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 MARCH 31, 2001

COMMISSION FILE NUMBER 000-28637

/ / TRANSITION REPORT UNDER SECTION 13 OR 15(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
(Issuer's telephone number, including area code)

Indicate by check mark whether the issuer (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 issuer 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 MAY 11, 2001
Common stock, no par value	62,202,943

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

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB
MARCH 31, 2001

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
BALANCE SHEETS
MARCH 31, 2001 AND DECEMBER 31, 2000

ASSETS	MARCH 31, 2001 (UNAUDITED)	DECEMBER 31, 2000 (NOTE)
CURRENT ASSETS		
Cash and cash equivalents	$5,221,947	$ 2,611,755
Prepaid expenses and other sundry assets	46,325	64,341
	5,268,272	2,676,096
PROPERTY AND EQUIPMENT, NET	368,980	390,821
	$5,637,252	$ 3,066,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 93,115	$ 44,746
Accrued compensation	150,756	258,598
Other accrued expenses	50,657	137,919
Convertible debenture	500,000	500,000
	794,528	941,263
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
4,687,684 (2000 - 4,687,684) Class C special stock	469	469
52,952,943 (2000 - 52,952,943) Common stock	17,782,857	17,782,857
Subscriptions to purchase common stock (Note 5)	3,397,970	-
	21,181,296	17,783,326
Deferred unearned compensation	(9,000)	(18,000)
Deficit accumulated during the development stage	(16,329,572)	(15,639,672)
	4,842,724	2,125,654
	$5,637,252	$ 3,066,917

Note: The balance sheet as of December 31, 2000 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.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF OPERATIONS
THREE MONTHS ENDED MARCH 31, 2001 AND 2000 AND THE CUMULATIVE
PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO MARCH 31, 2001
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,		CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO MARCH 31,
	2001	2000	2001
REVENUE			
Interest income	$ 32,109	$ 60,382	$ 778,645
EXPENSES			
Research and development	232,989	191,175	4,517,361
General and administration	465,058	301,175	6,275,296
Depreciation and amortization	23,962	23,852	405,796
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
	722,009	516,202	17,108,217
NET LOSS	$ (689,900)	$ (455,820)	$ (16,329,572)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.01)	$ (0.01)	$ (0.37)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	57,640,627	57,450,551	43,704,568

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF CASH FLOWS
THREE MONTHS ENDED MARCH 31, 2001 AND 2000 AND THE CUMULATIVE
PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO MARCH 31, 2001
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,		CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO MARCH 31,
	2001	2000	2001
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (689,900)	$ (455,820)	$ (16,329,572)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	23,962	23,852	405,796
Amortization of deferred unearned compensation	9,000	-	33,290
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	18,016	13,602	(43,357)
Accounts payable and accrued expenses	(146,735)	(42,822)	(445,659)
Due from SBI	-	-	(128,328)
Net cash used in operating activities	(785,657)	(461,188)	(10,973,285)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(2,121)	(11,334)	(898,211)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	-	-	500,000
(Conversion) issuance of Class "C" shares	-	(4)	469
Proceeds from subscription, sale or conversion of shares	3,397,970	10,464	16,592,974
Net cash provided by financing activities	3,397,970	10,460	17,093,443
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,610,192	(462,062)	5,221,947
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,611,755	5,274,552	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$5,221,947	$ 4,812,490	$ 5,221,947
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: subordinate voting shares issued therefor	-	-	4,545,563
	$ -	$ -	$ -
Income tax paid	$ -	$ -	$ -
Interest paid	$ -	$ -	$ -

See accompanying notes to the financial statements.

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 March 31, 2001, the results of operations for the three months ended March 31, 2001 and 2000 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2001, and the cash flows for the three months ended March 31, 2001 and 2000 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2001, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001.

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, 2000.

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 dilutive potential that would have an antidilutive effect on net loss per share.

3. LICENSE AND SUPPLY AGREEMENTS

On June 13, 2000, BioSante entered into a licensing agreement and a supply agreement with Antares Pharma Inc. (the entity that resulted from the merger of Permatec Technologie, AG with Medi-Ject Corporation), covering four hormone products for the treatment of testosterone deficiency in men and estrogen deficiency in women. The agreement requires BioSante to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, BioSante is also obligated to make milestone payments upon the occurrence of certain future events. Under terms of the supply agreement, Permatec has agreed to manufacture or have manufactured and sell exclusively to BioSante, and BioSante has agreed to purchase exclusively from Antares, BioSante's total requirements for the products covered under the license agreement between the two parties.

As allowed by the licensing agreement with Antares, on September 1, 2000, BioSante 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 BioSante, 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 BioSante's common stock at a 10% premium to the market price of BioSante'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, BioSante issued a convertible debenture to Paladin in the principal 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 BioSante common 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 BioSante common stock 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, BioSante has the right, in its sole discretion, after March 31, 2001, to require the debenture to be converted.

5. SUBSEQUENT EVENT

On April 4, 2001, BioSante closed a private placement, raising US$3.7 million upon the issuance of units, which consisted of an aggregate of 9,250,000 shares of common stock and five-year warrants to purchase an aggregate of 4,625,000 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock was US$0.40, the approximate market price of BioSante's common stock at closing. The exercise price of the warrant is US$0.50 per full share. Transaction costs related to the private placement have been netted against the proceeds. As of March 31, 2001, approximately $3.4 million of the private placement proceeds had been deposited with BioSante and are reflected in cash and "Subscriptions to purchase common stock" on the Balance Sheet.

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

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, 2000.

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 hormone deficiency in men and women. We also are engaged in the development of our nanoparticulate-based technology for novel vaccines, vaccine adjuvants and drug delivery systems.

We license our vaccine and drug delivery system technology, on an exclusive basis from the University of California. This technology is based on the use of extremely small 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 Antares Pharma Inc. (the entity that resulted from the merger of Permatec Technologie, AG and Medi-Ject Corporation) 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 Antares, 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 Antares 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 Antares 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 common 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. Since Paladin did not convert the debenture by March 31, 2001, we have the right to 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. In addition, we expect to begin human clinical trials with respect to our hormone replacement products by mid-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, and the cost of marketing the products, if approved;
- 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 MARCH 31, 2001 COMPARED TO THREE MONTHS ENDED MARCH 31, 2000

General and administrative expenses increased from $301,175 during the three month period ended March 31, 2000 to $465,058 during the three month period ended March 31, 2001. This increase of approximately 54% 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 slightly from $191,175 during the three month period ended March 31, 2000 to $232,989 during the three month period ended March 31, 2001 due primarily to the increased expenses associated with the clinical development of our 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 decreased from $60,382 during the three month period ended March 31, 2000 to $32,109 during the three month period ended March 31, 2001 as a result of lower invested cash balances between the three month periods. We expect interest income to increase in the following quarter due to our recently closed private placement (see Footnote 5, "Subsequent Event"), then to decline in subsequent periods as we use our cash balances for operations.

We incurred a net loss of $689,900 for the three month period ended March 31, 2001, compared to a net loss of $455,820 for the three month period ended March 31, 2000. The increase in the net loss is primarily due to the expenses associated with (1) new personnel-related expenses, (2) legal expenses related to increased collaboration and licensing activities, (3) increased expenses associated with the clinical development of our hormone replacement product portfolio, and (4) the remaining expenses related to the conducting of a Phase I human clinical trial testing the safety of our CAP nanoparticles. 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 $9.2 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. This figure does not include $3.7 million raised in a private placement closed April 4, 2001. In this private placement, we issued units, which consisted of an aggregate of 9,250,000 shares of common stock and five-year warrants to purchase an aggregate of 4,625,000 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $0.40, the approximate market price of our common stock at closing. The exercise price of the warrant is $0.50 per full share.

Our cash and cash equivalents were $5,221,947 and $2,611,755 at March 31, 2001 and December 31, 2000, respectively. The increase in our cash balances is due to cash deposits of approximately $3.4 million recorded as cash and cash equivalents at March 31, 2001 pursuant to our $3.7 million private placement closed April 4, 2001. The remaining balance of cash proceeds from the private placement was received in April 2001. We used cash in operating activities of $785,657 for the three month period ended March 31, 2001 versus cash used in operating activities of $461,188 for the three month period ended March 31, 2000. This change reflects the cash expenditures associated with increased general and administrative and research and development personnel-related expenses and legal fees associated with the increase in licensing and collaboration activities in addition to expenses related to the clinical development of our (1) hormone replacement product portfolio, and (2) Phase I CAP human clinical trial. Net cash used in investing activities was $2,121 for the three month period ended March 31, 2001 versus $11,334 used in investing activities for the three month period ended March 31, 2000. The uses of cash in investing activities during the three month period ended March 31, 2001 were capital expenditures for the purchase of a new laptop computer. Similarly, the uses of cash in investing activities for the three month period ended March 31, 2000 represented the purchase of three computers. Net cash provided by financing activities was $3,397,970 for the three months ended March 31, 2001 compared to $10,460 for the three months ended March 31, 2000. Net cash provided during the three months ended March 31, 2001 was the result of the receipt of cash proceeds as described above pursuant to the Company's private placement closed on April 4, 2001, while net cash provided during the three months ended March 31, 2000 was the result of the conversion of shares of class C stock into shares of common stock.

We did not have any material commitments for capital expenditures as of March 31, 2001. We have, however several financial commitments, including product development milestone payments to the licensor of our 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 will likely 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 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 hormone 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.

Our cash on hand as of March 31, 2001 was $5,221,947. We believe this cash will be sufficient to fund our operations through at least December 2002. 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, 2000:

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 $689,900 for the quarter ended March 31, 2001, and as of March 31, 2001, our accumulated deficit was $16,329,572.

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 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; and
- the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our own proposed products or products in the late-stage human clinical development phase or already on the market that we may in-license or otherwise acquire, 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 revenues or achieve profitability.

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.

WE LICENSE OUR HORMONE REPLACEMENT PRODUCTS AND OUR CAP TECHNOLOGY FROM THIRD PARTIES AND MAY LOSE THE RIGHTS TO LICENSE THEM.

We license our hormone replacement products from Antares Pharma, Inc. and our CAP technology from the University of California. We may lose the right to 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, Antares and the University of California 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 our hormone replacement 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 replacement products or CAP technology for a license fee, the termination of the license agreement could either, depending on 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.

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. In February 2000, we filed a patent application relating to our technology. However, our owned and licensed patents and patent applications will not ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease before others developed similar methods.
- Competitors may interfere with our 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 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 research and 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 that patent.
- We may also 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 is also 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. 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 are also 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 have often 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.

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 March 31, 2001, BioSante did not issue or sell any securities that were not registered under the Securities Act of 1933, as amended.

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS.

None

(b) REPORTS ON FORM 8-K

No reports on Form 8-K were filed during the quarter ended March 31, 2001.

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.

May 11, 2001 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, Secretary and Treasurer
(principal financial and accounting officer)

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION	LOCATION
None		