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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 2000

Commission file number 000-28637

/ / **TRANSITION REPORT UNDER SECTION 13 OR 16(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For The Transition Period From _____ To _____.

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of small business issuer as specified in its charter)

Wyoming	**58-2301143**
(State of Incorporation)	(IRS Employer Identification No.)

175 Olde Half Day Road
Lincolnshire, Illinois 60069
(Address of principal executive offices)

(847) 793-2458
(Registrant's telephone number)

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 past 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 / /

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date.

Class	**Outstanding as of November 14, 2000**
Common stock, no par value	52,952,943

Transitional Small Business Disclosure Format (check one): Yes / / No /x/

BIOSANTE PHARMACEUTICALS, INC.
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PART I—FINANCIAL INFORMATION

ITEM 1—FINANCIAL STATEMENTS

BioSante Pharmaceuticals, Inc.
(a development stage company)

Balance Sheets

September 30, 2000 and December 31, 1999

	September 30, 2000 (Unaudited)	December 31, 1999 (Note)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,234,983	$ 5,274,552
Prepaid expenses and other sundry assets	85,883	58,994
	3,320,866	5,333,546
PROPERTY AND EQUIPMENT, NET	404,283	446,083
	$ 3,725,149	$ 5,779,629
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 67,886	$ 76,057
Accrued compensation	37,301	182,973
Other accrued expenses	92,136	45,085
Convertible debenture	500,000	—
Due to licensor	—	25,000
	697,323	329,115
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
4,687,684 (1999—4,807,865) Class C special stock	469	481
52,952,943 (1999—52,642,686) Common stock	17,740,567	17,652,510
	17,741,036	17,652,991
Deficit accumulated during the development stage	(14,713,210)	(12,202,477)
	3,027,826	5,450,514
	$ 3,725,149	$ 5,779,629

Note: The balance sheet as of December 31, 1999 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles.

See accompanying notes to the financial statements.

BioSante Pharmaceuticals, Inc.

Statements of Operations

Three and nine months ended September 30, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2000
(Unaudited)

	Cumulative

	Three Months Ended September 30,		Nine Months Ended September 30,		period from August 29, 1996 (date of incorporation) to September 30, 2000
	2000	1999	2000	1999	
REVENUE					
Interest income	$ 60,184	$ 62,022	$ 182,070	$ 134,538	$ 700,888
EXPENSES					
Research and development	239,548	160,671	1,594,762	477,202	3,991,302
General and administration	416,219	232,932	1,024,674	592,364	5,156,331
Depreciation and amortization	25,156	23,160	73,367	67,980	356,701
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
	680,923	416,763	2,692,803	1,137,546	15,414,098
NET LOSS	$ (620,739)	$ (354,741)	$ (2,510,733)	$ (1,003,008)	$ (14,713,210)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.01)	$ (0.01)	$ (0.04)	$ (0.02)	$ (0.35)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	57,603,438	57,415,551	57,501,885	46,719,269	41,998,597

See accompanying notes to the financial statements.

BioSante Pharmaceuticals, Inc.

Statements of Cash Flows

Nine months ended September 30, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2000 (Unaudited)

	Nine Months Ended September 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2000
	2000	1999	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (2,510,733)	$ (1,003,008)	$ (14,713,210)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	73,367	67,980	356,701
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	(26,889)	(18,625)	(82,915)
Accounts payable and accrued expenses	(131,792)	(459,925)	(567,864)
Due to licensor	—	—	25,000
Due from SBI	—	—	(128,328)
Net cash used in operating activities	(2,596,047)	(1,413,578)	(9,576,071)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(31,567)	(4,219)	(884,419)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	500,000	—	500,000
(Conversion) issuance of Class "C" shares	(12)	—	469
Proceeds from sale or conversion of shares	88,057	4,225,343	13,195,004

Net cash provided by financing activities	588,045	4,225,343	13,695,473
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,039,569)	2,807,546	3,234,983
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,274,552	2,841,250	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,234,983	$ 5,648,796	$ 3,234,983
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	$ —	$ —	$ 5,377,000
Other net liabilities assumed	—	—	(831,437)
Less: common stock issued therefor	—	—	4,545,563
	$ —	$ —	$ —
Income tax paid	$ —	$ —	$ —
Interest paid	$ —	$ —	$ —

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB
SEPTEMBER 30, 2000

Notes to 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. as of September 30, 2000, the results of operations for the three and nine months ended September 30, 2000 and 1999 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2000, and the cash flows for the nine months ended September 30, 2000 and 1999 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2000, in conformity with generally accepted accounting principles. Operating results for the three and nine month periods ended September 30, 2000 are not necessarily indicative of the results that may be expected for the year ended December 31, 2000.

