812)
10.49	Form of Securities Purchase Agreement, dated August 16, 2012, between BioSante Pharmaceuticals, Inc. and each of the investors in the August 2012 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)
10.50	Form of Voting Agreement dated as of October 3, 2012 between certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)



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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.51	Form of Voting Agreement dated as of October 3, 2012 between Meridian Venture Partners II, L.P. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.52	Form of Voting Agreement dated as of October 3, 2012 between certain stockholders, directors and officers of BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.53	Form of Lock-Up Agreement dated as of October 3, 2012 between the chief executive officer and chief financial officer and certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.4 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.54	Department of Veterans Affairs Federal Supply Schedule Contract Award, effective July 15, 2012, and Amendment 1 thereto, dated August 22, 2012	Previously filed
10.55	Sublicense Agreement, dated as of October 30, 2009, by and between Jazz Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.(2)	Previously filed
10.56	Supplier Agreement Multisource and Onestop Generics Program, dated as of November 1, 2010, between McKesson Corporation and ANIP Acquisition Company(2)	Previously filed
10.57	Master Product Development and Collaboration Agreement, dated as of July 11, 2011, between ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and RiconPharma LLC(2)	Filed herewith
10.58	Amended and Restated Manufacturing and Supply Agreement, dated as of June 10, 2008, between ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and Alaven Pharmaceuticals, LLC., Addendum No. 1 thereto, dated as of December 1, 2010, and Addendum No. 2 thereto, dated as of July 10, 2012(2)	Previously filed

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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.59	Generic Wholesale Service Agreement, dated as of May 1, 2006, between ANI Pharmaceuticals, Inc. and Cardinal Health, Amendment No. 1 thereto assigning the agreement to ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., dated as of July 1, 2008, Letter from Cardinal Health dated December 22, 2008, and Amendment No. 2 to the agreement, dated as of April 1, 2012(2)	Previously filed
10.60	Development, Manufacturing and Supply Agreement, dated as of February 5, 2009, by and between ANI Pharmaceuticals, Inc. and County Line Pharmaceuticals, LLC, and Addendum thereto, dated March 10, 2010(2)	Previously filed
10.61	Manufacturing Transfer and Supply Agreement, dated March 31, 2010, by and between ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and County Line Pharmaceuticals, LLC, and Addendum thereto dated as of June 12, 2012(2)	Previously filed
10.62	Employment Agreement, dated February 25, 2009, by and between ANIP Acquisition Company and Arthur Przybyl(4)	Previously filed
10.63	Employment Agreement, dated May 6, 2009, by and between ANIP Acquisition Company and Charlotte Arnold(4)	Previously filed
10.64	Employment Agreement, dated May 1, 2007, by and between ANIP Acquisition Company and James Marken(4)	Previously filed
10.65	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Arthur Przybyl(4)	Previously filed
10.66	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Charlotte Arnold(4)	Previously filed
10.67	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and James Marken(4)	Previously filed
10.68	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Robert Jamnick(4)	Previously filed
10.69	Agreement regarding fee payment, dated as of October 3, 2012, by and between ANIP Acquisition Company and MVP Management Company	Previously filed

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<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
10.70	Agreement regarding fee payment, dated as of October 3, 2012, by and between ANIP Acquisition Company and Healthcare Value Capital LLC	Previously filed
10.71	Loan and Security Agreement, dated June 6, 2012, between Alostara Bank of Commerce and ANIP Acquisition Company	Previously filed
10.72	Note Purchase Agreement, dated January 28, 2011, between ANIP Acquisition Company, Meridian Venture Partners II, L.P. and the other parties thereto	Previously filed
10.73	Amendment No. 1 to Transaction Bonus Agreement, dated December 28, 2012, by and between ANIP Acquisition Company and Arthur Przybyl	Filed herewith
10.74	Amendment No. 1 to Transaction Bonus Agreement, dated December 28, 2012, by and between ANIP Acquisition Company and Charlotte Arnold	Filed herewith
14.1	Code of Conduct and Ethics	Incorporated by reference to Exhibit 14.1 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm with respect to BioSante Pharmaceuticals, Inc.	Filed herewith
23.2	Consent of Stout, Causey & Horning, P.A., Independent Registered Public Accounting Firm with respect to ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.	Filed herewith
23.3	Consent of Oppenheimer Wolff & Donnelly LLP	Included in Exhibit 5.1
23.4	Consent of Oppenheimer Wolff & Donnelly LLP	Included in Exhibit 8.1
23.5	Consent of SNR Denton US LLP	Included in Exhibit 8.2
24.1	Power of Attorney	Previously filed
99.1	Consent of Oppenheimer & Co. Inc.	Previously filed
99.2	Consent of Robert E. Brown, Jr.	Previously filed
99.3	Consent of Arthur S. Przybyl	Previously filed
99.4	Consent of Tracy L. Marshbanks, Ph.D.	Previously filed
99.5	Consent of Thomas A. Penn	Previously filed
99.6	Consent of Robert Schrepfer	Previously filed

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
99.7	Form of Proxy Card for the BioSante Pharmaceuticals, Inc. Special Meeting of Stockholders	Filed herewith
99.8	Form of Proxy Card for the ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. Special Meeting of Stockholders	Filed herewith
101	The following financial statements of BioSante Pharmaceuticals, Inc., formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets as of December 31, 2011 and 2010, (ii) Statements of Operations for the years ended December 31, 2011, 2010 and 2009, (iii) Statements of Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009, (iv) Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009, (v) unaudited Condensed Balance Sheets as of September 30, 2012, (vi) unaudited Condensed Statements of Operations for the nine months ended September 30, 2012 and 2011, (vii) unaudited Condensed Statements of Cash Flows for the nine months ended September 30, 2012 and 2011 and (viii) Notes to Financial Statements(5)	Furnished herewith

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- (1) All exhibits and schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Securities and Exchange Commission.
  - (2) Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.
  - (3) Intentionally omitted.
  - (4) Management contract or compensatory plan or arrangement required to be filed as an exhibit to this form.
  - (5) Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Registration Statement on Form S-4 shall be deemed to be not filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filings



Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]

MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT

BY AND AMONG

RICONPHARMA LLC

AND

ANIP ACQUISITION COMPANY d/b/a ANI PHARMACEUTICALS, INC.

JULY 2011

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]

This MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT is made as of the 11th day of July 2011, by and among ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware (“ANI”), having a place of business at 210 Main Street West, Baudette, MN 56623 and RiconPharma LLC, a limited liability company having its principal office at 100 Ford Road, Suite #9, Denville, NJ 07834 (“RiconPharma”). ANI and RiconPharma may each be referred to herein individually as a “Party” and collectively as the “Parties.”

**WHEREAS**, RiconPharma possesses expertise relating to the development of finished dosage forms of pharmaceutical products and ANI possesses expertise relating to the manufacture of finished pharmaceutical products and also possesses expertise relating to the marketing, distribution and sale of pharmaceutical products;

**WHEREAS**, the Parties desire, from time to time, to collaborate in a cost, asset, and profit sharing arrangement for the development, manufacturing, regulatory approval, and marketing of pharmaceutical products in the US and also to invest their respective resources in developing, obtaining regulatory approval for manufacturing and marketing such products in the manner to be set forth in a Amending Product Exhibit hereto (each, a “**Amending Product Exhibit**”); and

**WHEREAS**, each Amending Product Exhibit shall delineate the specific terms and conditions related to each new Product collaboration including, but not limited to, a description of the Product (hereinafter defined) to be developed, the estimated cost of development, and the percentage allocation of costs and profits; and

**NOW, THEREFORE**, in consideration of the foregoing and of the agreements, representations, covenants, and warranties contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **DEFINITIONS.**

For the purposes of this Agreement, the following terms shall have the following meanings:

- 1.1 “**Affiliate**” shall mean any person, directly or indirectly, controlling, controlled by, or under common control with, another person. Without limiting the generality of the foregoing, a person is considered to be in control of or to be controlled by another person if such person holds 50% or more of the outstanding voting equity interest in such other person or such other person holds 50% or more of its outstanding voting equity interest.
- 1.2 “**ANDA**” shall mean an abbreviated new drug application or similar health registration application that is or will be filed with a Regulatory Authority to obtain Regulatory Approval to market a Product in the Territory.
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- 1.3 “**API**” shall mean an active pharmaceutical ingredient in a Product shipped to ANI.
- 1.4 “**API Suppliers**” shall have the meaning set forth in Section 7.2 of this Agreement.
- 1.5 “**Approved Product**” shall mean a Product that shall have been granted all necessary approvals by all required Regulatory Authorities sufficient to permit the marketing and sale by ANI or an Affiliate of ANI of such Product in the Territory.
- 1.6 “**Base Price**” shall mean the price charged by ANI for a Unit of Product, which price shall be comprised of the cost of Raw Materials, Components, labor, overhead and profit per Unit, which is further described in the Amending Exhibit.
- 1.7 “**Batch**” with respect to a Product, shall mean a specific quantity of a Product that is intended to have uniform character and quality within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture, and designated by a batch number.
- 1.8 “**Bioequivalent Product**” shall mean with respect to a Product, a drug product that is a bioequivalent, as that term is used in the FDA Orange Book and that is identical in strength or concentration, contains the same active ingredient(s), is in the same dosage form, and utilizes the same route of administration as the Product.

- 1.9 “**Bioequivalence Study**” shall have the meaning set forth in Section 3.1 of this Agreement.
- 1.10 “**Calendar Quarter**” shall mean the periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31.
- 1.11 “**Certificate of Analysis**” shall mean a document, which is dated and signed by a duly authorized representative of the quality control or quality assurance department of ANI, certifying that a Batch of any Product meets all Specifications accompanied by the certificate(s) of analysis prepared and signed by any manufacturer(s) of the Product(s) in the Batch and Raw Materials for the Product in the Batch certifying that the Products and Raw Materials meet all applicable specifications.
- 1.12 “**Claim**” shall have the meaning set forth in Section 17.5 of this Agreement.
- 1.13 “**Commercially Reasonable Efforts**” with respect to the efforts to be expended by a Party regarding any objective under this Agreement, shall mean reasonable, diligent, good-faith efforts to accomplish such objective as a reasonable person or entity similarly situated would normally use to accomplish a similar objective under similar circumstances exercising reasonable business judgment.
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- 1.14 “**Components**” shall mean all labels, bottles, caps, seals, cardboard packaging, inserts and other materials (excluding Raw Materials) used to Label and package a Unit for shipment to ANI.
- 1.15 “**Confidential Information**” shall have the meaning set forth in Section 21 of this Agreement.
- 1.16 “**Continuing Party**” or “**Continuing Parties**” shall have the meaning set forth in Section 20.6 of this Agreement.
- 1.17 “**Cost of Goods**” shall mean the total amount contingently charged by ANI for the purchase of Products during any Calendar Quarter, each Unit invoiced at the Base Price.
- 1.18 “**Development Costs**” shall mean the costs incurred by the Parties in developing a Product, including but not limited to costs of formulation development, analytical development, scale-up, demo batches, bio-batch manufacturing, ICH Stability packaging and testing, bioequivalence studies, and ANDA filings.
- 1.19 “**Development Cost Percentage**” shall mean the percentage of Development Costs allocated to each Party in connection with developing Products and as set forth in the Amending Product Exhibit.
- 1.20 “**DMF**” shall mean the drug master file, confidential or otherwise, covering the manufacture and analysis of an API with respect to a Product in the Territory.
- 1.21 “**EDC**” shall have the meaning set forth in Section 3.2.
- 1.22 “**Effective Date**” shall mean the date of execution by the Parties of the first Amending Product Exhibit to this Agreement.
- 1.23 “**FDA**” shall mean the United States Food and Drug Administration, or any successor agency.
- 1.24 “**FD&C Act**” shall mean the Federal Food, Drug and Cosmetic Act of 1938, as amended, and the regulations thereunder, as the same may be amended from time to time.
- 1.25 “**Good Clinical Practices**” or “**GCPs**” shall mean the then-current standards for clinical trials for pharmaceuticals as set forth in the FD&C Act and applicable regulations promulgated thereunder.
- 1.26 “**Good Laboratory Practices**” or “**GLPs**” shall mean the then-current standards for laboratory activities for pharmaceuticals as set forth in the FD&C Act and applicable regulations promulgated thereunder.
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- 1.27 “**Good Manufacturing Practices**” or “**GMPs**” shall mean the then-current standards for the manufacture of pharmaceutical Products as set forth in the FD&C Act and applicable regulations promulgated thereunder.
- 1.28 “**Indemnity Claim**” shall have the meaning set forth in Section 17.5 of this Agreement.
- 1.29 “**Initial Marketing Date**” shall be the date listed on the FDA Form 2657 (New Product Listing Form) or its successor, indicating the first date a Product is distributed to customers in the Territory.
- 1.30 “**Invention(s)**” shall mean an invention conceived and reduced to practice in the course of the performance of and within the scope of this Agreement.
- 1.31 “**Know-How**” shall mean all proprietary technical and clinical information, data and know-how relating to a Product, whether or not patentable, which is owned or controlled as of the Effective Date or acquired or developed during the term of this Agreement by a Party hereto. Know-How shall include, without limitation, processes, formulas, discoveries and inventions whether relating to biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical safety, quality control and clinical data. The term “Know-How” shall exclude: (i) processes, information and data which is, as of the Effective Date, generally available to the public or later becomes generally available without breach by a Party of its obligations of confidentiality hereunder; or (ii) any general development or manufacturing know-how not specific to a Product.
- 1.32 “**Label**” and “**Labeling**” have the meaning given those terms by 21 CFR Part 201.

