UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

x **QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2005

o **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission File Number 1-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)

111 Barclay Boulevard
Lincolnshire, Illinois 60069
(Address of principal executive offices)

(847) 478-0500
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

As of August 12, 2005, 19,007,800 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

BIOSANTE PHARMACEUTICALS, INC.

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In this report, references to "BioSante," "the company," "we," "our" or "us," unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant™, NanoVant™, CAP-Oral™, BioAir™, Bio-E-Gel™, Bio-E/P-Gel™, LibiGel™, LibiGel-E/T™ and Bio-T-Gel™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
June 30, 2005 and December 31, 2004 (Unaudited)

	June 30, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 379,523**	**$ 1,170,025**
Short-term investments	**11,692,960**	**16,098,663**
Prepaid expenses and other sundry assets	**178,455**	**309,585**
	12,250,938	**17,578,273**
PROPERTY AND EQUIPMENT, NET	**241,806**	**249,088**
	$ 12,492,744	**$ 17,827,361**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 782,495**	**$ 1,169,037**
Accrued compensation	**493,448**	**531,882**
Other accrued expenses	**274,753**	**202,086**
Due to Antares	**-**	**3,750**
	1,550,696	**1,906,755**
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
391,286 (2004 - 391,286) Class C special stock	**398**	**398**
19,007,800 (2004 - 18,955,181) Common stock	**56,653,220**	**56,455,451**
	56,653,618	**56,455,849**
Deferred unearned compensation	**(322,209)**	**(497,959)**
Deficit accumulated during the development stage	**(45,389,361)**	**(40,037,284)**
	10,942,048	**15,920,606**
	$ 12,492,744	**$ 17,827,361**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and six months ended June 30, 2005 and 2004 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2005
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to
	2005	2004	2005	2004	June 30, 2005
REVENUE					
Licensing income	$ -	$ -	$ -	$ -	$ 4,592,943
Grant income	45,596	4,976	74,273	12,292	142,159
	45,596	4,976	74,273	12,292	4,735,102
EXPENSES					
Research and development	1,927,890	1,865,749	4,079,569	3,322,272	28,146,562
General and administration	775,174	743,244	1,495,669	1,743,255	16,777,415
Depreciation and amortization	26,043	25,740	50,985	49,023	812,348
Loss on disposal of capital assets	-	-	-	-	157,545
Costs of acquisition of Structured Biologicals Inc.-		-	-	-	375,219
Purchased in-process research and development-		-	-	-	5,377,000
	2,729,107	2,634,733	5,626,223	5,114,550	51,646,089
OTHER - Interest income	101,926	55,599	199,873	82,869	1,521,626
NET LOSS	$ (2,581,585)	$ (2,574,158)	$ (5,352,077)	$ (5,019,389)	$ (45,389,361)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.13)	$ (0.15)	$ (0.28)	$ (0.32)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	19,385,086	16,690,121	19,379,457	15,538,648	

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Six months ended June 30, 2005 and 2004 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2005
(Unaudited)

	Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30,
	2005	2004	2005
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (5,352,077)	$ (5,019,389)	$ (45,389,361)
Adjustments to reconcile net loss to			
net cash used in operating activities			
Depreciation and amortization	50,985	49,023	812,348
Amortization of deferred unearned compensation	-	-	42,290
Repurchase of licensing rights	-	-	125,000
Employee & director compensation - noncash	175,750	396,791	1,092,291
Purchased in-process research and development	-	-	5,377,000
Loss on disposal of equipment	-	-	157,545
Changes in other assets and liabilities			
affecting cash flows from operations			
Prepaid expenses and other sundry assets	131,130	68,211	(175,487)
Accounts payable and accrued expenses	(352,309)	268,864	856,055
Due to licensor (Antares/Regents)	(3,750)	25,885	-
Due from SBI	-	-	(128,328)
Net cash used in operating activities	(5,350,271)	(4,210,615)	(37,230,647)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES			
Purchase of short term investments, net	4,405,703	-	(11,692,960)
Purchase of capital assets	(43,703)	(62,213)	(1,177,589)
Net cash provided by (used in) investing activities	4,362,000	(62,213)	(12,870,549)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	-	-	500,000
Proceeds from sales or conversion of shares	197,769	18,111,497	49,980,719
Net cash provided by financing activities	197,769	18,111,497	50,480,719
NET (DECREASE) INCREASE IN CASH			
AND CASH EQUIVALENTS	(790,502)	13,838,669	379,523
CASH AND CASH EQUIVALENTS			
AT BEGINNING OF PERIOD	1,170,025	9,134,327	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 379,523	$ 22,972,996	$ 379,523
SUPPLEMENTAL SCHEDULE OF			
CASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	$ -	$ -	$ 5,377,000
Other net liabilities assumed	-	-	(831,437)
	-	-	4,545,563
Less: common stock issued therefor	-	-	4,545,563
	$ -	$ -	$ -
Income tax paid	$ -	$ -	$ -
Interest paid	$ -	$ 822	$ 3,421
SIGNIFICANT NON-CASH TRANSACTIONS			
Fair value of common stock warrants issued in connection			

with the sale of capital stock	**$ -**	**$ 513,551**	**$ 1,053,423**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-Q
JUNE 30, 2005

Notes to the Financial Statements (Unaudited)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of BioSante Pharmaceuticals, Inc. (the "Company") as of June 30, 2005, the results of operations for the three and six months ended June 30, 2005 and 2004 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2005, and the cash flows for the six months ended June 30, 2005 and 2004 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2005, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005.

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2004.