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in BioSante's Annual Report on Form 10-KSB for the year ended December 31, 1999.

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 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 BioSante 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 does not include options and warrants with the dilutive potential that would have an antidilutive effect on net loss per share.

3. LICENSE AND SUPPLY AGREEMENTS

On June 13, 2000, the Company entered into a licensing agreement and a supply agreement with Permatec Technologie, AG, a Swiss corporation, covering four hormone products for the treatment of testosterone deficiency in men and estrogen deficiency in women. Under the terms of the license agreement, Permatec granted the Company an exclusive license, with the right to grant sublicenses, to develop and, after receipt of all necessary approvals, market the products in the United States of America and nine other countries. In consideration for the license, the Company paid Permatec an initial license fee of $1,000,000, a portion of which may be applied against future royalty payments and/or sublicense upfront payments. The entire $1,000,000 has been expensed in accordance with the Company's policy to expense all license fees for products which have not yet successfully completed Phase II or similar clinical trials. The agreement requires the Company to pay Permatec 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 future events, however, the Company is unconditionally obligated to make minimum future milestone payments of $250,000, regardless of whether the contract milestones are ever achieved. Under terms of the supply agreement, Permatec has agreed to manufacture or have manufactured and sell exclusively to the Company, and

the Company has agreed to purchase exclusively from Permatec, the Company's total requirements for the products covered under the license agreement between the two parties.

As allowed by the licensing agreement with Permatec, on September 1, 2000, the Company entered into a sub-license agreement with Paladin Labs Inc. ("Paladin") to market the female hormone replacement products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in the 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 the Company's common stock at a 10% premium to the market price of the Company's common stock at the date of the equity investment.

4. CONVERTIBLE DEBENTURE

In connection with entering into the sub-license agreement with Paladin as described in Note 3, the Company issued a convertible debenture to Paladin in a face amount of $500,000. The debenture matures on September 1, 2001 and does not accrue interest unless it is not paid, or has not been converted into Company stock, by the maturity date. If unpaid, interest accrues at a rate of 10% from September 1, 2001 until paid or converted. The convertible debenture is convertible into common stock of the Company at $1.05 per share, which conversion price is subject to adjustment under certain circumstances. Commencing January 1, 2001, the debenture may be converted at the option of Paladin. In the event Paladin has not converted the debenture prior to March 31, 2001, the Company shall have the right, in its sole discretion, after March 31, 2001, to require the debenture to be converted.

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

This Form 10-QSB contains forward-looking statements. For this purpose, any statements contained in this Form 10-QSB that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "may," "will," "expect," believe," "anticipate," "estimate" or "continue" or the negative or other variations thereof or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, including those described under this section and the section entitled "Risk Factors" below and those contained under the caption "Risk Factors" contained in BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999.

The following discussion of the results of the operations and financial condition of BioSante should be read in conjunction with BioSante's financial statements and the related notes thereto.

Overview

We are an emerging development stage biopharmaceutical company developing hormone replacement products to treat testosterone deficiency in men and estrogen deficiency in women. We are also engaged in the development of vaccine adjuvants, proprietary novel vaccines and drug delivery systems.

We license a portion of our technology, on an exclusive basis from the University of California. This technology is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles" or "CAP", as immune system boosters and for drug delivery. We have identified three potential initial applications for our nanoparticle technology:

- the creation of improved versions of current vaccines by the "adjuvant" activity of our proprietary nanoparticles;
- the development of new, unique vaccines against diseases for which there currently are few or no effective methods of prevention, such as genital herpes; and
- the creation of inhaled forms of pharmaceutical compounds that currently must be given by injection, such as insulin.