- 1.33 **“Litigation Expenses”** shall mean expenses incurred in investigating, defending, or litigating any claims, demands, or actions related to a Product made or brought by a Third Party (including reasonable legal fees and the payment of damages and expenses to a Third Party).
- 1.34 **“Manufacturer and Development Technology”** shall mean all information, data, intellectual property and Know-How, whether patentable or not, which is owned or controlled by ANI or RiconPharma prior to or during the Term and which is necessary or useful in developing and manufacturing Products, in developing and conducting Bioequivalence Studies for the Products, in preparing and filing Regulatory Approvals for the Products and in maintaining such Regulatory Approvals.
- 1.35 **“Net Profits”** shall, with respect to any Product, Net Sales less Base Price in respect of such Product.
- 1.36 **“Net Sales”** shall mean the gross amounts invoiced by ANI for any Product sold to third less the sum of chargebacks, cash and quantity discounts, returns, rebates and such other credits granted by ANI or taken by customers with respect to such
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Product sales. Net Sales shall be determined in accordance with generally accepted accounting principles using the accrual method of accounting, consistent with historical practices of ANI. The sum of chargebacks, cash and quantity discounts, returns, rebates and such other credits will not exceed [ \*\*\* ] of gross amounts invoiced without the consent of both ANI and RiconPharma.

- 1.37 **“Non-Continuing Party”** or **“Non-Continuing Parties”** shall have the meaning set forth in Section 20.6 below.
- 1.38 **“Party”** shall mean either ANI or RiconPharma and **“Parties”** shall mean two or more of the following as the context dictates: ANI and RiconPharma.
- 1.39 **“Phase(s)”** shall have the meaning set forth in the Amending Product Exhibit of any Products in this Agreement.
- 1.40 **“Policy”** shall have the meaning set forth in Section 18.1 of this Agreement.
- 1.41 **“Product(s)”** shall mean the Product(s) set forth in each Amending Product Exhibit.
- 1.42 **“Product Action”** shall have the meaning set forth in Section 11.2 of this Agreement.
- 1.43 **“Profit Sharing Percentage”** shall mean the percentage of Net Profits allocated to each Party with respect to each Product as set forth in each Amending Product Exhibit to this Agreement for that Product.
- 1.44 **“Raw Materials”** shall mean the API and inactive ingredients used to manufacture a Product.
- 1.45 **“Recall”** shall have the meaning set forth in Section 11.1 of this Agreement.
- 1.46 **“Records”** shall have the meaning set forth in Section 19.1 of this Agreement.
- 1.47 **“Reference Product”** shall mean the product currently marketed and sold under the pharmaceutical brand identified in the Amending Product Exhibit.
- 1.48 **“Registration”**, with respect to a Product, shall mean the meeting of all of the requirements of all applicable Regulatory Authorities necessary to permit the commencement of marketing and selling such Product in the Territory by ANI or an Affiliate of ANI.
- 1.49 **“Regulatory Approval”** shall mean the authorizations and approvals of any Regulatory Authority (including, without limitation, approvals of ANDAs and NDAs) required for the commercial manufacture, distribution, marketing, promotion, offer for sale, use, import, export and sale of Product(s) in the Territory.
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- 1.50 **“Regulatory Authority”** shall mean any and all bodies and organizations regulating the manufacture, importation, marketing, distribution, use and sale of any of the Products in the Territory.
- 1.51 **“Retaining Party”** shall have the meaning set forth in Section 19.3 of this Agreement.
- 1.52 **“Sales and Marketing Company”** shall have the meaning set forth in Section 2.1 of this Agreement.
- 1.53 **“SIR”** shall have the meaning set forth in Section 18.1 of this Agreement.
- 1.54 **“Specifications”** shall mean the specifications for each Product as agreed to by the Parties and as approved by the applicable Regulatory Authority, which Specifications may be amended from time to time by written agreement between the Parties and as specifically requested by the applicable Regulatory Authority.
- 1.55 **“Term”** shall have the meaning set forth in Section 20.1 of this Agreement.
- 1.56 **“Territory”** shall mean the United States of America.
- 1.57 **“Third Party”** shall mean any person or entity other than a Party or any of its Affiliates.
- 1.58 **“Trademark”** means the trade name and/or trademark used and owned by a Party.
- 1.59 **“Unit”** shall have the meaning set forth in the Amending Product Exhibit.



## 2. THE COLLABORATION.

- 2.1 The Parties agree to collaborate in the selection of Products and in the development, manufacturing, registration and approval, and marketing of such Products as set forth in more detail in this Agreement and any applicable Amending Product Exhibit. Unless otherwise specified in an Amending Product Exhibit, RiconPharma will be responsible for developing the Products and ANI will be responsible for manufacturing and distribution of the Products in the Territory. The Parties shall be jointly responsible for directing any bioequivalence studies and obtaining Regulatory Approval for such pharmaceutical products, and ANI shall be responsible for maintaining such Regulatory Approvals. ANI or a separate sales and marketing company designated by ANI (a "Sales and Marketing Company") will be primarily responsible for the marketing, distribution and sale of the Products as well as customer service, rebate management, billing, warehousing and such other responsibilities as are regularly performed by a pharmaceutical distributor.
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- 2.2 The Parties shall jointly own all the rights, title, and interest in the Products (including without limitation, the ANDA for the Products). The respective percentages of ownership for each Product shall be one-half for each Party unless a different percentage is set forth in the Amending Product Exhibit for that Product. Subject to Section 2.3, neither Party, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, may: (i) assign this Agreement; (ii) sell or assign its ownership rights to a Product to a Third Party; or (iii) license or assign any other right, title, or interest in a Product.
- 2.3 In the event of a sale of more than 50% of a Party's total assets, as reflected in the Party's most recent annual financial statements, that Party may assign this Agreement or sell or assign its ownership rights to a Product without the prior written consent of the other Party. It is understood that any successor company, either through assignment or acquisition of the ownership rights from any Party, shall be bound by the terms and conditions contained within this Agreement.
- 2.4 ANI or a Sales and Marketing Company designated by ANI shall have the exclusive rights to market, distribute, offer for sale, and sell Products in the Territory during the Term of this Agreement.
- 2.5 True and complete copies of any Party's agreements with any Third Party or Affiliate for the manufacture or supply of any Product, Raw Materials or Components shall be attached as exhibits to this Agreement simultaneously with the delivery of an Amending Product Exhibit contemplating the inducement of such Third Party or Affiliate.
- 2.6 The Parties hereby appoint ANI as an Authorized Distributor of Record ("ADR") for all Products under this Agreement, and authorize ANI to designate additional ADRs on behalf of ANI for all Products.
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## 3. DEVELOPMENT.

- 3.1 RiconPharma shall be responsible for developing the Products, including, but not limited to, development of the Products, formulations, analytical methods, and the performance and coordination, including oversight, of any necessary clinical studies with ANI to determine if such Products are Bioequivalent to the Reference Products. Such clinical studies shall be conducted by Third Party contract research organizations selected by the Parties (each, a "Bioequivalence Study"). If a Bioequivalence Study does not demonstrate that the formulations developed by RiconPharma are bioequivalent to the Reference Products, and if the Parties determine that an additional Bioequivalence Study is advisable, then RiconPharma shall reformulate the Products for use in additional Bioequivalence Studies and any actual additional documented costs specifically attributed to the reformulation shall be shared by the Parties according to each Party's Development Cost Percentage set forth in the Amending Product Exhibit.
- 3.2 Development Costs for each Phase of a Product will be as set forth in the Amending Product Exhibit for that Product, and shall be shared by the Parties in accordance with each Party's Development Cost Percentage for that Product. Subject to Section 3.5, if a Party actually incurs Development Costs during a Phase in excess of that Party's share of Development Costs for the Phase (the "EDC"), the other Party shall, to the extent not already paid, reimburse that Party its respective share of the EDC within thirty (30) days after receipt by the other Party of written notice from the Party requesting reimbursement. Each notice must include the amount requested and the written support for the EDC.
- 3.3 For each Product, RiconPharma shall use its Commercially Reasonable Efforts to complete each Phase of development by the Completion Date for that Phase indicated in the Amending Product Exhibit for that Product.
- 3.3.1 Without limitation, RiconPharma will be responsible for all development functions (e.g. pre-formulations, formulations and analytical method development, technology transfer and scale-up support), and will provide necessary support in obtaining Regulatory Approval for such Products, and all such other responsibilities as are typically undertaken by a company engaged in pharmaceutical development.
- 3.3.2 Without limitation, ANI will be responsible for manufacturing the scale-up and demo batches, ICH stability testing, CMC, Biobatches, ANDA submissions, validations and all such other responsibilities as are typically undertaken by a company engaged in pharmaceutical manufacturing.
- 3.3.3 Without limitation, ANI or a Sales and Marketing Company designated by ANI will be responsible for sales, marketing and distribution and all such other responsibilities as are typically undertaken by a company engaged in pharmaceutical distribution.
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- 3.4 For each Product, RiconPharma will provide ANI with written notice of the completion of each Phase of development set forth in the Amending Product Exhibit for that Product and ANI will have ten (10) business days after the receipt of such notice within which to notify RiconPharma of any termination of that Amending Product Exhibit as provided in Section 20.4.

- 3.5 No Party shall have any obligation to reimburse the other Party for any portion of expenses incurred by a Party in excess of 105% of the anticipated Development Costs set forth in an Amending Product Exhibit unless such excess expenses have been approved, in writing, by all Parties prior to the time they are incurred
- 3.6 In the event that the Parties mutually agree to accept payment from a Third Party in exchange for not developing, manufacturing or marketing a Product, such payment shall be shared by the Parties in accordance with each Party's Profit Sharing Percentage set forth in the Amending Product Exhibit.

#### 4. COMMERCIALIZATION.

- 4.1 The Parties may market the Products under a trade name which ANI or a Sales and Marketing Company designated by ANI shall have the right to select, subject to the approval of both Parties, which approval will not be unreasonably withheld, conditioned or delayed. ANI shall own all trade names. The costs of searching, selecting, registering and enforcing a trade name for a Product, if any, shall be advanced by ANI. ANI shall be responsible for responding to regulatory inquiries relating to any trade names selected hereunder.
- 4.2 All Products sold by ANI shall bear the ANI Trademark and the applicable ANI NDC number and labeler code. To the extent permitted by applicable law and regulations, ANI shall be identified on the Product packaging as the manufacturer of the Products and ANI shall be identified on the Product packaging as the labeler/distributor of the Product.
- 4.3 ANI agrees that at all times during the Term, neither it nor any of its Affiliates will develop, manufacture, sell or distribute a product that is the same as a Product or a product that is a Bioequivalent Product of a Product in the Territory unless RiconPharma approves in writing.
- 4.4 RiconPharma agrees that at all times during the Term, neither it nor any of its Affiliates will develop, manufacture, sell or distribute a product that is the same as a Product or a product that is a Bioequivalent Product of a Product in the Territory unless ANI approves in writing.
- 4.5 All Parties may manufacture, distribute, promote, and sell products in the Territory other than (i) the Products, (ii) Bioequivalent Products of the Products, or (iii) a product that is the same as a Product, and may acquire such products from Third Party manufacturers.