2. 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 reflects 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, there is no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and six months ended June 30, 2005 does not include 1,099,530 and 1,107,364 outstanding common stock options, with exercise prices ranging from $2.10 to $7.60 per share, and 1,644,355 outstanding common stock warrants with exercise prices ranging from $2.15 to $8.75 per share, because of their antidilutive effect on net loss per share. The computation of diluted net loss per share for the three and six months ended June 30, 2004 does not include 1,239,133 and 1,253,384 outstanding common stock options, with exercise prices ranging from $2.10 to $7.60 per share, and 3,053,236 and 3,071,495 outstanding common stock warrants with exercise prices ranging from $2.15 to $8.75 per share, because of their antidilutive effect on net loss per share.

3. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which agreement has subsequently been amended, pursuant to which the University has granted the Company an exclusive license to seven United States patents owned by the University, including rights to sublicense such patents. The license agreement with the University of California requires the Company to undertake various obligations, including but not limited to, the payment of royalties based on net sales, when and if they occur, and the payment of minimum annual royalties (note 4).

In June 2000, the Company entered into a license agreement with Antares Pharma Inc., which agreement has subsequently been amended, covering four hormone therapy products for the treatment of men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain events.

As allowed by the licensing agreement with Antares, in September 2000, the Company entered into a sublicense agreement with Paladin Labs Inc. (Paladin) to market certain hormone therapy products in Canada. In exchange for the sublicense, Paladin agreed to make an initial investment in the Company, milestone payments and pay royalties on sales of the products in Canada. Several milestone payments have been made in the form of a series of equity investments by Paladin in the Company's common stock at a 10% premium to the market price of the Company's stock at the date of the equity investment.

In August 2001, the Company entered into a sublicense agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sublicensed the Company's estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties.

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company, regulatory milestones, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology is approved and subsequently marketed (note 4).

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., under which Teva USA agreed to develop one of the Company's hormone therapy products for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA and royalties on sales of the commercialized product upon approval in exchange for rights to develop and market a hormone therapy product.

4. COMMITMENTS

University of California License

The Company's license agreement with the University of California, as amended most recently in June 2004, requires the Company to undertake various obligations, including:

- Payment of royalties to the University based on a percentage of the net sales of any products incorporating the licensed technology;

- Payment of minimum annual royalties to be paid by February 28 of the following year in the amounts set forth below, to be credited against any earned royalties, for the life of the agreement;

Year	Minimum Annual Royalty Amount	Due Date
2005	$ 50,000	February 28, 2006
2006	75,000	February 28, 2007
2007	100,000	February 28, 2008
2008	200,000	February 28, 2009
2009	300,000	February 28, 2010
2010	400,000	February 28, 2011
2011	750,000	February 28, 2012
2012	750,000	February 28, 2013
2013	750,000	February 28, 2014
Total	$ 3,375,000	

$25,000 of the minimum royalties for 2005 were accrued during the six months ended June 30, 2005. Under the terms of the license agreement with the University of California, BioSante has the right to terminate the license agreement for any reason, with BioSante's only obligation being the payment of monies owed at the time of termination.

- Development of products incorporating the licensed technology until a product is introduced to the market;

- Payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which for the six months ended June 30, 2005 and 2004 amounted to $2,292 and $845, respectively;

- Meeting performance milestones relating to:

  - Hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;

  - Testing proposed products and obtaining government approvals;

  - Conducting clinical trials; and

  - Introducing products incorporating the licensed technology into the market; and

- Indemnifying, holding harmless and defending the University of California and its affiliates, as designated in the license agreement, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from or arising out of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability related to this obligation as to the Company’s knowledge no events have occurred that would require indemnification.

Antares Pharma, Inc. License

The Company’s license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares in June 2000. The Company funds (or has funded in the case of the Solvay agreement) the development of the hormone therapy products it licenses under this agreement. The Company has made and will continue to make milestone payments to Antares and if and when regulatory approval to market the products is received, the Company will pay royalties to Antares on any sales of products.

Wake Forest License

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and an option for triple hormone 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.

Future minimum payments due under this agreement are as follows:

Year	Minimum Amount Due
2005	$ 45,000
2006	80,000
2007	65,000
2008	90,000
2009	140,000
2010	90,000
2011	40,000
2012	140,000
2013	240,000
Thereafter	$ 800,000

$22,500 of the 2005 minimum payment was accrued during the six months ended June 30, 2005. Under the terms of the license agreement with Wake Forest University and Cedars-Sinai Medical Center, BioSante has the right to terminate the license agreement for any reason, with BioSante's only obligation being the payment of monies owed at the time of termination.

The Company has agreed to indemnify, hold harmless and defend Wake Forest University 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 to the Company’s knowledge no events have occurred that would require indemnification.

5. STOCK-BASED COMPENSATION

The Company follows the provisions of APB Opinion No. 25, “Accounting For Stock-Based Compensation” (“APB No. 25”) which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the measurement date (generally the date of grant) and the amount the employee must pay to acquire the stock. As a result of the Company’s application of APB No. 25, Statement of Financial Accounting Standards No. 148, “Accounting for Stock-Based Compensation - Transition and Disclosure” (SFAS 148), requires certain additional disclosures of the pro forma compensation expense arising from the Company’s fixed and performance stock compensation plans. The expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected term of the option, the current price of the underlying stock, its expected volatility, expected dividends on the stock and the expected risk-free rate of return during the term of the option. The compensation cost is recognized over the service period, usually the period from the grant date to the vesting date. The following table illustrates the effect on the Company’s net loss and net loss per share for the three and six months ended June 30, 2005 and 2004 if the Company had applied the fair value based method.

