BIOSANTE PHARMACEUTICALS INC
Form 10QSB
May 15, 2002

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended March 31, 2002

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)

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

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

(847) 478-0500
(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 ý NO o

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 10, 2002
Common stock, $0.0001 par value	63,218,798

Transitional Small Business Disclosure Format (check one): Yes o No ý

BIOSANTE PHARMACEUTICALS, INC.

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MARCH 31, 2002

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Balance Sheets

March 31, 2002 and December 31, 2001 (Unaudited)

	March 31, 2002	December 31, 2001
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 3,162,849	$ 4,502,387
Prepaid expenses and other sundry assets	83,737	91,859
	3,246,586	4,594,246
PROPERTY AND EQUIPMENT, NET	378,967	384,996
	$ 3,625,553	$ 4,979,242
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 142,471	$ 90,653
Accrued compensation	88,797	379,346
Other accrued expenses	51,325	24,444
Due to Antares	395,656	433,319
	678,249	927,762
COMMITMENTS		
STOCKHOLDERS EQUITY		
Capital stock		
Issued and Outstanding		
4,666,024 (2001 - 4,666,024) Class C special stock	467	467
63,218,798 (2001 - 63,218,798) Common stock	22,300,796	22,302,046
	22,301,263	22,302,513
Deficit accumulated during the development stage	(19,353,959)	(18,251,033)

		2,947,304		**4,051,480**
	$	**3,625,553**	**$**	**4,979,242**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Operations

Three months ended March 31, 2002 and 2001 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2002

(Unaudited)

	Three Months Ended March 31,		Cumulative period from August 29, 1996 (date of incorporation) to March 31, 2002
	2002	2001	
REVENUE			
Licensing income	$	$	$ 1,747,386
Interest income	23,259	32,109	944,211
	23,259	32,109	2,691,597
EXPENSES			
Research and development	644,394	232,989	7,070,710
General and administration	459,129	465,058	8,568,026
Depreciation and amortization	22,662	23,962	497,056
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
	1,126,185	722,009	22,045,556
NET LOSS	$ (1,102,926)	$ (689,900)	$ (19,353,959)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.02)	$ (0.01)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	67,884,822	57,640,627	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Three months ended March 31, 2002 and 2001 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2002

(Unaudited)

	Three Months Ended March 31,		Cumulative period from August 29, 1996 (date of incorporation to March 31, 2002
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (1,102,926)	$ (689,900)	$ (19,353,959)
Adjustments to reconcile net loss to net cash used in operating activities	2002	2001	
Depreciation and amortization	22,662	23,962	497,056
Amortization of deferred unearned compensation		9,000	42,290
Repurchase of licensing rights			125,000
Employee compensation paid in shares of common stock			151,000
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	8,122	18,016	(80,769)
Accounts payable and accrued expenses	(211,850)	(146,735)	(457,594)
Due to licensors	(37,663)		395,656
Due from SBI			(128,328)
Net cash used in operating activities	(1,321,655)	(785,657)	(13,275,103)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(16,633)	(2,121)	(999,458)
CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture			500,000
Proceeds from sale, subscription or conversion of shares	(1,250)	3,397,970	16,937,410
Net cash (used in) provided by financing activities	(1,250)	3,397,970	17,437,410
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,339,538)	2,610,192	3,162,849
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,502,387	2,611,755	

CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 3,162,849**	**$ 5,221,947**	**$ 3,162,849**
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.

BIOSANTE PHARMACEUTICALS, INC.

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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, 2002 and December 31, 2001, the results of operations for the three months ended March 31, 2002 and 2001 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2002, and the cash flows for the three months ended March 31, 2002 and 2001 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2002, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002.

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, 2001.

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 generally 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. PRIVATE PLACEMENT FINANCING

On April 4, 2001, BioSante closed a private placement raising $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 $0.40, the approximate market price of BioSante s common stock at closing. The exercise price of the warrant is $0.50 per full share. Transaction costs related to the

private placement have been netted against the proceeds.

4. COMMITMENTS

University of California License

BioSante s license agreement with the University of California requires BioSante 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 on February 28 of each year beginning in the year 2004 in the amounts set forth below, to be credited against earned royalties, for the life of the agreement;

Year	Minimum Annual Royalty Due
2004	$ 50,000
2005	100,000
2006	150,000
2007	200,000
2008	400,000
2009	600,000
2010	800,000
2011	1,500,000
2012	1,500,000
2013	1,500,000

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 year ended December 31, 2001 amounted to $11,358;

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;

Entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license; 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 exercise of the license agreement, including but not limited to, any product liability claims.

Antares Pharma, Inc. License

BioSante s license agreement with Antares required BioSante to make a $1.0 million upfront payment to Antares. $250,000 of this upfront payment was creditable against future milestone or other payments and was utilized in the third quarter of 2001. The result was a $250,000 reduction in research and development expense in the statement of operations during the quarter ended September 30, 2001 as the initial $1.0 million payment had been expensed in its entirety in 2000. BioSante expects to fund the development of the products, make milestone payments and once regulatory approval to market is received and sales of the products commence, pay royalties on the sales of products. BioSante must also make cash payments to Antares for manufacturing and formulation services incurred by Antares related to the products and must pay Antares a portion of any up front sublicense or milestone payment received by BioSante from the sublicense of the products.