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- 4.6 ANI shall consult with RiconPharma and determine the price at which it shall sell the Products in the Territory. ANI shall have sole discretion over the pricing, marketing, and sales of Products in the Territory including, but not limited to, marketing strategy, sales strategy, Product placement, Product distribution, the terms of sale of Products, and decisions whether to accept returns on Products from the Territory.
- 4.7 ANI shall at all times maintain a ninety (90) day rotating inventory of API and Components for all Products covered by an Amending Product Exhibit not terminated pursuant to Section 20.
- 4.8 ANI and RiconPharma shall promptly provide or make available for review all testing documentation, material safety data sheets, certificates of analysis and all similar materials as reasonably requested by its Customers.

#### 5. SHARING OF NET PROFITS.

- 5.1 Net Profits from the sale of a Product will be shared by the Parties in accordance with each Party's Profit Sharing Percentage set forth in the Amending Product Exhibit.
- 5.2 Within thirty (30) days after the end of each Calendar Quarter, ANI shall calculate the Net Sales and the Net Profits obtained from the sale of Products during such Calendar Quarter and shall distribute to RiconPharma its Profit Sharing Percentage of such Net Profits. ANI shall supply RiconPharma with a written report setting forth the Net Sales and Net Profits during such Calendar Quarter. If the Net Profits related to a Product for any Calendar Quarter is negative, then ANI may invoice RiconPharma for such amount due to ANI in accordance with this Agreement and in proportion to each Party's Profit Sharing Percentage of such quarterly loss, such payment to be made within thirty (30) days of such invoice.

#### 6. TAXES AND WITHHOLDING.

All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by applicable laws or regulations. If the paying Party is so required to deduct or withhold, such Party shall: (i) promptly notify the Party entitled to receive such payment of such requirement; (ii) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier to occur of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the Party entitled to receive such payment; and (iii) promptly forward to such other Party an official receipt (or certified copy) or other documentation reasonably acceptable to such other Party evidencing such payment to such authorities. Unless otherwise required by law, each Party shall be responsible for the calculation and payment of its own taxes.

#### 7. REGULATORY APPROVAL AND REGISTRATIONS.

- 7.1 ANI shall be responsible for obtaining all Regulatory Approvals for the Products necessary for the Registration of such Product in the Territory including the preparation of all ANDAs for the Products. ANI shall prepare all documents such as CMC and perform all other work necessary to obtain Regulatory Approvals and Registration of the Products in the Territory. The Parties will support the ANDA filing and help in obtaining Regulatory Approval for such Products, including, without limitation:
- (a) seeking all necessary approvals to permit the conduct of Bioequivalence Studies using the Products;
  - (b) seeking all necessary Regulatory Approvals and Registrations from the appropriate Regulatory Authority in the Territory to manufacture, distribute, market and sell each of the Products in the Territory;

- (c) preparing other applicable filings and obtaining approvals in connection with its advertising and promotional materials related to each of the Products; and
  - (d) the quality control testing of all Raw Materials used in the manufacture of each of the Products in accordance with the standards of the United States Pharmacopeia and any other specification which may be required by a Regulatory Authority;
  - (e) the pharmacokinetic and stability tests of the Products and the manufacture and scale-up of exhibit and registration stability Batches of the Products;
  - (f) the conduct of ongoing stability trials as required by any Regulatory Authority in the Territory; and
  - (g) the preparation and completion of any additional documentation necessary for the Registration of the Products in the Territory.
- 7.2 RiconPharma shall provide ANI with the identities of Raw Material sources including sources for the supply of approved APIs for the Products ("API Suppliers"). ANI will ensure that API Suppliers have maintained and, if required, filed appropriate DMFs in respect of the APIs used in the Products.
- 7.3 The testing and studies referred to in Sections 3.1 and 8.1 shall be conducted in accordance with all applicable GLPs and with all reasonable diligence. The Parties shall jointly review and comment upon, prior to submission, any documents submitted to any Regulatory Authority pertaining to the testing and study of a Product described in Sections 3.1 and 8.1 and DMFs covering any API in any Product.
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- 7.4 No Party may attempt to modify the ANDA for a Product after Regulatory Approval in any way without the consent of the other Party.
- 7.5 Each Party shall immediately notify the other Party of any (a) inspections by any Regulatory Authority, including, without limitation, inspections as a result of the recall of, or any other regulatory issue related to, any of the Products and/or (b) material notices received from any Regulatory Authority. Each Party shall immediately notify the other Party if it becomes aware of any concern with respect to any Product that may affect the efficacy or safety of any of the Products.

## **8. MANUFACTURE AND SUPPLY OF THE PRODUCTS, QUALITY CONTROL.**

- 8.1 ANI shall ensure that all Products supplied will be manufactured and packaged in accordance with GMPs and will conform to the Specifications, the applicable Regulatory Approval(s), and other regulations and requirements of the Regulatory Authorities.
- 8.2 ANI shall perform, or ensure the performance of, release testing of Products in a manner consistent with GMP testing methods agreed upon by the Parties as set forth on the Specifications. ANI shall provide RiconPharma with a Certificate of Analysis with each shipment of the Products stating that the Products in that shipment conform to the Specifications. ANI will ensure that a copy of the Certificate of Analysis with respect to each Batch of Product supplied (a) is faxed prior to shipping such Batch (confirmed by hard copies mailed) and (b) accompanies each Batch. ANI shall not ship any Batch of the Product if such Batch does not conform to the Specifications.
- 8.3 ANI shall ensure that each Batch of the Product is labeled and that each of the Batch numbers is applied to each such Batch, as required by the Regulatory Authorities.
- 8.4 ANI shall provide and maintain suitable storage and transport conditions for all Products shipped and shall provide complete written instructions with respect to proper conditions for the transport and storage of the Product. Upon receipt of any Batch of the Product from ANI, a Sales and Marketing Company shall provide and maintain storage conditions that comply with any written instructions provided by ANI in respect of the storage of Product.

## **9. PACKAGING AND LABELING.**

ANI shall package and Label the Products shipped under this Agreement or ensure that such Products are packaged and Labeled in strict compliance with the Specifications and the packaging and Labeling requirements of the Regulatory Authorities. ANI shall be responsible for the accuracy and content of the Labeling.

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## **10. REGULATORY REPORTING AND COMPLIANCE**

- 10.1 Regardless of which Party or Parties hold the ANDA, ANI shall have the sole responsibility for monitoring and ensuring the material compliance with all statutes, regulations, guidelines and other requirements of the Regulatory Authorities pertaining to the Products, the Registration, and/or the Regulatory Approval. ANI shall be responsible for ensuring appropriate work is performed with respect to supplementing or amending the approved ANDA and for complying with all reporting requirements relating to the Products and the Regulatory Approvals. Those duties include, without limitation, responding to physician questions regarding the Products and the submission of annual reports and adverse drug experience reports for the Products to the Regulatory Authority and the performance of all due diligence with respect to any adverse drug experience reports.
- 10.2 If RiconPharma receives a report or any other information regarding an adverse drug experience attributed to a Product, it shall promptly provide ANI with all such information. If either Party receives a communication from the Regulatory Authority regarding a Product, it will promptly notify the other Party in writing about that communication and shall provide a copy thereof. Upon request both ANI and RiconPharma shall provide each other with any other information they have or receive, if any, that ANI reasonably requires to comply with its obligations under Section 10.1.
- 10.3 Subject only to the specific duties imposed by Section 10.2, RiconPharma shall have no duties or responsibilities of any kind with respect to reporting to the Regulatory Authority or monitoring or ensuring compliance with any requirements of the Regulatory Authority.

## **11. RECALLS AND OTHER PRODUCT ACTIONS**

- 11.1** Each Party shall promptly notify the other Party in writing of any order, request or directive of the Regulatory Authority or an order of a court to recall or withdraw a Product anywhere in the Territory (hereinafter "Recall"). The Party in whose name the ANDA is held shall be responsible for coordinating all communication in connection with the Recall, including all coordination and communications with the Regulatory Authority.
- 11.2** In the event that a Party believes it may be necessary to conduct a voluntary recall, field correction, market withdrawal, stock recovery or other similar action (hereinafter "Product Action") with respect to any Product which was sold under this Agreement, such Party shall promptly consult with the other Party in good faith as to how best to proceed, it being understood and agreed that no Party shall be prohibited hereunder from taking any action that it is required to take by applicable law.

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- 11.3** In the case of a Recall or Product Action, each Party shall make a permanent, complete and accurate record of all costs incurred by it in connection with the Recall or Product Action, a copy of which shall be delivered to the other Party as soon after the completion of such Recall or Product Action as may be practicable.
- 11.4** In the case of a Recall or Product Action that is covered by a recall insurance policy held by any Party, the Party holding the recall insurance policy shall be fully reimbursed the deductible amount in equal proportion by the Parties in accordance with the Profit Sharing Percentage for that Product. In the event that the recall expenses exceed insurance coverage, the Parties shall, except in the case of a Recall or Product Action that is covered by an indemnity obligation, share the expenses in accordance with the Profit Sharing Percentage for that Product.
- 11.5** In the case of a Recall or Product Action that is not covered by any indemnity obligation of a Party under Section 17 of this Agreement, the costs incurred by the Parties in connection with the Recall or Product Action shall be shared by the Parties in accordance with the Profit Sharing Percentage for that Product. In that event, if one Party has paid more than its share of the costs in connection with the Recall or Product Action, the other Parties, in accordance with their Profit Sharing Percentage for that Product, shall reimburse the overpaying Party the amount of the overpayment within sixty (60) days of receiving the record contemplated by Section 11.3.

## **12. ORDERS AND DELIVERY OBLIGATIONS.**

- 12.1** The manufacturing Batch size of the Product that shall be listed on the corresponding Amending Product Exhibit. ANI or a Sales and Marketing Company designated by ANI shall accept orders for full-Batch quantities of the Product at the Base Price, as set forth in the corresponding Amending Product Exhibit.
- 12.2** The Amending Product Exhibit will set forth the Base Price for each Product. The Base Price may change from time to time based on the actual changes in the cost of Raw Materials, Components, labor, overhead, and costs related to stability testing and regulatory support services. ANI shall provide, at RiconPharma's request, documentation illustrating how such Base Price changes have been calculated prior to the implementation of such change. Notwithstanding any other provision in this Agreement, ANI may not increase the labor and overhead elements of the Base Price calculation greater than [ \*\*\* ] without the express advance written consent of ANI and RiconPharma, which consent shall not be unreasonably withheld, conditioned or delayed.

## **13. RECORDS.**

- 13.1** ANI will maintain records and documents documenting the Base Price of each Product and ANI will maintain records and documents documenting Net Sales

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and all transactions relating to the sale of each Product for a time period equal to the greater of:

- (a) the period meeting all known regulations of the applicable Regulatory Authorities with respect to such Product; and
- (b) five (5) years from the date of sale.
- 13.2** ANI shall maintain all records relating to the manufacture of the Products necessary to materially comply with all applicable laws, rules and regulations in each regulatory jurisdiction within the Territory and, if different, the regulatory jurisdiction of manufacture of the Products. Specifically, but without limitation, ANI shall maintain all records and samples (including retention samples) reasonably necessary to support GMPs and other regulatory requirements in such regulatory jurisdictions. All records relating to the manufacture of the Product shall be available for inspection, audit and copying by RiconPharma and its representatives and agents at ANI's office upon reasonable advance request and during normal business hours. All such records shall be maintained for a period of not less than three (3) years or such longer period as may be required by law, rule or regulation. All records relating to the manufacture, stability and quality control of each Product shall be retained for a period of not less than the approved shelf life of such Product as set forth in the related Regulatory Approval plus two (2) years.
- 13.3** RiconPharma shall maintain all records relating to the development of the Products necessary to materially comply with all applicable laws, rules and regulations in each regulatory jurisdiction within the Territory. All records relating to the development of each Product shall be available for inspection, audit and copying by ANI and its representatives and agents at RiconPharma's office upon reasonable advance request and during normal business hours. All such records shall be maintained for a period of not less than the period the Product is sold is by ANI or such longer period as may be required by law, rule or regulation.