	Three Months Ended June 30, 2005	Three Months Ended June 30, 2004
Net loss		
As reported	**$ (2,581,585)**	$ (2,574,158)
Stock-based compensation included in net loss as reported	**87,875**	102,875
Total stock-based employee compensation determined under fair value based method for all awards	**(178,892)**	(587,974)
Net loss, pro forma	**$ (2,672,602)**	$ (3,059,257)
Basic and diluted net loss per share		
As reported	**$ (0.13)**	$ (0.15)
Pro forma	**$ (0.14)**	$ (0.18)

	Six Months Ended June 30, 2005	Six Months Ended June 30, 2004
Net loss		
As reported	**$ (5,352,077)**	$ (5,019,389)
Stock-based compensation included in net loss as reported	**175,750**	396,791
Total stock-based employee compensation determined under fair value based method for all awards	**(370,735)**	(979,874)
Net loss, pro forma	**$ (5,547,062)**	$ (5,602,472)
Basic and diluted net loss per share		
As reported	$ (0.28)	$ (0.32)
Pro forma	$ (0.29)	$ (0.36)

There were 4,000 and 19,000 options granted during the three and six months ended June 30, 2005, respectively, and 7,000 and 37,000 options granted during the three and six months ended June 30, 2004, respectively.

During the second quarter 2003, the Company granted 307,000 options, 285,000 of which to certain officers of the Company. The 285,000 options were to vest upon the achievement of certain milestones in connection with the Company's evaluation of strategic alternatives. In March 2004, the vesting periods related to these options were amended whereby the options now vest over a three year period from the date of grant. As a result of the amended option terms, $1,054,500 of compensation expense will be recognized over the remaining vesting period. For the three and six months ended June 30, 2005 the Company recorded $87,875 and $175,750, respectively, of compensation expense related to these options. For the three and six months ended June 30, 2004 the Company recorded $87,084 and $381,000, respectively, of compensation expense related to these options.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing-model.

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue. No warrants were issued during the three and six month periods ended June 30, 2005. There were an aggregate of 92,646 warrants issued as compensation for services rendered during the three and six months ended June 30, 2004.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (Revised 2004), Share-Based Payment (SFAS No. 123 (R)), which requires all companies to measure compensation cost for all share-based payments (including employee stock options) at fair value. In April 2005, the SEC announced the adoption of a rule that defers the required effective date of SFAS No. 123 (R) until the beginning of the first fiscal year beginning after June 15, 2005. Companies are permitted to adopt the standard earlier than the required date. We are in the process of reviewing the impact of the provisions of SFAS No. 123 (R).

6. STOCKHOLDERS' EQUITY

During the three months ended June 30, 2005, options to purchase 14,000 shares of common stock were exercised for total cash proceeds of $40,600.

During the six months ended June 30, 2005, 31,250 common stock warrants and 14,270 common stock options were exercised for total cash proceeds of $197,769. During the six months ended June 30, 2005, 11,500 common stock warrants were exercised on a cashless basis, resulting in the issuance of 6,575 shares of common stock and the withholding of 4,925 shares of common stock to pay the exercise price of such warrants. These warrants were originally issued in connection with a private placement of common stock as a non-cash financing transaction. The 4,925 shares of common stock withheld to pay the exercise price of the warrants were cancelled by the Company, and, as a result, reduced the number of outstanding shares of common stock, on a fully diluted basis.

7. SUBSEQUENT EVENTS

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and an option for triple hormone contraception. In July 2005, the Company converted the option agreement for triple hormone contraception into a license agreement. 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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the caption "Forward-Looking Statements" below. The following discussion of the results of operations and financial condition of BioSante should be read in conjunction with our financial statements and the related notes thereto.

Overview

We are a development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CAP, primarily for vaccine adjuvants or immune system boosters and drug delivery systems.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions, and most recently, from subcontract revenue. We have not commercially introduced any products and do not expect to do so until late 2006 at the earliest depending upon the timing of our filing with the U.S. Food and Drug Administration of a New Drug Application with respect to our Bio-E-Gel product and the approval of such application.

To date, we have used primarily equity financing and licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. Our cash, cash equivalents and short-term investments were $12,072,483 as of June 30, 2005. We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash resources and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be made that we will not need additional cash prior to such time.

Our business operations to date have consisted mostly of research and development activities, and we expect this to continue for the immediate future. If and when our Bio-E-Gel or other proposed products receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market or co-market the product ourselves.

We spent an average of approximately $650,000 to $700,000 per month on research and development activities during the six months ended June 30, 2005. Our research and development expenses increased $757,297 or 23 percent, to $4,079,569 for the six months ended June 30, 2005 from $3,322,272 for the six months ended June 30, 2004, and increased $62,141 or 3% to $1,927,890 for the three months ended June 30, 2005 from $1,865,749 for the three months ended June 30, 2004. The year to date increase is due primarily to the increased expense associated with the clinical development of certain of our hormone therapy products, including the Phase III clinical trial of our Bio-E-Gel product, which was completed at the end of March 2005. The increase in expense for the three month period relates primarily to expenses associated with the New Drug Application to be submitted for Bio-E-Gel. We expect our research and development expenses to decrease in the third quarter of 2005 until the commencement of our LibiGel Phase III trials, which we plan to commence toward the end of 2005. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) resources available; (2) our development schedule, including the timing of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees fund the development of our proposed products; and (5) competitive developments. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds for research and development activities.

Our general and administrative expenses decreased $247,586 or 14 percent to $1,495,669 for the six months ended June 30, 2005 from $1,743,255 for the same period in 2004, and increased $31,930 or 4 percent, to $775,174 for the three months ended June 30, 2005 from $743,244 for the three months ended June 30, 2004. The year to date reduction in general and administrative expenses was primarily a result of a decrease in the recognition of non-cash compensation expense during the six months ended June 30, 2005 compared to the same six month period in 2004. The three month period increase in general and administrative expenses was due primarily to an increase in personnel and other compensation related expenses. Our general and administrative expenses may fluctuate from year-to-year depending upon the amount of legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

Since our inception, we have experienced significant operating losses. We incurred a net loss of $2,581,585 and $5,352,077 for the three and six month periods ended June 30, 2005 compared to a net loss of $2,574,158 and $5,019,389 for the three and six month periods ended June 30, 2004. As of June 30, 2005, our accumulated deficit was $45,389,361. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs progress and various preclinical and clinical trials commence and continue. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products;
- the timing and cost of making necessary regulatory filings and obtaining approvals;
- the timing and cost of obtaining third party reimbursement; and
- the cost of sales and marketing activities.