In June 2000, we entered into a license agreement with Permatec Technologie, AG of Switzerland under which we in-licensed a group of hormone replacement products. These products address a variety of hormone deficiencies that affect both men and women. Symptoms of these hormone deficiencies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

Three of the four new products we in-licensed are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), and a combination of estradiol and a progestogen (another female hormone). These gels are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are being formulated to be applied once per day and to be absorbed into the skin without a trace of residue. The fourth product is an estradiol patch for application on the skin once per week with patch delivery of estradiol lasting seven days.

Under the terms of our license agreement with Permatec, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the three single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Australia, New Zealand,

China, Malaysia, Indonesia and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of the proposed hormone products, we paid Permatec an upfront license fee of $1 million. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, after all necessary regulatory approvals are received, pay royalties to Permatec on sales of the products.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone replacement products in Canada to Paladin Labs Inc. In exchange for the sub-license, 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 company's common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. Upon execution of the sub-license agreement, Paladin made an initial investment of US$500,000 in our company in the form of a convertible debenture, convertible into our common stock at US$1.05 per share. Paladin may convert the debenture at any time after January 1, 2001. If Paladin does not convert the debenture by March 31, 2001, we may require it to be converted.

Our strategy over the next 12 months is to continue development of our nanoparticle technology and to actively seek collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the U.S. Food and Drug Administration (commonly referred to as the "FDA") to initiate a Phase I clinical trial of our proprietary calcium phosphate nanoparticles (CAP) as a vaccine adjuvant and delivery system based on an Investigational New Drug (IND) Application that we filed in July 2000. The Phase I trial was a double-blind, placebo-controlled trial in 18 subjects to determine the safety of CAP as a vaccine adjuvant. The trial was completed and there was no apparent difference in side effect profile between CAP and placebo; statistical analysis is still in progress. In addition, we expect to begin human clinical trials with respect to our hormone replacement products by early 2001, in order to obtain FDA approval to market these products.

Pursuant to our hormone replacement product portfolio in-license, we expect to hire commercial development, clinical and regulatory employees as appropriate. Alternatively, in lieu of and possibly in addition to hiring additional employees, we may elect to enter into arrangements with third parties to contract for similar tasks of hired employees.

All of our revenue to date has been derived from interest earned on invested funds. 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, various preclinical and clinical trials commence and we continue to seek product in-licenses or otherwise acquire new products. 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 pre-clinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of obtaining third party reimbursement; and
- the costs of licensure or acquisition of new products.

In order to generate revenues, we must successfully develop and commercialize the products currently in our portfolio or additional products that we may in-license or otherwise acquire, or we must enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the additional products we may in-license or otherwise

acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

Results of Operations

Three Months Ended September 30, 2000 Compared to Three Months Ended September 30, 1999

General and administrative expenses increased from $232,932 during the three month period ended September 30, 1999 to $416,219 during the three month period ended September 30, 2000. This increase of approximately 79% is due primarily to expenses related to hiring new personnel and the higher legal expenses related to the increase in our collaboration and licensing activities.

Research and development expenses increased from $160,671 during the three month period ended September 30, 1999 to $239,548 during the three month period ended September 30, 2000 due primarily to the expenses associated with our Phase I CAP human clinical trial conducted during the quarter. As a result of our hormone replacement product in-license entered into in June 2000, we expect that our research and development expenses will increase significantly. We also are required under the terms of our license agreement with the University of California to have available certain amounts of funds dedicated to research and development activities. The amount of our research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

Interest income decreased slightly from $62,022 during the three month period ended September 30, 1999 to $60,184 during the three month period ended September 30, 2000. We expect interest income to decline in future periods as we use our cash balances for operations.

We incurred a net loss of $620,739 for the three month period ended September 30, 2000, compared to a net loss of $354,741 for the three month period ended September 30, 1999. The increase in the net loss is primarily due to the expenses associated with (1) conducting a Phase I human clinical trial testing the safety of our CAP nanoparticles, (2) new personnel-related expenses, and (3) legal expenses related to increased collaboration and licensing activities. We anticipate that our operating losses will continue for the foreseeable future.