## **14. INTELLECTUAL PROPERTY RIGHTS.**

- 14.1** Each Party shall own all Inventions made solely by its employees and agents, and all patent applications and patents claiming such Inventions. All Inventions made jointly by employees or agents of the Parties and all patent applications and patents claiming such Inventions shall be owned jointly by the Parties. All determinations of invention under this Section 14 shall be in accordance with U.S. law
- 14.2** The Party owning the Invention shall make all decisions with respect to patent filings and shall have the right to select patent counsel and to take such other actions as are necessary to prepare, file, prosecute and maintain patent protection with regard to the Inventions under Section 14.1.

Inventions, the Parties shall jointly determine in what countries, if any, patent applications claiming such joint Inventions should be filed. In the event that either Party does not wish to share in the expenses of filing, prosecuting or maintaining such joint Inventions in any country, such Party shall promptly assign or cause to be assigned to the other Party all of its right, title and interest in and to such joint Inventions in the subject country. Thereafter, such joint Invention shall be treated as an Invention solely owned by such other Party within the subject country for all purposes of this Agreement. In the event the Parties desire to proceed with the filing, prosecution and maintenance of such joint invention, they shall share in all expenses related thereto in accordance with each Party's Development Cost Percentage on the Amending Product Exhibit for the Product to which the Invention relates or most closely relates.

- 14.3** Each Party shall be responsible for prosecuting and maintaining its own patent applications and patents. Except as otherwise provided in Section 14.2, all expenses for filing, prosecuting and maintaining a Party's patent applications and patents shall be borne by such Party.
- 14.4** Each Party shall execute such documents as may be necessary to obtain, perfect or maintain any jointly owned patent rights filed pursuant to this Agreement. The Parties agree to cooperate with one another so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such jointly owned patent rights.
- 14.5** Each Party shall have the sole right, in its own name and at its own expense, to enforce patent rights relating to Inventions that it owns against any Third Party. The Parties shall jointly determine which Party shall have the right and responsibility to institute, prosecute and control any action or proceeding with respect to the infringement or misappropriation of jointly owned patent rights.
- 14.6** In connection with any action taken by either Party against a Third Party to protect or enforce any patent right hereunder, the other Party shall, if requested, consult with the Party taking such action, and make its employees available as witnesses or as evidence any materials and/or data reasonably necessary for the furtherance of such action. Expenses incurred in connection with providing witnesses and/or making materials or data available shall be borne by the Party taking action against the Third Party.
- 14.7** If a Party is sued for infringing any Third Party patent out of the manufacture, use, sale or importation of a Product in the Territory, the Parties shall promptly discuss the course of action to be taken to resolve or defend such litigation. Each Party shall provide the other Parties with such assistance as is reasonably necessary and shall cooperate in the defense of such action.
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**15. RELATIONSHIP OF RICONPHARMA AND ANI.**

- 15.1** The relationship of RiconPharma and ANI created by this Agreement is that of developer and contract manufacturer, and not that of a partnership, principal and agent, franchisor and franchisee, or joint or co-ventures. In the performance of this Agreement, no Party shall have any authority to assume or create any obligation or responsibility, either expressed or implied, on behalf of or in the name of any other Party, or to bind any other Party or its Affiliates in any manner whatsoever.
- 15.2** If this Agreement is terminated for any reason, the Parties shall not thereafter use, or permit anyone else under its control to use, any other Party's name in the promotion of its business or the offer for sale of any goods.

**16. REPRESENTATIONS AND WARRANTIES.**

- 16.1** Each Party hereby represents and warrants to the other Parties that:
- (a) it is a corporation or other entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or organization;
  - (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate or other entity action and does not require any shareholder or member action or approval;
  - (c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;
  - (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under: (i) a loan agreement, guaranty, financing agreement, agreement affecting a Product or other agreement or instrument affecting a Product; (ii) the provisions of its charter or other operative documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;
  - (e) it has the full right, power and authority to grant all of the right, title and interest in the licenses, if any, granted to the other Party under this Agreement;
  - (f) it is financially solvent and has the financial resources to perform its obligations under this Agreement; and
  - (g) it is not debarred under the Generic Drug Enforcement Act of 1992; it does not and will not use in any capacity the services of any person
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debarred under the Generic Drug Enforcement Act of 1992; and neither it nor any of its employees, agents, suppliers, or contractors has engaged in any activity which could lead to it becoming debarred under the Generic Drug Enforcement Act of 1992.

**16.2** ANI covenants, represents, and warrants that:

- (a) it shall at all times comply with all material applicable laws, rules, and regulations relating to its activities under this Agreement;
  - (b) all Products shipped shall be manufactured, packaged, stored, and shipped by ANI materially in accordance with all GMPs and all other applicable laws, rules and government regulations in effect at the time of shipping of the Product;
  - (c) the Labeling content for the Products will at all times comply with the Regulatory Approval for the Product and be the same as the Labeling for the Reference Product except for differences allowed by applicable regulations;
  - (d) all Products shipped shall conform to the Specifications, the Regulatory Approval, and the Registration and be merchantable and shall not be misbranded or adulterated;
  - (e) it shall take all commercially reasonable precautions customary in the industry in manufacturing, testing, packaging, labeling and handling the Products to ensure the quality, safety and fitness thereof;
  - (f) that each Unit of the Products shall bear an expiration date of no less than twenty-four (24) months following the date of its manufacture, unless the RLD has an expiration date of less than twenty-four (24) months, in which case the expiration date borne by the Products shall reflect the stability of the RLD;
  - (g) it shall materially comply with all requirements of the laws and regulations of the Regulatory Authority and applicable state law requirements governing the marketing, sale and distribution of Products;
  - (h) it shall maintain adequate warehousing, distribution facilities, documentation and personnel to provide reasonable distribution, staffing for customer service, billing, marketing and accounting with respect to the Products; and
  - (i) copies of all agreements ANI has with any Third Party or Affiliate for manufacture or supply of any Product, Raw Materials or Components in effect on the date hereof are attached as exhibits to this Agreement and the copies attached as exhibits are true and complete copies of those agreements.
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**16.3** RiconPharma covenants, represents, and warrants that:

- (a) it shall at all times comply with all applicable laws, rules, and regulations relating to its activities under this Agreement;
- (b) based on its preliminary analysis, RiconPharma believes that Commercially Reasonable Efforts will result in the ability to develop and manufacture and obtain Regulatory Approval for the Products;
- (c) all of the research and development activities pertaining to the Products shall be conducted in accordance with all applicable laws and regulations, GMPs, GLPs and GCP and all applicable guidelines promulgated by any Regulatory Authority having jurisdiction over the Products in the Territory;
- (d) copies of all agreements RiconPharma has with any Third Party or Affiliate for manufacture or supply of any Product, Raw Materials or Components in effect on the date hereof are attached as exhibits to this Agreement and the copies attached as exhibits are true and complete copies of those agreements.

## **17. INDEMNIFICATION**

- 17.1** RiconPharma shall indemnify, defend, and hold harmless ANI and its respective Affiliates, directors, officers, owners, employees, and agents from and against any and all claims, demands, lawsuits, causes of action, actions or other proceedings, losses, liabilities, injuries, damages, and expenses, including reasonable attorneys' fees and costs from any actual or alleged infringement of patent, trademark, trade dress or other intellectual property rights or interests of any Third Party by the Products, the sale of the Products and/or the development of the Products. The indemnity obligations in the preceding sentence shall not apply to an actual infringement caused solely by the willful misconduct of ANI.
  - 17.2** ANI shall indemnify, defend, and hold harmless RiconPharma and their respective Affiliates, directors, officers, owners, employees, and agents from and against any and all claims, demands, lawsuits, causes of action, actions or other proceedings, losses, liabilities, injuries, damages, and expenses, including reasonable attorneys' fees and costs from any actual or alleged infringement of patent, trademark, trade dress or other intellectual property rights or interests of any Third Party by the Labeling of the Products and/or the methods, design, or processes utilized in connection with the manufacturing or packaging of the Products. The indemnity obligations in the preceding sentence shall not apply to an actual infringement caused solely by the willful misconduct of RiconPharma.
  - 17.3** RiconPharma shall indemnify, defend, and hold harmless ANI and their respective Affiliates, directors, officers, employees, owners and agents from and against any and all claims, demands, lawsuits, causes of actions, actions or other
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proceedings (including voluntary and involuntary Product Recalls, Product Actions, and other FDA enforcement actions), losses, liabilities, injuries, damages and expenses, including reasonable attorneys' fees and costs arising from or relating to: (i) the breach of any representation, warranty or covenant made or given by RiconPharma in this Agreement; (ii) any breach of any obligations under Section 10 of this Agreement; (iii) the design or formulation of any Products including, but not limited to, any defect in design, whether patent or latent; and/or (iv) any negligent act or omission by RiconPharma or its Affiliates.

- 17.4** ANI shall indemnify, defend, and hold harmless RiconPharma and its respective Affiliates, directors, officers, employees, owners and agents from and against any and all claims, demands, lawsuits, causes of actions, actions or other proceedings (including voluntary and involuntary Product Recalls, Product Actions, and other FDA enforcement actions), losses, liabilities, injuries, damages and expenses, including reasonable

attorneys' fees and costs arising from or relating to: (i) the breach of any representation, warranty or covenant made or given by ANI in this Agreement; (ii) any defect in Raw Materials or Components that ANI knew or reasonably should have known through testing in compliance with GMPs, including, but not limited to, any defect from or relating to the handling, storage, formulation, testing, supply, packaging, purchase, or manufacture of any Raw Materials or Components; (iii) the handling or storage by ANI of any Products; (iv) the manufacture, testing, or packaging of any Products including, but not limited to, any defect in manufacturing; (v) the Labeling of the Products including, but not limited to, any defect in warning; and (vi) any grossly negligent act or omission by ANI or its Affiliates.

- 17.5 A Party shall give written notice to the other Party of a claim, demand, lawsuit, cause of action, action or other proceeding (including voluntary and involuntary Product Recalls, Product Actions, and other FDA enforcement actions), loss, liability, injury, damage and/or expense, including reasonable attorneys' fees and costs (hereinafter individually and collectively a "Claim") for which the Party contends it is entitled to be defended, indemnified and held harmless under Sections 17.1 through 17.4 (hereinafter individually and collectively an "Indemnity Claim") within 30 days after the Party making the Indemnity Claim becomes aware of the Claim; provided, however, that the failure to give such notice within the 30 day period shall not waive or in any way impair a Party's right to be indemnified, defended or held harmless unless the delay in providing such notice has a material adverse effect on the indemnifying Party. An Indemnity Claim shall be deemed accepted unless within 30 days after receiving the Indemnity Claim notice, the receiving Party notifies the other Party in writing that the receiving Party will not defend, indemnify and hold the sending Party harmless
- 17.6 An indemnified Party shall reasonably cooperate with the indemnifying Party with respect to any investigation or defense of any Claim.

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- 17.7 Upon receiving notice of a Claim, ANI may, for purposes of funding reserves for Litigation Expenses and related damages, withhold Net Profits that would otherwise be distributed to RiconPharma pursuant to Section 5.2, place such amounts in escrow and use such reserves to pay Litigation Expenses from a Claim or to pay the deductible or SIR and related damages on any Policy.
- 17.8 The indemnifying Party shall have the right to control the defense or settlement of an Indemnity Claim that it has accepted. The indemnified Party may participate in (but not control) the defense of a Claim at its sole cost and expense.
- 17.9 Where a Party refuses to accept an Indemnity Claim, the other Party's defense of the Claim will not be deemed a waiver or admission of any kind against the refusing Party for indemnity, defense and to be held harmless under this Section 17.
- 17.10 A Party may not settle a Claim without the consent of another Party [if such settlement would require the other Party to submit to an injunction].