Hormone Therapy Products. Our hormone therapy products address a variety of hormone therapies for symptoms that affect both men and women. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen. Our hormone therapy products under development include Bio-E-Gel, LibiGel, Bio-E/P-Gel, Bio-E/T-Gel and Bio-T-Gel. Human clinical trials have begun on several of our hormone therapy products, which are required to obtain FDA approval to market the products. Our proposed Bio-E-Gel product completed a pivotal Phase III clinical trial at the end of March 2005. Our proposed LibiGel product successfully completed a Phase II clinical trial in June 2004, and we are currently in the planning stage for our Phase III clinical trials. Our proposed Bio-E/P-Gel product is licensed to Solvay Pharmaceuticals, B.V. Phase II clinical trials have been completed and we are hopeful Solvay will initiate a Phase III clinical trial within twelve months. Our proposed Bio-T-Gel product is also currently in development.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sublicenses, to the single active ingredient products containing testosterone and estradiol for all therapeutic indications in the U.S. and several foreign countries. We acquired exclusive marketing rights, with the right to grant sublicenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of these hormone therapy products, we paid Antares an upfront license fee of $1.0 million in June 2000. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, pay royalties to Antares on sales of the products if and when the products are brought to market. In a series of amendments executed during 2001 between BioSante and Antares, we returned to Antares the license rights to an estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, and Antares granted us a credit for approximately $600,000 of manufacturing and formulation services, which have been fully utilized, and a license for the combination estradiol plus testosterone gel product in the U.S and several foreign countries.

In August 2001, we entered into a sublicense agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sublicenses our estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, we received a $950,000 milestone payment pursuant to the Solvay sublicense agreement. Solvay is responsible for all costs of development and marketing of the product. We have retained co-promotion rights to the product and will be compensated for sales generated by us over and above those attributable to Solvay’s marketing efforts.

We have sublicensed the marketing rights to our portfolio of hormone therapy products (other than the estrogen/progestogen combination product) in Canada to Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made.

In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if the product gets approved and subsequently marketed. In July 2005, we converted the option agreement for triple hormone contraception into a license agreement. The financial terms of the license include an upfront payment by us in exchange for exclusive rights to the license, and regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed.

In December 2002, we entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA agreed to develop one of our hormone therapy products for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA and royalties on sales of the commercialized product upon approval in exchange for rights to develop and market a hormone therapy product.

Bio-E-Gel and LibiGel are both non-partnered products; and therefore, we can better control the timing and future development and commercialization of these products, subject to customary and inevitable uncertainties associated with the product development process, regulatory approvals and market acceptance of such products.

Those products we have licensed to others (*e.g.* Bio-E/P-Gel) are reliant on our partners for timely development, obtaining required regulatory approvals, commercialization and an ongoing commitment to the products, subject to regulatory and market conditions. From time to time, based on various circumstances including market analysis or a change in the strategic plan of the partner, a partner may elect to restructure its arrangement which may result in entering into a revised agreement or a mutual termination. Any restructuring or termination of these agreements by such partners as Solvay or Teva could adversely affect development of the products in these agreements if we are unable to license the proposed products to another qualified partner on substantially the same or better economic terms or continue the development and future commercialization of the proposed products ourselves.

CAP Technology and Proposed Products. Our CAP technology, several of whose issued patents we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles," as immune system boosters, for drug delivery and to purify the milk of transgenic animals, among other uses. Our strategy with respect to CAP is to continue development of our nanoparticle technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. In addition to continuing our own product development in the potential commercial applications of our CAP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CAP technology. We believe these collaborations may enable us to accelerate the development of potential improved vaccines and vaccines that can be delivered other than by injection as well as delivery by non-injected routes products that now must be injected.

In January 2003, we announced the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Navy's Naval Medical Research Center's (NMRC) Malaria Program for the development of a malaria vaccine. The development agreement leverages our expertise with NMRC's expertise to develop an enhanced vaccine for malaria. Under the agreement, we will provide the NMRC with BioVant, our proprietary vaccine adjuvant and delivery system, and the NMRC will provide DNA plasmids or proteins encoding antigens for Plasmodium spp., the parasite that causes malaria. It is hoped that the resulting DNA vaccine will improve the effectiveness of the ensuing humoral and cell-mediated immunity against malaria and therefore be more effective as it activates both arms of the immune system. The NMRC will cover all costs associated with the CRADA.

In June 2003, we announced the signing of another CRADA with the U.S. Army's Medical Research Institute of Infectious Disease (USAMRIID) for the development of non-injected biodefense vaccines, including anthrax, staph and ricin. The USAMRIID has agreed to grant us an exclusive license to any U.S. patent application or issued patent as a result of the work under the CRADA. The USAMRIID will cover all costs associated with the CRADA.

In September 2003, we announced that we were awarded a $100,000 Small Business Innovation Research grant from the National Institutes of Health to support our development of formulations for the oral delivery of insulin using our CAP technology. We recognized $90,000 as a contra-expense for this grant in our December 31, 2004 financial statements, and $0 as a contra-expense for the three and six month periods ended June 30, 2005. We receive the funds as reimbursement of research and development expenses. We have completed the work outlined under this grant and are currently investigating our options with respect to a Phase II SBIR grant.