5. NEW ACCOUNTING PRONOUNCEMENTS

On July 20, 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 141, Business Combinations and SFAS No. 142, Goodwill and Other Intangible Assets . These statements establish new accounting and reporting standards for business combinations and associated goodwill and intangible assets. They require, among other things, elimination of the pooling of interests method of accounting, no amortization of acquired goodwill, and a periodic assessment for impairment of all goodwill and intangible assets acquired in a business combination. SFAS 141 is effective for all business combinations accounted for by the purchase method that are completed after June 30, 2001. SFAS 142 was adopted on January 1, 2002. There was no impact on BioSante s financial statements as a result of the adoption of SFAS 142.

6. SUBSEQUENT EVENTS

In April 2002, BioSante 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 BioSante, regulatory milestones, maintenance payments and royalty payments by BioSante if the product gets approved and subsequently marketed.

In May 2002, BioSante filed a registration statement on Form SB-2 with the Securities and Exchange Commission. The filing relates to a proposed best-efforts, self underwritten offering by BioSante of up to $10 million in shares of common stock. The per share public offering price will be determined shortly after the registration statement is declared effective.

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

This Form 10-QSB contains forward-looking statements relating to our financial condition, results of operations and business, including statements pertaining to:

our substantial and continuing losses;

our raising of additional capital through future equity financings;

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; and

our existing cash and whether and how long these funds will be sufficient to fund our operations.

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 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, 2001. We are not obligated to publicly update or revise any forward looking statement, whether as a result of new information, future events or otherwise, except as otherwise required by law. For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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 a development stage biopharmaceutical company engaged in the development and commercialization of hormone replacement products to treat hormone deficiencies in both men and women. We also are engaged in the development and commercialization of vaccine adjuvants or immune system boosters, drug delivery systems and the purification of the milk of transgenic animals, all applications using calcium phosphate nanoparticles, or CAP.

Our hormone replacement products, which we license on an exclusive basis from Antares Pharma, Inc., 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.

The products we in-licensed from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), a combination of estradiol and testosterone and a combination of estradiol and progestogen (another female hormone). The 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 formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Indonesia, Malaysia, Australia, New Zealand, China 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 hormone replacement products, we paid Antares an upfront license fee of $1.0 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 a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for the combination estradiol plus testosterone gel product.

On August 7, 2001, BioSante entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay sub-licensed BioSante s estrogen/progestogen combination transdermal hormone replacement 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. Solvay will be responsible for all costs of development and marketing of the product. BioSante has retained co-promotion rights to the product and will be compensated for sales generated by BioSante over and above those attributable to Solvay s marketing efforts. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by BioSante prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

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 BioSante 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 $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $1.05 per share. On August 13, 2001, BioSante exercised its right and declared the debenture converted in full. Accordingly, 476,190 shares of BioSante common stock were issued to Paladin on August 23, 2001. During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 189,394 shares of its common stock to Paladin.

Our strategy with respect to our hormone replacement product portfolio is to conduct human clinical trials of our hormone replacement products, which are required to obtain approval from the U.S. Food and Drug Administration, or FDA, to market the products in the United States.

Our CAP technology, which 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, among other uses. We have identified three potential applications for our CAP technology:

the creation of improved versions of current vaccines by the adjuvant activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response;

the creation of inhaled and oral forms of drugs that currently must be given by injection (*e.g.*, insulin); and

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

Our strategy with respect to CAP over the next 12 months, is to continue development of our nanoparticle technology and actively to seek collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the FDA to initiate a Phase I clinical trial of our CAP as a vaccine adjuvant and delivery system based on an Investigational New Drug 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 in October 2000. The results showed that there was no apparent difference in side effect profile between CAP and placebo.

On October 1, 2001, BioSante licensed its Bio-Vant™ calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay BioSante milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using Bio-Vant™ and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-Vant™, BioSante will share in milestone payments and royalties received by Corixa. The license agreement covers access to Bio-Vant™ for a variety of cancer, infectious and autoimmune disease vaccines.

Our goal is to develop and commercialize our portfolio of hormone replacement products and CAP technology into a wide range of pharmaceutical products and to expand this product portfolio as appropriate. Our strategy to obtain this goal is to:

Accelerate the development of our hormone replacement products.

Continue the development of our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses.

License or otherwise acquire other drugs that will add value to our current product portfolio.

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

We currently expect to add employees as we continue to develop and commercialize our hormone replacement products and products incorporating our CAP technology or in-license or otherwise acquire products in late-stage human clinical development.

All of our revenue to date has been derived from interest earned on invested funds and upfront payments earned on sub-licensing transactions. We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $2,611,361 for the year ended December 31, 2001, resulting in an accumulated deficit of $18,251,033. We incurred a net loss of $1,102,926 for the three months ended March 31, 2002, and as of March 31, 2002, our accumulated deficit was $19,353,959. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs expand 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 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 proposed products in pre-clinical development, in late-stage human clinical development, 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.