## 18. INSURANCE.

- 18.1 Not later than the Initial Marketing Date with respect to a Product, each Party shall obtain and maintain during the Term of this Agreement and for a period of three years after the Termination of this Agreement at its own expense insurance policies, including product liability insurance, providing coverage for any personal injury or property damage allegedly caused by the Products or the acts and omissions of the Parties relating to the Products (the "Policies") with liability limitations of: (i) in the cases of ANI, not less than [ \*\*\* ] per occurrence and in the aggregate; and (ii) in RiconPharma's case [ \*\*\* ] per occurrence and in the aggregate if there is one Amending Product Exhibit to this Agreement. If there is more than one Amending Product Exhibit to this Agreement, or if the total dollar value of sales of Products by ANI exceeds [ \*\*\* ], the liability limitations for the RiconPharma Policies shall be a minimum of [ \*\*\* ] per occurrence and in the aggregate. Each Party shall deliver a certificate of insurance on an Accord form or equivalent to the other Party evidencing that the Policies are in effect and providing that the Policies will not be cancelled or modified without first giving 30 days advance notice to the certificate holder. Any Party may request to be named as an additional insured on the Policies obtained and maintained by the other Party, subject to approval by the insurance provider. The Policies obtained and maintained by each Party shall provide contractual liability insurance providing coverage for the indemnity, defense and hold harmless obligations undertaken by that Party under this Agreement.
- 18.2 Subject only to Section 18.3 below, the Policies obtained and maintained by RiconPharma shall be primary to any Policies obtained and maintained by ANI with respect to any Claim. The Policies shall have a maximum deductible or self-insurance retention ("SIR") of [ \*\*\* ] per policy.

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- 18.3 ANI's Policies shall be primary with respect to RiconPharma's Policies as to any Claim for which ANI owes indemnity and defense to RiconPharma under Section 17.4 of this Agreement.

## 19. AUDITS AND INSPECTIONS.

- 19.1 Each Party shall keep complete and accurate accounts, records, books and data with respect to its obligations hereunder including the books and records identified and described in Section 13 of this Agreement (the "Records"). Each Party shall have the right at reasonable times upon prior written notice to another Party, to inspect copy and audit the Records relating to the other Party's performance and obligations under this Agreement. A Party shall permit authorized representatives of the other Party to inspect the Party's facilities and quality systems in connection with the Product during standard business hours and for reasonable periods for the purpose of assuring that the Party is complying with the federal and state laws and regulations relating to the production of the Product. Such inspection shall be at the inspecting Party's sole expense and upon at least five (5) business days advance written notice to the other Party.
- 19.2 In the event of an audit or inspection of one of the Party's facilities by any Regulatory Authority, that Party shall supply the other Parties with notice of the audit or inspection and a copy of any report received from such Regulatory Authority and the inspected Party shall provide such Regulatory Authority with a prompt, accurate and complete response to any deficiencies or observations noted during the audit or inspection. The Party inspected or audited agrees that it shall promptly address, and if necessary correct, any and all such deficiencies or observations, and obtain any required approval or reclassification from the Regulatory Authority.
- 19.3 In the event of an audit or inspection of one of the facilities of a Third Party manufacturer or supplier of any Raw Materials or Components, the Party who hired or contracted with the Third Party (the "Retaining Party") shall notify the other Party of the audit or inspection and provide to the other Parties a copy of any report the Retaining Party receives issued by the Regulatory Authority pertaining to the audit or inspection.

## 20. TERM AND TERMINATION.

- 20.1 This Agreement shall become effective on the Effective Date and continue until terminated in accordance with this Agreement (the “Term”).
- 20.2 The Parties may jointly agree in writing, at any time, to terminate any Product Exhibit to this Agreement. In the event that any Amending Product Exhibit to this Agreement is terminated pursuant to this Section 20.2, the effect of such termination shall be as set forth in the agreement between the Parties documenting that termination. In the event that all Amending Product Exhibit to this

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Agreement have been terminated, a Party may terminate this Agreement by providing the other Parties with thirty (30) days’ prior written notice.

- 20.3 This Agreement or any Amending Product Exhibit may be terminated effective immediately by written notice by a Party to the other Party at any time during the Term of this Agreement for material breach by the other Party of any provision of this Agreement, which breach remains uncured for thirty (30) days from the date written notice of such breach is given to the breaching Party; provided, however, that if such breach is not cured within the stated period and the breaching Party uses Commercially Reasonable Efforts to cure such breach, the stated period will be extended by an additional thirty (30) days.
- 20.4 Prior to the issuance of an ANDA for a Product, a Party may terminate its interest and involvement in the Amending Product Exhibit for that Product upon thirty (30) days’ prior written notice to the other Party. In that event, the terminating Party shall be required to pay or reimburse the non-terminating Party for its respective share of the Development Costs as set forth in the Amending Product Exhibit. In addition, the terminating Party shall not pursue the development, manufacture, marketing, distribution or sale of such Product or a Bioequivalent Product manufactured by a Third Party for a period of five (5) years after the effective date of such termination.
- 20.5 After the issuance of an ANDA for a Product, a Party that desires to terminate its interest or involvement in an Amending Product Exhibit to this Agreement with respect to such Product other than by reason of Section 20.3, shall give the other Parties not less than sixty (60) days’ prior written notice thereof, such termination to be effective at the conclusion of such sixty (60) day period.
- 20.6 If a Party terminates its interest in an Amending Product Exhibit to this Agreement by reason of Sections 20.4 or 20.5, or the other Party terminates this Agreement or any Amending Product Exhibit pursuant to Section 20.3, the Party not terminating or in breach, as applicable (the “Continuing Party”), may continue to develop, market, manufacture, and sell the Product on the Amending Product Exhibit, as the case may be, and shall have the right to purchase the rights of the breaching or terminating Party as the case may be (the “Non-Continuing Party”) in and to the Product. The Non-Continuing Party shall contemporaneously assign or license, as applicable, to the Continuing Parties, all of the Non-Continuing Party’s rights (including proprietary rights) to continue to develop, make, have made, use, import, market, offer for sale or sell the Products, including any Manufacturer and Development Technology. The assigned or licensed rights, as applicable, shall include, without limitation, Regulatory Approvals (including the ANDA), the trade name for the Product and the manufacturing rights, the good will related to the Product, accounts receivable, and inventory of the Product. The purchase price of such assigned or licensed rights shall be [ \*\*\* ] and the following additional provisions shall apply:

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- (a) **By ANI.** If ANI is the Non-Continuing Party then, subject to the terms and conditions of this Agreement, (i) it shall grant to RiconPharma non-exclusive license in and to Manufacturing and Development Technology it has to the extent necessary for RiconPharma to perform ANI’s obligations and exercise its rights under this Agreement, including, without limitation, any and all obligations and rights that need to be performed or exercised by or on behalf of ANI to develop, make, have made, use, import, market, offer for sale or sell the Product in accordance with this Agreement and (ii) at the request of RiconPharma, ANI shall manufacture the Product in compliance with the terms and conditions of this Agreement for a period not to exceed twelve (12) months following the notice of termination. Following any termination in respect of which ANI is the Non-Continuing Party, ANI shall use Commercially Reasonable Efforts to assist RiconPharma in transferring the manufacturing of the Product to a Third Party. For a period of twelve (12) months following the notice of termination, ANI shall not develop, apply for Regulatory Approval for, manufacture, import, market, sell or promote any product that is a direct substitute for the Product, including any Bioequivalent Product. If the ANDA is in ANI’s name, it shall execute all documents and take all other actions necessary to transfer the ANDA in accordance with the instructions of ANI and RiconPharma,
- (b) **By RiconPharma.** If RiconPharma is the Non-Continuing Party then, subject to the terms and conditions of this Agreement, it shall grant to ANI non-exclusive license in and to Manufacturing and Development Technology it has to the extent necessary for ANI to perform RiconPharma’s obligations and exercise its rights under this Agreement, including, without limitation, any and all obligations and rights that need to be performed or exercised by or on behalf of RiconPharma to develop, make, have made, use, import, market, offer for sale or sell the Product in accordance with this Agreement. For a period of twelve (12) months following the notice of termination, RiconPharma shall not develop, apply for Regulatory Approval for, manufacture, import, market, sell or promote any product that is a direct substitute for the Product, including any Bioequivalent Product. If the ANDA is in RiconPharma’s name, it shall execute all documents and take all other actions necessary to transfer the ANDA in accordance with the instructions of ANI.

## 21. CONFIDENTIALITY.

During the term of this Agreement, each Party will be exposed to confidential proprietary technical information belonging to the other Party that pertains to the operation of the other Party’s businesses or the operation of its business in general, including but not limited to the formulations, related technical information and data, packaging, research, operations, manufacturing processes, marketing, strategy, know-how and product information for a Product. Each Party agrees not to (i) disclose, during the term of this Agreement or thereafter, to any other person any Confidential Information of the Party,

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or (ii) use, after the term of this Agreement, any Confidential Information of the other Party for any purpose. “Confidential Information” includes all information that derives independent economic value from not being generally known, or not being readily ascertainable by proper means, by other persons who can obtain economic value from the disclosure or use of such information, and any other information identified by a Party as being



Confidential Information. For purposes of this Agreement, "Confidential Information" does not include any information that (i) at the time of disclosure or thereafter is publicly available (other than as a result of a violation of this Paragraph), (ii) was or becomes available to the recipient on a non-confidential basis from a source other than the disclosing Party, provided that such source is not and was not bound by a confidentiality agreement with or other obligation of secrecy to the disclosing Party; or (iii) is independently acquired or developed by the recipient without violating any of its obligations under this Paragraph. The obligations of the Parties set forth in this Paragraph shall survive the termination or expiration of this Agreement.

**22. FORCE MAJEURE.**

No Party shall be liable or be in breach of any provision of this Agreement for any failure or delay on its part to perform any obligation where such failure or delay has been occasioned by any act of God, war, riot, fire, explosion, flood, sabotage, unavailability of fuel, labor, containers or transportation facilities, accidents of navigation or breakdown or damage of vessels or other conveyances for air land or sea, other impediments or hindrances to transportation, government intervention (other than that of a duly-authorized Regulatory Authority), strikes or other labor disturbances or any other cause beyond the control of the Parties.

**23. NOTICES.**

All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and sent to the address or number below by facsimile transmission or Federal Express or another recognized overnight mail service that utilizes a written form of receipt for next day or next business day delivery. The notice shall be deemed duly given (a) if faxed by 4:00 p.m., New York time, on the date sent by fax provided there is a confirmation by the transmitting machine showing the proper number of pages were transmitted without error or (b) if sent by overnight mail, on the business day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next business day delivery. A Party may change its address or fax number for receiving notice by the proper giving of notice hereunder:

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**To: ANI**

ANI Pharmaceuticals, Inc.  
210 Main Street West  
Baudette, MN 56623  
USA  
Attention: Vice President & CFO  
Fax: +1(218) 634-3540

**To: RiconPharma**

RiconPharma LLC  
100 Ford Road, Suite #9  
Denville, NJ 07834  
USA  
Attention: President & CEO  
Fax: +1(973) 627-4735

**24. EXECUTION OF ALL NECESSARY ADDITIONAL DOCUMENTS.**

Each Party agrees that it will forthwith upon the request of the other Party execute and deliver all documents and will take all such other actions as the other Party may reasonably request from time to time in order to effectuate the provision and purposes of this Agreement.

**25. WAIVER.**

Any failure of a Party to enforce at any time any of the provisions of this Agreement shall not be deemed or construed to be a waiver of such provisions or a waiver of any right of such Party thereafter to enforce each and every such provision on any succeeding occasion or breach thereof.

**26. ASSIGNMENT AND AMENDMENT.**

**26.1** Other than an assignment pursuant to Section 2.3, neither this Agreement nor any rights hereunder shall be assigned by a Party without the prior written consent of the other Party, and then only upon approval of the other Party and acceptance of such assignment in written form approved by such Party, which approval shall not be unreasonably withheld, conditioned or delayed. In the event of an assignment by a Party to any Affiliate thereof as permitted hereunder, the assigning Party shall not be released from its obligations hereunder, and shall guarantee the full performance by such Affiliate of such obligations.

**26.2** No amendment hereof shall be binding unless made in writing and signed by each of the Parties hereto.

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**27. ENTIRE AGREEMENT.**

This Agreement, including the Amending Product Exhibits to this Agreement, incorporates the entire understanding of the Parties and revokes and supersedes any and all agreements, contracts, understandings or arrangements that might have existed heretofore among the Parties regarding the subject matter hereof, and all prior agreements and understandings between the Parties and relating to the subject matter hereof are superseded by this Agreement. No Party shall be liable or bound to another Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may also be executed via facsimile, which facsimile shall be deemed an original.