In January 2004, we announced the signing of a subcontract with DynPort Vaccine Company LLC for the development of anthrax vaccines for delivery via alternative routes of administration, including nasal, oral and needle-free transcutaneous routes. Under the subcontract, we provide BioVant and DynPort provides recombinant antigens to be used in potential vaccines against anthrax. The objective is to assess the immunogenic potential of BioVant when used in anthrax vaccines versus the immunogenic response of anthrax vaccines that use Alhydrogel as the vaccine adjuvant. The subcontract is in support of the U.S. Department of Defense Joint Vaccine Acquisition Program. The subcontract is valued at approximately $658,000 per the terms of the contract. We have successfully completed the first year of this three year contract and have progressed to the second phase. We recorded revenue related to this contract of $45,596 and $74,273 for the three and six month periods ended June 30, 2005 and $4,976 and $12,292 for the three and six month periods ended June 30, 2004, respectively.

Results of Operations

Three Months Ended June 30, 2005 Compared to Three Months Ended June 30, 2004

The following table sets forth our results of operations for the three months ended June 30, 2005 and 2004.

	Three Months Ended June 30,			
	2005	**2004**	**$ Change**	**% Change**
Revenue	$ 45,596	$ 4,976	$ 40,620	816.3%
Expenses				
Research and development	1,927,890	1,865,749	62,141	3.3%
General and administrative	775,174	743,244	31,930	4.3%
Interest income	101,926	55,599	46,327	83.3%
Net loss	$ (2,581,585)	$ (2,574,158)	$ (7,427)	(0.3)%

We earned no licensing income during either of the three month periods ended June 30, 2005 and 2004. We earned $45,596 and $4,976 in grant revenue during the three month period ended June 30, 2005 and 2004, respectively, due to the reimbursement from Dynport Vaccine Company LLC (Dynport is funded by the U.S. Department of Defense) of certain development expenses related to our subcontract agreement with Dynport for the development of anthrax vaccines using our CAP technology for delivery via alternative routes of administration.

Research and development expenses for the three months ended June 30, 2005 increased 3 percent compared to research and development expenses for the three months ended June 30, 2004 primarily as a result of completion of clinical development of certain of our hormone therapy products, including the Phase III clinical trial of our Bio-E-Gel product, which was completed at the end of March 2005, in addition to the expenses related to the New Drug Application to be submitted for Bio-E-Gel. We expect our research and development expenses to remain at this same level until the filing of our Bio-E-Gel New Drug Application. Upon filing, we expect our research and development expenses to decrease until the commencement of our LibiGel Phase III trials, which we plan to commence toward the end of 2005.

General and administrative expenses for the three months ended June 30, 2005 increased 4 percent compared to general and administrative expenses for the three months ended June 30, 2004, primarily as result of additional personnel and other compensation related expenses in 2005.

Interest income for the three months ended June 30, 2005 increased 83 percent compared to interest income during the three months ended June 30, 2004 primarily as a result of higher average cash balances and interest rates on invested cash balances in 2005.

The overall decrease in net loss for the three months ended June 30, 2005 compared to the three months ended June 30, 2004 was primarily the result of the increase in expenses as described above partially offset by an increase in grant revenue and interest income.

Six Months Ended June 30, 2005 Compared to six Months Ended June 30, 2004

The following table sets forth our results of operations for the six months ended June 30, 2005 and 2004.

	Six Months Ended June 30,			
	2005	**2004**	**$ Change**	**% Change**
Revenue	$ 74,273	$ 12,292	$ 61,981	504.2%
Expenses				
Research and development	4,079,569	3,322,272	757,297	22.8%
General and administrative	1,495,669	1,743,255	(247,586)	(14.2)%
Interest income	199,873	82,869	117,004	141.2%
Net loss	$ (5,352,077)	$ (5,019,389)	$ (332,688)	(6.6)%

We earned no licensing income during either of the six month periods ended June 30, 2005 and 2004. We earned $74,273 and $12,292 in grant revenue during the six month period ended June 30, 2005 and 2004, respectively, due to the reimbursement from Dynport Vaccine Company LLC (Dynport is funded by the U.S. Department of Defense) of certain development expenses related to our subcontract agreement with Dynport for the development of anthrax vaccines using our CAP technology for delivery via alternative routes of administration.

Research and development expenses for the six months ended June 30, 2005 increased 23 percent compared to research and development expenses for the six months ended June 30, 2004 primarily as a result of increased expenses associated with the clinical development of certain of our hormone therapy products, including the Phase III clinical trial of our Bio-E-Gel product, which was completed at the end of March 2005. We expect our research and development expenses to remain at this same level until the filing of our Bio-E-Gel New Drug Application. Upon filing, we expect our research and development expenses to decrease until the commencement of our LibiGel Phase III trials, which we plan to commence toward the end of 2005.

General and administrative expenses for the six months ended June 30, 2005 decreased 14 percent compared to general and administrative expenses for the six months ended June 30, 2004 primarily as a result of a decrease in the recognition of non-cash compensation expense during the six months ended June 30, 2005 compared to the same six month period in 2004. The non-cash compensation expense was a result of an amendment to certain options to purchase an aggregate of 285,000 shares of common stock at an exercise price of $2.10 per share that were granted in the second quarter 2003 and were amended to change the vesting periods from milestone-based vesting schedules to time-based vesting schedules. The amended stock options vest in three equal annual installments over a three year period from the date of grant. As a result of the stock option amendments, we will recognize a $1,054,500 compensation expense over a three year period beginning in the first quarter 2004.

Interest income for the six months ended June 30, 2005 increased 141 percent compared to interest income during the six months ended June 30, 2004 primarily as a result of higher average cash balances and interest rates on invested cash balances in 2005.

The overall increase in net loss for the six months ended June 30, 2005 compared to the six months ended June 30, 2004 was primarily the result of higher expenses, as described above.