Nine Months Ended September 30, 2000 Compared to Nine Months Ended September 30, 1999

General and administrative expenses increased from $592,364 during the nine month period ended September 30, 1999 to $1,024,674 during the nine month period ended September 30, 2000. This increase of approximately 73% is due primarily to an increase in the expenses associated with our company becoming an OTC Bulletin Board-listed, public reporting company in addition to those reasons described above.

Research and development expenses increased from $477,202 during the nine month period ended September 30, 1999 to $1,594,762 during the nine month period ended September 30, 2000, due primarily to a $1 million upfront payment in June 2000 to the licensor of the hormone replacement product portfolio. As a result of our hormone replacement product in-license entered into in June 2000, we expect that our research and development expenses will increase significantly. We also are required under the terms of our license agreement with the University of California to have available certain amounts of funds dedicated to research and development activities. The amount of our research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

Interest income increased from $134,538 during the nine month period ended September 30, 1999 to $182,070 during the nine month period ended September 30, 2000. We expect interest income to decline in future periods as we use our cash balances for operations.

We incurred a net loss of $2,510,733 for the nine month period ended September 30, 2000, compared to a net loss of $1,003,008 for the nine month period ended September 30, 1999. In addition to the reasons as described above, the increase in the net loss is primarily due to the $1 million upfront in-license fee we paid to the licensor of the hormone replacement product portfolio in June 2000. As of September 30, 2000, BioSante had an accumulated deficit of $14,713,210. We anticipate that our operating losses will continue for the foreseeable future.

Liquidity and Capital Resources

To date, we have raised equity financing to fund our operations, and we expect to continue this practice to fund our ongoing operations. Since inception, we have raised net proceeds of approximately $9.6 million from private equity financings, class A and class C stock conversions, warrant exercises and in the third quarter 2000, the issuance of a $500,000 convertible debenture.

Our cash and cash equivalents were $3,234,983 and $5,274,552 at September 30, 2000 and December 31, 1999, respectively. The decrease in our cash balances is due to cash used in operating activities. We used cash in operating activities of $691,965 for the three month period ended September 30, 2000 versus cash used in operating activities of $323,616 for the three month period ended September 30, 1999. This change reflects the cash expenditures associated with our Phase I CAP human clinical trial conducted during the third quarter of 2000, increased personnel-related expenses and legal fees associated with the increase in licensing and collaboration activities. Net cash used in investing activities was $4,200 for the three month period ended September 30, 2000 versus no cash used in investing activities for the three month period ended September 30, 1999. The uses of cash in investing activities during the three month period ended September 30, 2000 were capital expenditures for the purchase of a new air conditioning unit for the laboratory facility in Smyrna, Georgia. There were no uses of cash in investing activities for the three month period ended September 30, 1999. Net cash provided by financing activities was $565,085 for the three months ended September 30, 2000 compared to $12,110 for the three months ended September 30, 1999. Net cash provided during the three months ended September 30, 2000 was primarily the result of the issuance of a $500,000 convertible debenture, the conversion of shares of class C stock into shares of common stock and the issuance of shares of common stock in lieu of cash bonuses to two members of management, while net cash provided during the three months ended September 30, 1999 was the result of the conversion of shares of class C stock into shares of common stock.

We used cash in operating activities of $2,596,047 for the nine month period ended September 30, 2000 versus cash used in operating activities of $1,413,578 for the nine month period ended September 30, 1999. This change reflects a $1 million upfront payment to the licensor of the hormone replacement product portfolio we acquired in June 2000. Net cash used in investing activities was $31,567 for the nine month period ended September 30, 2000 versus $4,219 for the nine month period ended September 30, 1999. The uses of cash in investing activities during 2000 were capital expenditures for the purchase of an air conditioning unit for the laboratory facility and for six computers. The significant uses of cash in investing activities for the nine month period ended September 30, 1999 included capital expenditures for office furniture. Net cash provided by financing activities was $588,045 for the nine months ended September 30, 2000 compared to $4,225,343 for the nine months ended September 30, 1999. Net cash provided during the nine months ended September 30, 2000 was primarily the result of the issuance of a $500,000 convertible debenture and conversions of shares of class C stock into shares of common stock. Net cash provided by financing activities during the nine months ended September 30, 1999 was the result of a $4.2 million private placement of our common stock in May 1999.