**28. GOVERNING LAW; ARBITRATION; LANGUAGE.**

**28.1** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without giving effect to conflict of law principles thereof, and the Parties consent to and agree to submit to the jurisdiction of the courts of, and accept service of process from, the State of New York, state and federal, with respect to any Claim or other claim, action, lawsuit, or proceeding relating to or out of this Agreement. The Parties expressly agree that, to the maximum extent permitted by law, the requirements of any multilateral or bilateral treaties, now or hereafter existing, between two or more countries that place any obligations or duties on a Party or the Parties that are inconsistent with or in addition to any of its obligations and duties under this Agreement, shall not apply to this Agreement or to the Parties' performance hereunder without the consent of all Parties. This Agreement shall exclude, and not be governed by, either the provisions of the International Sale of Goods Act, or the United Nations Convention on the International Sale of Goods, regardless of that Convention's legal or statutory adoption by any jurisdiction.

**28.2** In the event of any Indemnity Claim or other dispute, claim, question or disagreement out of or relating to this Agreement, or the breach hereof, the Parties shall use Commercially Reasonable Efforts to settle such Indemnity Claim or other dispute, claim, question or disagreement. To this end, the Parties shall consult and negotiate with each other in good faith and, recognizing mutual interests, attempt to reach a just and equitable solution satisfactory to each of the Parties. If the Parties do not reach such resolution within a period of thirty (30) days, any Indemnity Claim or other dispute, claim, question or disagreement out of or relating to this Agreement, or the breach hereof, where the total amount in controversy between the Parties is less than [ \*\*\* ], shall be determined and settled by binding arbitration in New York County, New York before a three member panel of the American Arbitration Association or JAMS in accordance with the provisions of the tribunal's then applicable Commercial Arbitration Rules. Notice of the demand for arbitration shall be made in writing to the other Party and to the arbitral tribunal. Nothing contained in this Section 28.2 shall prevent a Party

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from seeking interim or final equitable relief from the arbitral tribunal of a state or federal court of competent jurisdiction in the State of New York. In no event shall the demand for arbitration be made after the date when institution of legal or equitable proceedings based on the claim or dispute would be barred by the applicable statute of limitations. Any award rendered by the arbitration panel shall be final and conclusive upon the Parties and a judgment thereon may be entered in any court having competent jurisdiction.

**28.3** Each Party represents that it has been represented by legal counsel in connection with this Agreement. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

**29. SEVERABILITY.**

If any term or provision of this Agreement shall be held invalid or unenforceable, the remaining terms hereof shall not be affected, but shall be valid and enforced to the fullest extent permitted by law.

**30. HEADINGS.**

The headings used in this Agreement are intended for guidance only and shall not be considered part of this written understanding between the Parties hereto and shall have no effect on the meaning of the provisions hereof.

**31. SURVIVAL.**

All representations, warranties, and covenants of the Parties and the terms and conditions of Sections 3.2, 5, 10, 11, 14, 17, 18, 21, and 28 shall survive the termination of any Amending Product Exhibit and/or this Agreement, notwithstanding any language in the Agreement to the contrary.

[remainder of page intentionally left blank; signature page follows]

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**Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [\*\*\*]**

IN WITNESS WHEREOF, this Agreement has been executed by the Parties on the date first above written.

**ANIP Acquisition Company**

By: /s/ Charlotte C. Arnold  
Name: Charlotte C. Arnold  
Title: Vice President & CFO

**RiconPharma LLC**

By: /s/ Raj Devalapalli  
Name: Raj Devalapalli  
Title: President & CEO

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**AMENDING PRODUCT EXHIBIT A-1  
 MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT  
 (The "Agreement"), by and among RiconPharma LLC ("RiconPharma") and ANI Pharmaceuticals ("ANI"), dated as of July 11, 2011**

**PRODUCTS** The Product to which this Product Exhibit (this "Product") applies is: [\*\*\*].

**DOSAGE STRENGTH** [\*\*\*]

**TERRITORY** United States.

**ESTIMATED DEVELOPMENT COST:** [\*\*\*]

- |    |                                                                |       |
|----|----------------------------------------------------------------|-------|
| 1. | Formulation Development                                        | [***] |
| 2. | Bio-studies                                                    | [***] |
| 3. | Manufacturing Development                                      | [***] |
| 4. | Out of Pocket Expenses (API, RLD's Standards, Impurities etc.) | [***] |

**ANDA HOLDER:** The ANDA for this Product shall be in the name of ANI, provided that the Product is manufactured commercially by ANI or an ANI Affiliate. Should the product be manufactured commercially by RiconPharma or a RiconPharma Affiliate, the ANDA shall be in the name of RiconPharma. The asset and the intellectual properties for this Product will be jointly owned (50/50) by RiconPharma and ANI.

**MILESTONE PAYMENTS AND DELIVERABLES:**

Phase	Activities	Est. Amt for ANI	Est. Amt for Ricon	Time Lines
Phase I	Upon Signing	[***]	[***]	[***]
Phase II	Out of pocket expenses	[***]	[***]	[***]
Phase III	Formulation Completed	[***]	[***]	[***]
Phase IV	Tech Transfer Completed	[***]	[***]	[***]
Phase V	Tech Transfer Initiated	[***]	[***]	[***]
Phase VI	Methods Verified	[***]	[***]	[***]
Phase VII	Exhibit Batch/Stability 3 months	[***]	[***]	[***]
Phase VIII	Upon Signing (Bio-Studies)	[***]	[***]	[***]
Phase IX	Upon Dosing	[***]	[***]	[***]
Phase X	Upon Providing Report	[***]	[***]	[***]
Total	Cost of Development	[***]	[***]	[***]

**Profit Sharing:**

RiconPharma –	50%
ANI Pharmaceuticals –	50%

**Miscellaneous**

This Amending Product Exhibit shall be deemed to be an integral part of the Master Product Development and Collaboration Agreement, and exhibits to this Amending Product Exhibit shall be deemed to be an integral part thereof. If there is any conflict between the provisions of the Agreement and this Amending Product Exhibit, the provisions of this Amending Product Exhibit shall be determinative.

Effective Date of the Exhibit A-1: July 11, 2011

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amending Product Exhibit to be effective as of the Effective Date.

RICONPHARMA LLC

ANIP ACQUISITION COMPANY

By: RAJ K. DEVALAPALLI

By: CHARLOTTE C. ARNOLD

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: President & CEO

Title: Vice President & CFO

PRODUCTS The Product to which this Product Exhibit (this "Product") applies is: [\*\*\*].  
DOSAGE STRENGTH [\*\*\*]  
TERRITORY United States.

ESTIMATED TRANSFER PRICE: [\*\*\*]

ESTIMATED DEVELOPMENT COST: [\*\*\*]

- 1. Formulation Development [\*\*\*]
- 2. Bio-studies [\*\*\*]
- 3. Manufacturing Development [\*\*\*]
- 4. Out of Pocket Expenses (API, RLD's Standards, Impurities etc) [\*\*\*]

ANDA HOLDER: ANDA for this Product shall be in the name of ANI, provided that the Product is manufactured commercially by ANI or an ANI Affiliate. Should the product be manufactured commercially by RiconPharma or a RiconPharma Affiliate, the ANDA shall be in the name of RiconPharma. The asset and the intellectual properties for this Product will be jointly owned (50/50) by RiconPharma and ANI.

MILESTONE PAYMENTS AND DELIVERABLES:

Phase	Activities	Est. Amt for ANI	Est. Amt for Ricon	Time Lines
Phase I	Upon Signing	[***]	[***]	[***]
Phase II	Out of pocket expenses	[***]	[***]	[***]
Phase III	Formulation Completed	[***]	[***]	[***]
Phase IV	Tech Transfer Completed	[***]	[***]	[***]
Phase V	Tech Transfer Initiated	[***]	[***]	[***]
Phase VI	Methods Verified	[***]	[***]	[***]
Phase VII	Exhibit Batch/Stability 3 months	[***]	[***]	[***]
Phase VIII	Upon Signing (Bio-Studies)	[***]	[***]	[***]
Phase IX	Upon Dosing	[***]	[***]	[***]
Phase X	Upon Providing Report	[***]	[***]	[***]
Total	Cost of Development	[***]	[***]	[***]

Profit Sharing:

RiconPharma – 50%  
ANI Pharmaceuticals – 50%

Miscellaneous

This Amending Product Exhibit shall be deemed to be an integral part of the Master Product Development Agreement, and exhibits to this Amending Product Exhibit shall be deemed to be an integral part thereof. If there is any conflict between the provisions of the Agreement and this Amending Product Exhibit, the provisions of this Amending Product Exhibit shall be determinative.

Effective Date of the Exhibit A-2: July 11, 2011

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amending Product Exhibit to be effective as of the Effective Date.

RICONPHARMA LLC

ANIP ACQUISITION COMPANY

By: RAJ K. DEVALAPALLI

By: CHARLOTTE C. ARNOLD

Print Name:

Print Name:

Title: President & CEO

Title: Vice President & CFO

AMENDING PRODUCT EXHIBIT A-3  
MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT  
(The "Agreement"), by and among RiconPharma LLC ("RiconPharma") and ANI Pharmaceuticals ("ANI"), dated as of July 11, 2011

PRODUCTS The Product to which this Product Exhibit (this "Product") applies is: [\*\*\*]

DOSAGE STRENGTH [ \*\*\* ]

TERRITORY United States.

ESTIMATED TRANSFER PRICE: [ \*\*\* ]

ESTIMATED DEVELOPMENT COST: [ \*\*\* ]

- 1. Formulation Development [ \*\*\* ]
- 2. Bio-studies [ \*\*\* ]
- 3. Manufacturing Development [ \*\*\* ]
- 4. Out of Pocket Expenses (API, Raw Materials, Impurities etc.) [ \*\*\* ]

**ANDA HOLDER:** The ANDA for this Product shall be in the name of ANI, provided that the Product is manufactured commercially by ANI or an ANI Affiliate. Should the product be manufactured commercially by RiconPharma or a RiconPharma Affiliate, the ANDA shall be in the name of RiconPharma. The asset and the intellectual properties for this Product will be jointly owned (50/50) by RiconPharma and ANI.

**MILESTONE PAYMENTS AND DELIVERABLES:**

Phase	Activities	Est. Amt for ANI	Est. Amt for Ricon	Time Lines
Phase I	Upon Signing	[ *** ]	[ *** ]	[ *** ]
Phase II	Out of pocket expenses	[ *** ]	[ *** ]	[ *** ]
Phase III	Formulation Completed	[ *** ]	[ *** ]	[ *** ]
Phase IV	Tech Transfer Completed	[ *** ]	[ *** ]	[ *** ]
Phase V	Tech Transfer Initiated	[ *** ]	[ *** ]	[ *** ]
Phase VI	Methods Verified	[ *** ]	[ *** ]	[ *** ]
Phase VII	Exhibit Batch/Stability 3 months	[ *** ]	[ *** ]	[ *** ]
Phase VIII	Upon Signing (Bio-Studies)	[ *** ]	[ *** ]	[ *** ]
Phase IX	Upon Dosing	[ *** ]	[ *** ]	[ *** ]
Phase X	Upon Providing Report	[ *** ]	[ *** ]	[ *** ]
Total	Cost of Development	[ *** ]	[ *** ]	[ *** ]

**Profit Sharing:**

RiconPharma – 50%  
ANI Pharmaceuticals – 50%

**Miscellaneous**

This Amending Product Exhibit shall be deemed to be an integral part of the Master Product Development Agreement, and exhibits to Amending Product Exhibit shall be deemed to be an integral part thereof. If there is any conflict between the provisions of the Agreement and this Amending Product Exhibit, the provisions of this Amending Product Exhibit shall be determinative.

Effective Date of the Exhibit A-3: July 11, 2011

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amending Product Exhibit to be effective as of the Effective Date.

RICONPHARMA LLC

ANIP ACQUISITION COMPANY

By: RAJ K. DEVALAPALLI

By: CHARLOTTE C. ARNOLD

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: President & CEO

Title: Vice President & CFO

**AMENDING PRODUCT EXHIBIT A-4  
MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT  
(The "Agreement"), by and among RiconPharma LLC ("RiconPharma") and ANI Pharmaceuticals ("ANI"), dated as of July 11, 2011**

**PRODUCTS** The Product to which this Product Exhibit (this "Product") applies is: [\*\*\*].

**DOSAGE STRENGTH** [\*\*\*]

**TERRITORY**

United States.