Liquidity and Capital Resources

Working Capital

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and most recently, from a subcontract. To date, we have used primarily equity financing and received licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. Since inception, we have raised net proceeds of approximately $50.5 million from equity financings, class A and class C stock conversions, warrant and option exercises and the issuance of a $500,000 convertible debenture, and have received $4.6 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash, cash equivalents and short-term investments available to fund current operations were $12,072,483 and $17,268,688 at June 30, 2005 and December 31, 2004, respectively. We expect our cash balance to decrease as we continue to use cash to fund our operations. We do not have any debt for borrowed money.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash balance and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be given that we will not need additional cash prior to such time. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses, and if we receive FDA approval of any of our proposed products, the amount of resources we devote to sales and marketing capabilities;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

If we raise additional funds through the issuance of equity securities, our stockholders may experience dilution, which could be significant. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. If financing is not available when required or is not available on acceptable terms, we may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the development of our proposed products, commercial introduction of our products or restrict us from acquiring new products that we believe may be beneficial to our business.

Uses of Cash and Cash Flow

We used cash in operating activities of $5,350,271 for the six months ended June 30, 2005 versus cash used in operating activities of $4,210,615 for the six months ended June 30, 2004. The increase in cash used in operating activities largely reflects the increased net loss and decrease in accounts payable and accrued expenses, partially offset by a decrease in prepaid expenses and non-cash stock compensation expense, as described above. We used cash in investing activities of $43,703 for the six months ended June 30, 2005, for the purchase of computer equipment, cubicles, office furniture and new lab equipment and received $4,405,703 from the sale of auction rate securities, versus $62,213 for the six months ended June 30, 2004, which was used for the purchase of computer equipment, lab equipment and filing cabinets. Net cash provided by financing activities was $197,769 for the six months ended June 30, 2005, which consisted primarily of cash received due to warrant and option exercises, and was $18,111,497 for the six months ended June 30, 2004 which consisted primarily of cash received from our May 2004 private placement.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of June 30, 2005. We have, however, several potential financial commitments, including product development milestone payments to the licensor of our hormone therapy products, payments under our license agreements with the University of California and Wake Forest University, as well as minimum annual lease payments. We refer you to the table summarizing the timing of these future contractual obligations and commitments contained in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004. There has been no material change in this information.

We expect to continue to spend capital on:

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- establishment of our own marketing capabilities or a search for third party sales and marketing partners to sell and market our products for us; and
- the licensure or acquisition of new products.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;

- progress, timing and scope of our pre-clinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;
- time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

In addition, our license agreement with the licensor of our hormone therapy products requires us to make certain payments as development milestones are achieved, and our license agreement with the University of California requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve research and development milestones. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

- enter into additional leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

Off-Balance Sheet Arrangements

Except for operating leases entered in the ordinary course of business and customary indemnification obligations under our license, financing and other agreements, we do not have any off-balance sheet arrangements.

Critical Accounting Policies

The discussion and analysis of our financial statements and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these 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 Securities and Exchange Commission 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 the company 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, we have identified certain of our accounting policies as critical accounting policies. Our critical accounting policies are described in "Item 6. Management's Discussion and Analysis or Plan of Operation" section of our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004. Although we believe that our 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.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. Statements that are not historical are forward-looking and reflect expectations and assumptions. We try to identify forward-looking statements in this report and elsewhere by using words such as "may,""will,""should,""expects,""anticipates,""contemplates,""estimates,""believes,""plans,""projected,""predicts,""potential" or "continue" or the negative of these or similar terms. Our forward-looking statements generally relate to:

- the timing of the commencement and completion of our clinical trials, the filing of our regulatory applications and other regulatory status of our proposed products;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of marketing capabilities and licensure or acquisition of new products;
- our existing cash and whether and how long these funds will be sufficient to fund our operations;
- our need and ability to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to BioSante. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described below in this section and also contained under the caption "Item 1. Description of Business—Forward-Looking Statements" in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2004.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described above, as well as others that we may consider immaterial or do not anticipate at this time. The foregoing risks and uncertainties are not exclusive and further information concerning the company and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

We have a history of operating losses, expect continuing losses and may never achieve profitability.

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of $5,352,077 for the six months ended June 30, 2005, and as of June 30, 2005, our accumulated deficit was $45,389,361.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and revenue earned from a subcontract. We have not commercially introduced any products. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of obtaining third party reimbursement; and
- the timing and cost of sales and marketing activities.

In order to generate new and significant revenues, we must successfully develop and commercialize our own proposed products or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate significant revenues or achieve profitability.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will need to raise substantial additional capital to fund our operations sometime in the future. Based on our current rate of cash outflows, we believe that our cash and short-term investments of $12,072,483 at June 30, 2005, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. We have based this estimate on assumptions, however, that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;

- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses, and if we receive FDA approval of any of our proposed products and choose to commercialize them ourselves, the amount of resources we devote to sales and marketing capabilities;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

We are a development stage company, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues;
- limited marketing and manufacturing experience;
- an expected reliance on third parties for the development and commercialization of some of our proposed products;
- a competitive environment characterized by numerous, well-established and well-capitalized competitors;
- uncertain market acceptance of our proposed products; and
- reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

Our proposed products are in the development stages and will likely not be commercially introduced for several years, if at all.

Our proposed products are in the development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. We have not commercially introduced any products and do not expect to do so until late 2006 at the earliest depending upon the timing of our filing with the FDA of a New Drug Application with respect to our Bio-E-Gel product and the approval of such application. We cannot assure you that any of our proposed products will:

- be successfully developed;
- prove to be safe and efficacious in clinical trials;
- 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 successfully marketed or achieve market acceptance by physicians and patients.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed or withdrawn, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each product or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never 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 are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management's credibility, the value of our company and our operating results and liquidity would be adversely affected. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. Even after obtaining regulatory approval, we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture are subsequently discovered. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition.