We did not have any material commitments for capital expenditures as of September 30, 2000. We have, however several financial commitments, including product development milestone payments to the licensor of our proposed hormone products, payments under the license agreement with the University of California, as well as minimum annual lease payments.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we may need to raise substantial additional capital to fund our operations. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our own product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business. 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 manufacturers and marketing partners to manufacture 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 obtain the necessary regulatory approvals for those facilities or to seek third party manufacturers to manufacture our products for us;
- 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 proposed hormone products requires us to make certain payments 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.

Our cash on hand as of September 30, 2000 was $3,234,983. We believe this cash will be sufficient to fund our operations through at least December 2001. We have based this estimate, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing

research and development activities, acquire new products or take advantage of other unanticipated opportunities. Any additional equity financings may be dilutive to our existing shareholders, and debt financing, if available, may involve restrictive covenants on our business. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to 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.

Risk Factors

There are several important factors that could cause our actual results to differ materially from those anticipated by us or which are reflected in any of our forward-looking statements. These factors, and their impact on the success of our operations and our ability to achieve our goals, include the following and those listed under the caption "Risk Factors" in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 1999:

We are a development stage company with a short operating history, 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;
- the lack of manufacturing experience and limited marketing experience;
- an expected reliance on third parties for the development and commercialization of our proposed products;
- a competitive environment characterized by numerous, well-established and well-capitalized competitors; 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 product development stages and will likely not be commercially introduced for several years, if at all.

Our proposed products are in the product development stages and will require further development, pre-clinical and clinical testing and investment prior to commercialization in the United States and abroad. 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;
- 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; or
- be successfully marketed.

We do not anticipate that any of our proposed products will receive the requisite regulatory approvals for commercialization in the United States or abroad for a number of years, if at all, and we cannot assure you that any of our proposed products, if approved and marketed, will generate significant product revenue and provide an acceptable return on our investment.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed, 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 vaccine or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter pre-clinical 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 could be adversely affected.

Moreover, even if the FDA approves a product, such approval may be conditioned upon commercially unacceptable limitations on the indications for which a product may be marketed, and further studies may be required to provide additional data on safety or effectiveness. The FDA may also require post-marketing surveillance programs to monitor the product's side effects. The later discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions on the product or manufacturer, including the withdrawal of the product from the market.

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, pre-clinical studies on animals and clinical trials on humans on each 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. 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;
- longer treatment time required to demonstrate efficacy;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

Because our industry is very competitive and 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 will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we are currently developing or will develop.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to interest rate risk on the investments of our excess cash. 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. Due to the nature of our short-term investments, we have concluded that we do not have a material market risk of exposure.

PART II—OTHER INFORMATION

ITEM 2—CHANGES IN SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2000, we issued a $500,000 convertible debenture, 28,341 shares of common stock pursuant to the conversion of class C stock and 190,076 shares of common stock pursuant to the granting of a common stock bonus, in lieu of cash, to two members of management.

These issuances were made in reliance on Section 4(2) or Rule 701 under the Securities Act of 1933. In order to rely on these exemptions from the registration requirements, we made inquiries to establish that these sales qualified for the exemptions. In particular, we confirmed that:

- all offers and sales were made by personal contact from our officers or directors or other persons closely associated with us;
- each investor made representations that the investor was sophisticated in relation to the investment and we have no reason to believe these representations were incorrect;
- each purchaser gave assurance of investment intent and the certificates for the shares bear a restrictive legend; and
- offers and sales within any offering were made to a limited number of persons.

ITEM 6—EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

Exhibit Number	Description
27.1	Financial Data Schedule

(b) Reports on Form 8-K

On July 11, 2000, we filed a Current Report on Form 8-K to disclose the material terms of our license agreement with Permatec Technologie A.G.

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

November 14, 2000

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
Donenberg Chief Financial Officer,
Secretary and Treasurer
(principal financial and accounting officer)

EXHIBIT INDEX

Exhibit Number	Description	Location
27.1	Financial Data Schedule	Filed herewith

QuickLinks

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM SEPTEMBER 30, 2000 AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

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9-MOS
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JAN-01-2000
SEP-30-2000
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