**ESTIMATED TRANSFER PRICE:** Actual Cost plus 25% (Excluding API should not exceed \$2.00)**ESTIMATED DEVELOPMENT COST:** [\*\*\*]

- |    |                                                              |       |
|----|--------------------------------------------------------------|-------|
| 1. | Formulation Development                                      | [***] |
| 2. | Bio-studies                                                  | [***] |
| 3. | Manufacturing Development                                    | [***] |
| 4. | Out of Pocket Expenses (API, Raw Materials, Impurities etc.) | [***] |

**ANDA HOLDER:** The ANDA for this Product shall be in the name of ANI, provided that the Product is manufactured commercially by ANI or an ANI Affiliate. Should the product be manufactured commercially by RiconPharma or a RiconPharma Affiliate, the ANDA shall be in the name of RiconPharma. The asset and the intellectual properties for this Product will be jointly owned (50/50) by RiconPharma and ANI.

**MILESTONE PAYMENTS AND DELIVERABLES:**

Phase	Activities	Est. Amt for ANI	Est. Amt for Ricon	Time Lines
Phase I	Upon Signing	[***]	[***]	[***]
Phase II	Out of pocket expenses	[***]	[***]	[***]
Phase III	Formulation Completed	[***]	[***]	[***]
Phase IV	Tech Transfer Completed	[***]	[***]	[***]
Phase V	Tech Transfer Initiated	[***]	[***]	[***]
Phase VI	Methods Verified	[***]	[***]	[***]
Phase VII	Exhibit Batch/Stability 3 months	[***]	[***]	[***]
Phase VIII	Upon Signing (Bio-Studies)	[***]	[***]	[***]
Phase IX	Upon Dosing	[***]	[***]	[***]
Phase X	Upon Providing Report	[***]	[***]	[***]
Total	Cost of Development	[***]	[***]	[***]

**Profit Sharing:**

RiconPharma –	50%
ANI Pharmaceuticals –	50%

**Miscellaneous**

This Amending Product Exhibit shall be deemed to be an integral part of the Master Product Development Agreement, and exhibits to this Amending Product Exhibit shall be deemed to be an integral part thereof. If there is any conflict between the provisions of the Agreement and this Amending Product Exhibit, the provisions of this Amending Product Exhibit shall be determinative.

Effective Date of the Exhibit A-4: July 11, 2011

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amending Product Exhibit to be effective as of the Effective Date.

RICONPHARMA LLC

ANIP ACQUISITION COMPANY

By: RAJ K. DEVALAPALLIBy: CHARLOTTE C. ARNOLD

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: President &amp; CEO

Title: Vice President &amp; CFO

**AMENDING PRODUCT EXHIBIT A-5  
MASTER PRODUCT DEVELOPMENT AND COLLABORATION AGREEMENT**

(The "Agreement"), by and among RiconPharma LLC ("RiconPharma") and ANI Pharmaceuticals ("ANI"), dated as of July 11, 2011

**PRODUCTS** The Product to which this Product Exhibit (this "Product") applies is: [\*\*\*].**DOSAGE STRENGTH** [\*\*\*].**TERRITORY** United States.**ESTIMATED TRANSFER PRICE:** [\*\*\*]

<b>ESTIMATED DEVELOPMENT COST:</b>	[***]
1. Formulation Development	[***]
2. Bio-studies	[***]
3. Manufacturing Development	[***]
4. Out of Pocket Expenses (API, Raw Materials, Impurities etc.)	[***]

**ANDA HOLDER:** The ANDA for this Product shall be in the name of ANI, provided that the Product is manufactured commercially by ANI or an ANI Affiliate. Should the product be manufactured commercially by RiconPharma or a RiconPharma Affiliate, the ANDA shall be in the name of RiconPharma. The asset and the intellectual properties for this Product will be jointly owned (50/50) by RiconPharma and ANI.

**MILESTONE PAYMENTS AND DELIVERABLES:**

Phase	Activities	Est. Amt for ANI	Est. Amt for Ricon	Time Lines
Phase I	Upon Signing	[***]	[***]	[***]
Phase II	Out of pocket expenses	[***]	[***]	[***]
Phase III	Formulation Completed	[***]	[***]	[***]
Phase IV	Tech Transfer Completed	[***]	[***]	[***]
Phase V	Tech Transfer Initiated	[***]	[***]	[***]
Phase VI	Methods Verified	[***]	[***]	[***]
Phase VII	Exhibit Batch/Stability 3 months	[***]	[***]	[***]
Phase VIII	Upon Signing (Bio-Studies)	[***]	[***]	[***]
Phase IX	Upon Dosing	[***]	[***]	[***]
Phase X	Upon Providing Report	[***]	[***]	[***]
Total	Cost of Development	[***]	[***]	[***]

**Profit Sharing:**

RiconPharma – 50%  
ANI Pharmaceuticals – 50%

**Miscellaneous**

This Amending Product Exhibit shall be deemed to be an integral part of the Master Product Development Agreement, and exhibits to this Amending Product Exhibit shall be deemed to be an integral part thereof. If there is any conflict between the provisions of the Agreement and this Amending Product Exhibit, the provisions of this Amending Product Exhibit shall be determinative.

Effective Date of the Exhibit A-5: July 11, 2011

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Amending Product Exhibit to be effective as of the Effective Date.

RICONPHARMA LLC

ANIP ACQUISITION COMPANY

By: RAJ K. DEVALAPALLI

By: CHARLOTTE C. ARNOLD

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: President & CEO

Title: Vice President & CFO

**AMENDMENT NO. 1 TO**  
**TRANSACTION BONUS AGREEMENT**

**THIS AMENDMENT NO. 1 TO TRANSACTION BONUS AGREEMENT** (“Amendment”) is entered into this 28<sup>th</sup> day of December, 2012 (the “Effective Date”), by and between ANIP Acquisition Company (the “Company”) and Arthur Przybyl (the “Executive”).

**WHEREAS**, the Executive currently is employed by the Company as its Chief Executive Officer;

**WHEREAS**, the Company and the Executive are parties to that Transaction Bonus Agreement dated as of September 22, 2012 (the “Original Agreement”);

**WHEREAS**, the Company executed an Agreement and Plan of Merger in connection with the BioSante transaction on October 3, 2012, the consummation of which is expected to occur in the first half of 2013;

**WHEREAS**, pursuant to the Original Agreement, upon the consummation of the BioSante Transaction, Executive is to receive the Closing Date Bonus in cash, provided such cash is immediately used to purchase shares of the Series D Preferred Stock of the Company, which will be exchanged for shares of BioSante common stock in the BioSante Transaction;

**WHEREAS**, in connection with the BioSante Transaction, Executive has entered into a lock-up agreement with BioSante, pursuant to which Executive has agreed not to sell any of the shares of BioSante common stock which it receives in the BioSante Transaction for a period of six months (the “Lock-up Period”); and

**WHEREAS**, the Company and Executive desire by this writing to amend certain provisions of the Original Agreement relating to the timing of the payments to be made thereunder.

**NOW THEREFORE**, each Party, intending to be legally bound, does hereby agree as follows:

**1. DEFINITIONS:**

Capitalized terms used herein and not defined shall have the meanings given to them in the Original Agreement.

**2. DATE OF PAYMENT**

(a) Executive’s Closing Date Bonus, calculated in accordance with the Original Agreement, will be deposited by the Company into a Grantor Trust, whose trustee may be Wells Fargo, National Association or another institution (the “Trust”). Immediately upon receipt of the funds, the Trust shall use such cash to purchase, and the Company will sell to the Trust, on the Business Day immediately preceding the Closing Date of the BioSante Transaction the Executive’s Percentage of the issued and outstanding Series D Shares, which upon consummation of the BioSante Transaction will be converted into shares of Biosante common stock (the “Shares”).

(b) The Trust will hold and not release any Shares until the expiration of the Lock-up Period (the “Release Date”). The Company will notify the trustee of the Trust in writing upon the occurrence of the Release Date. On each Wednesday following the Release Date, the Trust will release the Shares in equal weekly installments (rounded to the nearest whole Share) through and including March 5, 2014 (the “Release Period”), either (i) to the Company, who will grant them to the Executive and transfer them to an Approved Broker/Dealer on behalf of the Executive or (ii) to an Approved Broker/Dealer on behalf of the Executive; provided, however, that the number of Shares released in any given week during the Release Period will not exceed two times the maximum number of Shares that can be sold under Rule 144,

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promulgated under the Securities Act of 1933, as amended in such week. Any Shares not released as a result of the preceding proviso shall be released pro rata over the remaining Release Period, subject to the limitations of the same proviso.

(c) On each Monday, the Company will provide Executive and the Approved Broker/Dealer with a calculation of the amount of withholding taxes (including FICA and income) that will be payable on the Shares to be released on the succeeding Wednesday (the “Taxes”). Such calculation will be based on the then current trading price of the Shares.

(d) For purposes hereof, an “Approved Broker/Dealer” means a broker/dealer, designated by Executive in writing to the Company and Trust, who has agreed in writing to sell, as promptly as practicable, out of the Shares released to it by the Trust, one-half of the Shares released, rounded down to the nearest whole number of Shares, on a weekly basis. Any Approved Broker/Dealer shall have acknowledged receipt of instructions to remit the proceeds of each sale of Shares, up to the amount of the Taxes, to the Company as promptly as practicable.

**3. MISCELLANEOUS**

(a) The Company agrees that it will take such actions as may be necessary to permit the sale of the Shares in accordance with the terms set forth in Section 2.

(b) Except as expressly amended hereby, the Original Agreement shall remain in full force and effect following the execution and delivery of this Amendment.

(c) This Amendment may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and such counterparts together shall constitute one instrument.

(d) The validity, construction, and effect of this Amendment shall be determined in accordance with the laws of the State of Delaware (without giving effect to principles of conflicts of laws thereof).



IN WITNESS WHEREOF, the Company and the Executive have executed this Amendment as of the Effective Date.

**EXECUTIVE:**

/s/ Arthur S. Przybyl

\_\_\_\_\_  
Arthur S. Przybyl

**THE COMPANY:**

ANIP ACQUISITION COMPANY

By: /s/ Charlotte Arnold

\_\_\_\_\_  
Name: Charlotte Arnold

Title: Vice President and Chief Financial Officer

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## AMENDMENT NO. 1 TO

TRANSACTION BONUS AGREEMENT

**THIS AMENDMENT NO. 1 TO TRANSACTION BONUS AGREEMENT** (“Amendment”) is entered into this 28th day of December, 2012 (the “Effective Date”), by and between ANIP Acquisition Company (the “Company”) and Charlotte Arnold (the “Executive”).

**WHEREAS**, the Executive currently is employed by the Company as its Vice President and Chief Financial Officer;

**WHEREAS**, the Company and the Executive are parties to that Transaction Bonus Agreement dated as of September 22, 2012 (the “Original Agreement”);

**WHEREAS**, the Company executed an Agreement and Plan of Merger in connection with the BioSante transaction on October 3, 2012, the consummation of which is expected to occur in the first half of 2013;

**WHEREAS**, pursuant to the Original Agreement, upon the consummation of the BioSante Transaction, Executive is to receive the Closing Date Bonus in cash, provided such cash is immediately used to purchase shares of the Series D Preferred Stock of the Company, which will be exchanged for shares of BioSante common stock in the BioSante Transaction;

**WHEREAS**, in connection with the BioSante Transaction, Executive has entered into a lock-up agreement with BioSante, pursuant to which Executive has agreed not to sell any of the shares of BioSante common stock which it receives in the BioSante Transaction for a period of six months (the “Lock-up Period”); and

**WHEREAS**, the Company and Executive desire by this writing to amend certain provisions of the Original Agreement relating to the timing of the payments to be made thereunder.

**NOW THEREFORE**, each Party, intending to be legally bound, does hereby agree as follows:

**1. DEFINITIONS:**

Capitalized terms used herein and not defined shall have the meanings given to them in the Original Agreement.