To obtain regulatory approval to market our products, costly and lengthy pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct, at our own expense or the expense of current or potential licensees, clinical trials on humans on each of our proposed products. Pre-clinical studies on animals must be conducted on some of our proposed products. We expect the number of pre-clinical studies and 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. We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. 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 us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

- slow patient enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

Delays in our clinical trials could allow our 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.

A decision by the FDA to require Procter & Gamble to conduct additional studies to learn more about the long-term safety of testosterone treatment in women for FSD prior to granting approval of Procter & Gamble's Intrinsa testosterone patch could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to abandon the product depending on the extent of the additional time and cost to develop LibiGel.

In December 2004, the FDA's Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of Procter & Gamble's Intrinsa testosterone patch for hypoactive sexual desire disorder. The panel's main concern was the desire to have long-term safety data particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Currently, the FDA has not publicly stated nor set any type of public policy as to what additional duration of a safety trial would be required for approval. This FDA action with respect to Intrinsa or testosterone products in general may affect the regulatory pathway for our LibiGel product, as well as other similarly competitive products to treat FSD with testosterone therapy. If the FDA requires Procter & Gamble to conduct additional studies to learn more about the long-term safety of testosterone treatment in women for FSD prior to granting approval of Procter & Gamble's Intrinsa testosterone patch, such a decision could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to abandon further development of the product depending on the extent of the additional time and cost to develop LibiGel.

Several pharmaceutical products were recently found to have potentially life threatening side effects and have been subsequently removed from the market. These drugs had been previously approved for sale by the FDA. The withdrawals of approved drugs from the market create an increased risk for the pharmaceutical industry in general and an increased risk specifically for our proposed products that they may not receive the required regulatory approval on a timely basis or ever.

Several drugs have been recently removed from the market. Most recently, the withdrawal of Vioxx by Merck & Co., Inc. and Tysabri by Biogen Idec Inc. has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, the recent withdrawals may result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilence after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians' desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

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 hormone therapy products and the trading price of our common stock.

The market for hormone therapy products has been negatively affected by the Women's Health Initiative study and other studies that have found that the overall health risks from the use of certain hormone therapy products exceed the benefits from the use of those products among healthy postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its Women's Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy 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 healthy 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 was also halted. Our proposed hormone therapy products differ from the products used in the Women's Health Initiative 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. There currently are no studies published comparing the safety of our proposed hormone therapy products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms have declined as a result of these published studies. The release of any follow-up or other studies that show adverse affects from hormone therapy, including in particular, hormone therapies similar to our proposed products, would also adversely affect our business.

Because our industry is very competitive and many of our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

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

We license the technology underlying most of our proposed hormone therapy products and a portion of our CAP technology from third parties and may lose the rights to license them, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

We license most of the technology underlying our proposed hormone therapy products from Antares Pharma, Inc. and a portion of our CAP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license the technology underlying our proposed hormone therapy products or CAP technology could harm our business and future operating results. For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone therapy technology or CAP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc. or the University of California could either, depending upon the terms of the outlicense agreement, cause us to breach our obligations under the outlicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the outlicense fees.

We have licensed two of our proposed hormone therapy products to third parties and any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect our business. In addition, these third parties also may compete with us with respect to some of our proposed products.

We have licensed two of our proposed hormone therapy product to third parties, Solvay Pharmaceuticals, B.V. and Teva Pharmaceuticals USA, Inc., which have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. These proposed products are thus 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. Solvay and Teva may have different and, sometimes, competing priorities. We cannot assure you that Solvay and Teva will remain focused on the development and commercialization of our partnered products or will not otherwise breach the terms of our agreements with them, especially since these third parties may also compete with us with respect to some of our proposed products. Any breach by Solvay or Teva of their obligations under these agreements or a termination of these agreements by these parties could adversely affect development of the products in these agreements if we are unable to sublicense the proposed products to another party on substantially the same or better terms or continue the development and future commercialization of the proposed products ourselves.

We do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions and may remain dependent upon others for these functions.

We do not have a manufacturing facility that can be used for production of our products. In addition, at this time, we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions. In the course of our development program, we may be required to enter into additional arrangements with other companies, universities or clinical investigators for our animal testing, human clinical testing, manufacturing and sales and marketing activities. Alternatively, we may decide to add additional personnel and perform some of these functions ourselves, such as sales and marketing activities. If our licensees or other third parties in which we have entered into agreements breach their obligations under our agreements to perform these functions or if we are otherwise unable to retain third parties for these purposes on acceptable terms or perform such functions successfully ourselves, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by our licensees or other third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise impair our competitive position. Our dependence on our licensees and other third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

Even if our proposed products receive FDA approval, they may not achieve expected levels of market acceptance, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

Even if we are able to obtain required regulatory approvals for our proposed products, the success of those products is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our new products could be impacted by several factors, including:

- the availability of alternative products from competitors;
- the price of our products relative to that of our competitors;
- the timing of our market entry; and
- the ability to market our products effectively.

Some of these factors are not within our control. Our proposed 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 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, these studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply we could experience material adverse effects on our business, financial position and results of operations, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, we must comply with FDA requirements with respect to the development of our proposed products and our clinical trials, and if any of our proposed products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of our products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

If we are unable to protect our proprietary technology, we 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. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties.

Where appropriate, we seek patent protection for certain aspects of our technology. However, our owned and licensed patents and patent applications may not ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our licensor's patent applications will result in actual patents.

- Competitors may interfere with our patents and patent process in a variety of ways. Competitors may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore we cannot use our technology as claimed under our patent. Competitors may also contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

- We are in the development stage and are in the process of developing proposed products. Even if we receive a patent, it may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our proposed 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. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

- Enforcing patents is expensive and may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose those patents.