Results of Operations

Three Months Ended March 31, 2002 Compared to Three Months Ended March 31, 2001

General and administrative expenses decreased slightly from $465,058 during the three month period ended March 31, 2001 to $459,129 during the three month period ended March 31, 2002.

Research and development expenses increased from $232,989 during the three month period ended March 31, 2001 to $644,394 during the three month period ended March 31, 2002. This increase is the result of certain manufacturing and formulation services provided by and paid to Antares and increased expenses during the three month period ended March 31, 2002 associated with the clinical development of our hormone replacement product portfolio. As a result of our hormone replacement product in-license agreement 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 for research and development activities. The amount of our research and development expenditures 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 $32,109 during the three month period ended March 31, 2001 to $23,259 during the three month period ended March 31, 2002 as a result of lower average cash balances, coupled with lower interest rates.

We incurred a net loss of $1,102,926 for the three month period ended March 31, 2002, compared to a net loss of $689,900 for the three month period ended March 31, 2001. The increase in the net loss is the result of increased expenses during the three month period ended March 31, 2002 associated with (1) clinical development and personnel-related expenses, (2) legal expenses related to increased patent, collaboration and licensing activities, and (3) increased expenses associated with the clinical development of our hormone replacement product portfolio. We anticipate that we will incur operating losses for the foreseeable future.

Liquidity and Capital Resources

To date, we have raised equity financing and received licensing income 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 $12.9 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, which was converted into 173,611 shares of common stock in the third quarter of 2001. In addition, as a result of licensing upfront payments and milestones, we have received an additional $2.1 million.

Our cash and cash equivalents were $3,162,849 and $4,502,387 at March 31, 2002 and December 31, 2001, respectively. The decrease in our cash balances is due to cash used in operating activities. We used cash in operating activities of $1,321,655 for the three month period ended March 31, 2002 versus cash used in operating activities of $785,657 for the three month period ended March 31, 2001. This change reflects the cash expenditures associated with: (1) increased research and development and personnel-related expenses, (2) legal fees associated with the increase in patent, licensing and collaboration activities, (3) increased expenses related to the clinical development of our hormone replacement product portfolio and expenses related to manufacturing and formulation services provided by Antares, and (4) reduction of accounts payable and accrued expenses. Net cash used in investing activities was $16,633 for the three month period ended March 31, 2002 versus $2,121 used in investing activities for the three month period ended March 31, 2001. The uses of cash in investing activities during both three month periods ended March 31, 2002 and 2001 were capital expenditures for the purchases of computer equipment. Net cash used in financing activities was $1,250 for the three months ended March 31, 2002 compared to cash provided by financing activities of $3,397,970 for the three months ended March 31, 2001. The net cash used in financing activities of $1,250 was the result of transaction costs associated with a previous financing, while the net cash provided during the three months ended March 31, 2001 was the result of the receipt of cash proceeds (net of transaction costs) from our private placement of units which closed in April 2001 and licensing milestone payments received.

We did not have any material commitments for capital expenditures as of March 31, 2002. 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.

The following table summarizes the timing of these future contractual obligations and commitments:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 274,688	$ 142,811	$ 131,877		
Commitments Under License Agreement with UCLA	6,800,000		50,000	$ 250,000	$ 6,500,000
Commitments Under License Agreement with Wake Forest	1,240,000	100,000	55,000	145,000	940,000
Total Contractual Cash Obligations	$ 8,314,688	$ 242,811	$ 236,877	$ 395,000	$ 7,440,000

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, 2002 was $3,162,849. We believe this cash will be sufficient to fund our operations through March 2003. On May 3, 2002, we filed a shelf registration statement on Form SB 2 relating to a proposed best efforts, self-underwritten offering of up to $10,000,000 in shares of our common stock. The per share public offering price will be determined shortly after the registration statement is declared effective. If we are able to sell all of the shares offered in the shelf offering, we believe that with the net proceeds of the shelf offering and our existing cash, we will have sufficient working capital to meet our needs through December 2003. We have based these estimates, 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 Certain Important Factors in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001:

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 $1,102,926 for the three month period ended March 31, 2002, and as of March 31, 2002, our accumulated deficit was $19,353,959.

All of our revenue to date has been derived from interest earned on invested funds and upfront payments earned on sub-licensing transactions. 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 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 may need to raise substantial additional capital to fund our operations sometime in the future. 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 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 the technology underlying our proposed hormone replacement products and our CAP technology from third parties and may lose the rights to license them.

We license the technology underlying our proposed hormone replacement products from Antares Pharma, Inc. and 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 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 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 do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We may, therefore, be dependent upon others for our clinical testing, manufacturing, sales and marketing.

Our current facilities do not include accommodation for the testing of our proposed products in animals or in humans for the clinical testing required by the FDA. We do not have a manufacturing facility that can be used for full-scale production of our products. In addition, at this time, we have very limited sales and marketing personnel. In the course of our development program, we will therefore be required to enter into

arrangements with other companies or universities for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If we are unable to retain third parties for these purposes on acceptable terms, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by 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 third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

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, 2002, 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, 2002.

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 14, 2002

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)