**2. DATE OF PAYMENT**

(a) Executive’s Closing Date Bonus, calculated in accordance with the Original Agreement, will be deposited by the Company into a Grantor Trust, whose trustee may be Wells Fargo, National Association or another institution (the “Trust”). Immediately upon receipt of the funds, the Trust shall use such cash to purchase, and the Company will sell to the Trust, on the Business Day immediately preceding the Closing Date of the BioSante Transaction the Executive’s Percentage of the issued and outstanding Series D Shares, which upon consummation of the BioSante Transaction will be converted into shares of Biosante common stock (the “Shares”).

(b) The Trust will hold and not release any Shares until the expiration of the Lock-up Period (the “Release Date”). The Company will notify the trustee of the Trust in writing upon the occurrence of the Release Date. On each Wednesday following the Release Date, the Trust will release the Shares in equal weekly installments (rounded to the nearest whole Share) through and including March 5, 2014 (the “Release Period”), either (i) to the Company, who will grant them to the Executive and transfer them to an Approved Broker/Dealer on behalf of the Executive or (ii) to an Approved Broker/Dealer on behalf of the Executive; provided, however, that the number of Shares released in any given week during the Release

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Period will not exceed two times the maximum number of Shares that can be sold under Rule 144, promulgated under the Securities Act of 1933, as amended in such week. Any Shares not released as a result of the preceding proviso shall be released pro rata over the remaining Release Period, subject to the limitations of the same proviso.

(c) On each Monday, the Company will provide Executive and the Approved Broker/Dealer with a calculation of the amount of withholding taxes (including FICA and income) that will be payable on the Shares to be released on the succeeding Wednesday (the “Taxes”). Such calculation will be based on the then current trading price of the Shares.

(d) For purposes hereof, an “Approved Broker/Dealer” means a broker/dealer, designated by Executive in writing to the Company and Trust, who has agreed in writing to sell, as promptly as practicable, out of the Shares released to it by the Trust, one-half of the Shares released, rounded down to the nearest whole number of Shares, on a weekly basis. Any Approved Broker/Dealer shall have acknowledged receipt of instructions to remit the proceeds of each sale of Shares, up to the amount of the Taxes, to the Company as promptly as practicable.

**3. MISCELLANEOUS**

(a) The Company agrees that it will take such actions as may be necessary to permit the sale of the Shares in accordance with the terms set forth in Section 2.

(b) Except as expressly amended hereby, the Original Agreement shall remain in full force and effect following the execution and delivery of this Amendment.

(c) This Amendment may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, and such counterparts together shall constitute one instrument.

(d) The validity, construction, and effect of this Amendment shall be determined in accordance with the laws of the State of Delaware (without giving effect to principles of conflicts of laws thereof).

IN WITNESS WHEREOF, the Company and the Executive have executed this Amendment as of the Effective Date.

**EXECUTIVE:**

Charlotte Arnold

\_\_\_\_\_  
Charlotte Arnold

**THE COMPANY:**

ANIP ACQUISITION COMPANY

By: /s/ Arthur S. Przybyl

\_\_\_\_\_  
Name: Arthur S. Przybyl

Title: Pres & CEO

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the use in this Amendment No. 1 to Registration Statement No. 333-185391 of our report dated March 13, 2012 (December 11, 2012 as to the effects of the reverse stock split described in Note 2) relating to the financial statements of BioSante Pharmaceuticals, Inc. and our report dated March 13, 2012 relating to the effectiveness of BioSante Pharmaceuticals, Inc.'s internal control over financial reporting, appearing in the joint proxy statement/prospectus, which is part of such Registration Statement.

We also consent to the reference to us under the heading "Experts" in such joint proxy statement/ prospectus.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois

January 18, 2013

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 1 to the Registration Statement on Form S-4 No. 333-185391 of BioSante Pharmaceuticals, Inc. of our report dated November 20, 2012 relating to the financial statements of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., which appears in such Registration Statement.

We also consent to the reference to us under the heading "Experts" in such joint proxy statement/prospectus.

/s/ Stout, Causey & Horning, P.A.

Stout, Causey & Horning, P.A.

Sparks, Maryland

January 18, 2013

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# BioSante Pharmaceuticals

**BIO S ANTE PHARMACEUTICALS, INC.**  
**111 BARCLAY BOULEVARD**  
**LINCOLN SHIRE, N. 60069**  
**ATTN: PHILIP B. DONENBERG**

Investor	Address	Line	1
Investor	Address	Line	2
Investor	Address	Line	3
Investor	Address	Line	4
Investor	Address	Line	5

John Sample  
 1234 ANYWHERE STREET  
 ANY CITY, ON A1A 1A1



**VOTE BY INTERNET** - [www.proxyvote.com](http://www.proxyvote.com)  
 Use the Internet to transmit your voting instructions and for electronic delivery of information up until 11:59 P.M. Eastern Time the day before the cut-off date or meeting date. Have your proxy card in hand when you access the web site and follow the instructions to obtain your records and to create an electronic voting instruction form.

**ELECTRONIC DELIVERY OF FUTURE PROXY MATERIALS**  
 If you would like to reduce the costs incurred by our company in mailing proxy materials, you can consent to receiving all future proxy statements, proxy cards and annual reports electronically via e-mail or the Internet. To sign up for electronic delivery, please follow the instructions above to vote using the Internet and, when prompted, indicate that you agree to receive or access proxy materials electronically in future years.

**VOTE BY PHONE** - 1-800-690-6903  
 Use any touch-tone telephone to transmit your voting instructions up until 11:59 P.M. Eastern Time the day before the cut-off date or meeting date. Have your proxy card in hand when you call and then follow the instructions.

**VOTE BY MAIL**  
 Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided or return it to Vote Processing, c/o Broadridge, 51 Mercedes Way, Edgewood, NY 11717.

<p><b>NAME</b>                  THE COMPANY NAME INC. - COMMON                  THE COMPANY NAME INC. - CLASS A                  THE COMPANY NAME INC. - CLASS B                  THE COMPANY NAME INC. - CLASS C                  THE COMPANY NAME INC. - CLASS D                  THE COMPANY NAME INC. - CLASS E                  THE COMPANY NAME INC. - CLASS F                  THE COMPANY NAME INC. - 401 K</p>	<p><b>CONTROL #</b> → 00000000000</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td><b>SHARES</b></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> <tr><td></td><td>123,456,789,012.12345</td></tr> </table> <p style="text-align: center;"><b>PAGE 1 OF 2</b></p>	<b>SHARES</b>	123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345		123,456,789,012.12345
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TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS:  KEEP THIS PORTION FOR YOUR RECORDS  
DETACH AND RETURN THIS PORTION ONLY

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED.

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**The Board of Directors recommends you vote FOR proposals 1 through 5.**

	For	Against	Abstain
1 Proposal to adopt the agreement and plan of merger dated as of October 3, 2012, between BioSante Pharmaceuticals, Inc. (BioSante) and ANIP Acquisition Company d/b/a ANI Pharmaceuticals (ANI), as amended, and the transactions contemplated thereby, including the merger and the issuance of shares of BioSante common stock in the merger.	0	0	0
2 Proposal to approve an amendment to BioSante's Certificate of Incorporation to effect a reverse split of common stock and class C special stock at the discretion of BioSante and ANI at a ratio of either one-for-two, one-for-three, one-for-four or one-for-five.	0	0	0
3 Proposal to approve an amendment to BioSante's Certificate of Incorporation to change the corporate name from "BioSante Pharmaceuticals, Inc." to "ANI Pharmaceuticals, Inc."	0	0	0
4 Proposal to approve, on an advisory (non-binding) basis, the compensation payable to certain executive officers of BioSante under existing arrangements in connection with the merger.	0	0	0
5 Proposal to adjourn the special meeting, if necessary, to solicit additional proxies if there are insufficient votes in favor of proposals 1, 2 and/or 3.	0	0	0

**NOTE:** In their discretion, the proxies are authorized to vote on any other business property brought before the special meeting or any adjournment or postponement of the special meeting.

Investor	Address	Line	1
Investor	Address	Line	2
Investor	Address	Line	3
Investor	Address	Line	4
Investor	Address	Line	5

John Sample  
 1234 ANYWHERE STREET  
 ANY CITY, ON A1A 1A1

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name, by authorized officer.

Signature [PLEASE SIGN WITHIN BOX]	JOB #	Date	Signature (Joint Owners)
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SHARES  
CUSIP #  
SEQUENCE #

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**BIOSANTE PHARMACEUTICALS, INC.  
SPECIAL MEETING OF STOCKHOLDERS**

**Friday, March 15, 2013**

**8:00 a.m., CDT**

**BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, IL 60069**

**Important Notice Regarding the Availability of Proxy Materials for the Special Meeting:** The Joint Proxy Statement/Prospectus is available at [www.proxyvote.com](http://www.proxyvote.com).

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**BIOSANTE PHARMACEUTICALS, INC.**

**This proxy is solicited on behalf of the Board of Directors of BioSante Pharmaceuticals, Inc., for use at the Special Meeting of Stockholders on March 15, 2013.**

By signing, dating and returning this proxy card, you revoke all prior proxies, including any proxy previously given by telephone or Internet, and appoint Stephen M. Simes and Phillip B. Donenberg, or either of them, with full power of substitution to vote your shares on the matters shown on the reverse side and any other matter which may properly come before the Special Meeting of Stockholders to be held on and at any adjournment or postponement of the meeting.

**You are encouraged to specify your choice by marking the appropriate boxes on the reverse side.**

This proxy, when properly signed, will be voted in the manner directed. **If no direction is given, this proxy will be voted FOR Proposals 1, 2, 3, 4 and 5, in the proxies' discretion, upon such other matters as may properly come before the meeting.**

**Continued and to be signed on reverse side**



ANIP Acquisition Company d/b/a  
 ANI Pharmaceuticals, Inc.  
 210 Main Street West  
 Baudette, Minnesota 56623  
 Attention: Investor Relations  
 Tel: (218) 634.3500  
 Email: arthur.przybyl@anipharma.com

**VOTE BY MAIL** Mark, sign and date your proxy card and return it in the postage-paid envelope we have provided.

Name and Address of Investor:

Number and Class of Shares Voted:

TO VOTE, MARK BLOCKS BELOW IN BLUE OR BLACK INK AS FOLLOWS :   x

THIS PROXY CARD IS VALID ONLY WHEN SIGNED AND DATED.

**The Board of Directors recommends you  
 vote FOR proposals 1 and 2.**

	For	Against	Abstain
1. Proposal to adopt the agreement and plan of merger dated as of October 3, 2012 between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. ("ANI"), as amended, and the transactions contemplated thereby, including the merger.	o	o	o
2. Proposal to approve an adjournment of the ANI special meeting, if necessary, to solicit additional proxies if there are not sufficient votes in favor of Proposal No. 1.	o	o	o

Please sign exactly as your name(s) appear(s) hereon. When signing as attorney, executor, administrator, or other fiduciary, please give full title as such. Joint owners should each sign personally. All holders must sign. If a corporation or partnership, please sign in full corporate or partnership name, by authorized officer.

Signature \_\_\_\_\_ Date \_\_\_\_\_

Title \_\_\_\_\_

**ANIP ACQUISITION COMPANY D/B/A  
 ANI PHARMACEUTICALS, INC.**

**SPECIAL MEETING OF STOCKHOLDERS**

**Friday, March 15, 2013**

**9:00 a.m., EDT**

**At the offices of:  
 MVP Capital Partners  
 259 N. Radnor-Chester Road, Suite 130  
 Radnor, Pennsylvania 19087**

**ANIP ACQUISITION COMPANY D/B/A  
 ANI PHARMACEUTICALS, INC.**

**This proxy is solicited on behalf of the Board of Directors of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., for use at the Special Meeting of Stockholders on March 15, 2013.**

By signing, dating and returning this proxy card, you revoke all prior proxies, and appoint Arthur S. Przybyl and Charlotte C. Arnold, or either of them, with full power of substitution to vote your shares on the matters shown on the reverse side and any other matter which may properly come before the Special Meeting of Stockholders to be held on and at any adjournment or postponement of the meeting.



**You are encouraged to specify your choice by marking the appropriate boxes on the reverse side.**

This proxy, when properly signed, will be voted in the manner directed. **If no direction is given, this proxy will be voted FOR Proposals 1 and 2 and, in the proxies' discretion, upon such other matters as may properly come before the meeting.**

**Continued and to be signed on reverse side**

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