- We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

It also is unclear whether our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors. Enforcing a claim that someone else illegally obtained and is using our 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. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our 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 until the patents are issued and also are maintained in secrecy for a period of time outside the United States. Accordingly, we can conduct only limited searches to determine whether our technology infringes any patents or patent applications of others. Any claims of patent infringement would be time-consuming and could likely:

- result in costly litigation;

- divert the time and attention of our technical personnel and management;

- cause product development delays;

- require us to develop non-infringing technology; or

- require us 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 our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

We have very limited staffing and will continue to be dependent upon key employees.

Our success is dependent upon the efforts of a small management team and staff. We have employment arrangements in place with all of our executive officers, but none of our executive officers is legally bound to remain employed for any specific term. Although we have key man life insurance on our President and Chief Executive Officer, Stephen M. Simes, we do not have key man life insurance policies covering any of our other executive officers or employees. If key individuals leave BioSante, we could be adversely affected if suitable replacement personnel are not quickly recruited. There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business. Our future success depends upon our ability to continue to attract and retain qualified personnel.

The price and trading volume of our common stock has been, and may continue to be, volatile.

Historically, the market price and trading volume of our common stock has fluctuated over a wide range. In 2004, our common stock traded in a range from a low of $3.92 to a high of $10.89, and our daily trading volume ranged from 9,300 shares to 5,042,300 shares. It is likely that the price and trading volume of our common stock will continue to fluctuate in the future. The securities of small capitalization, biopharmaceutical companies, including our company, from time to time experience significant price and volume fluctuations, often unrelated to the operating performance of these companies. In particular, the market price and trading volume of our common stock may fluctuate significantly due to a variety of factors, including:

- governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products or our competitors' products;
- the results of our clinical trials or those of our competitors;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors or licensees of our technology;
- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- developments or disputes concerning patents or other proprietary rights;
- our ability to obtain needed financing;
- period-to-period fluctuations in our financial results, including our cash, cash equivalents and short-term investment balance, operating expenses, cash burn rate or revenues;
- loss of key management;
- common stock sales in the public market by one or more of our larger stockholders, officers or directors;
- other potentially negative financial announcements, including delisting of our common stock from the American Stock Exchange, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC; and
- economic conditions in the United States and abroad.

In addition, the occurrence of any of the risks described above or elsewhere in this report or otherwise in reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our common stock. For example, in December 2004, primarily as a result of the unanimous vote by the FDA's Reproductive Health Drugs Advisory Committee panel against recommendation for approval of Procter & Gamble's Intrinsa testosterone patch for hypoactive sexual desire disorder, the price of our common stock decreased over 35% in one trading day and over 50% over the course of three trading days. In addition, on the day of and first two trading days after the public announcement of FDA advisory panel's recommendation, the daily trading volume of our common stock went from an average of approximately 166,000 shares per day to an average of over approximately 3 million shares per day for those same three days and then back down to an average of approximately 140,000 shares per day.

Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities. We may be the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessment of the effectiveness of our internal controls over financial reporting (ICFR) a report by our Registered Independent Public Accounting Firm addressing management's assessment and independent audit of ICFR. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. While we feel that our key controls are currently effective, we continue to enhance our ICFR by adding additional resources in key functional areas and bringing all of our operations up to the level of documentation, segregation of duties, and systems security necessary, as well as transactional control procedures required, under the new standard issued by the Public Company Accounting Oversight Board.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effects on our operations, in part because there is no precedent available by which to measure compliance adequacy. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the American Stock Exchange. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in ICFR, we will be unable to assert that our ICFR is effective. If we are unable to assert that our ICFR is effective as of December 31, 2006 (or such later date, if applicable) (or if our auditors are unable to attest that management's report is fairly stated, they are unable to express an opinion on our management's evaluation or on the effectiveness of the internal controls or they issue an adverse opinion on ICFR), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective ICFR in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective ICFR could have an adverse effect on our common stock price.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to interest rate risk on the investments of our excess cash, although due to the nature of our short-term investments, we have concluded that such risk is not material. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we invest in short-term securities with maturities of less than one year.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our quarter ended June 30, 2005 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

Recent Sales of Unregistered Equity Securities

During the three months ended June 30, 2005, we did not issuance any equity securities that were not registered under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities during the three months ended June 30, 2005, and our board of directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 6, 2005, at the Annual Meeting of Stockholders of BioSante, our stockholders elected seven directors, all of whom had previously served as BioSante directors, and ratified the appointment of Deloitte & Touche LLP, our independent registered public accounting firm, for the fiscal year ending December 31, 2005. The votes on each of these matters were as follows:

	For	Against/ Withheld	Abstain	Broker Non-Vote
1. Election of Directors				
Louis W. Sullivan	14,633,475	30,270	0	0
Stephen M. Simes	14,635,075	28,670	0	0
Victor Morgenstern	14,633,275	30,470	0	0
Fred Holubow	14,635,125	28,620	0	0
Ross Mangano	14,635,176	28,569	0	0
Edward C. Rosenow	14,633,871	29,874	0	0
Peter Kjaer	14,634,425	29,320	0	0
2. Appointment of Independent Registered Public Accounting Firm	14,648,359	12,738	2,648	0

ITEM 6. EXHIBITS

The following exhibits are being filed or furnished with this quarterly report on Form 10-Q:

31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14

31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14

32.1 Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

August 12, 2005

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Stephen M. Simes
President and Chief Executive Officer
(principal executive officer)

By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
(principal financial and accounting officer)

BIOSANTE PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith

Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14

I, Stephen M. Simes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2005

/s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer
(principal executive officer)

Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14

I, Phillip B. Donenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2005

Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
(principal financial officer)

Certification of CEO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen M. Simes, Vice Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2005

/s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer

Certification of CFO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip B. Donenberg, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2005

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary