BIOSANTE PHARMACEUTICALS INC
Form 10QSB
May 15, 2003

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, 2003

Commission file number 000-28637

o **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 13, 2003**
Common stock, $0.0001 par value	8,571,169

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

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB

MARCH 31, 2003

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Balance Sheets

March 31, 2003 and December 31, 2002 (Unaudited)

	March 31, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 3,411,700**	**$ 4,883,697**
Due from Teva Pharmaceuticals USA, Inc.	**65,494**	**520,063**
Prepaid expenses and other sundry assets	**148,240**	**144,155**
	3,625,434	**5,547,915**
PROPERTY AND EQUIPMENT, NET	**308,341**	**331,889**
	$ 3,933,775	**$ 5,879,804**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 247,758**	**$ 470,871**
Accrued compensation	**209,063**	**313,287**
Other accrued expenses	**49,259**	**236,758**
Due to Antares	**48,791**	**235,303**
	554,871	**1,256,219**
COMMITMENTS		
STOCKHOLDERS EQUITY		
Capital stock		
Issued and Outstanding		
466,602 (2002 - 466,602) Class C special stock	**467**	**467**
8,571,169 (2002 - 8,571,169) Common stock	**26,684,841**	**26,684,841**
	26,685,308	**26,685,308**
Deficit accumulated during the development stage	**(23,306,404)**	**(22,061,723)**
	3,378,904	**4,623,585**
	$ 3,933,775	**$ 5,879,804**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Operations

Three months ended March 31, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003

(Unaudited)

	Three Months Ended March 31		Cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003
	2003	2002	
REVENUE			
Licensing income	$ 65,494	$	$ 4,582,943
Interest income	18,819	23,259	1,003,559
	84,313	23,259	5,586,502
EXPENSES			
Research and development	803,153	644,394	12,016,287
General and administration	502,293	459,129	10,376,814
Depreciation and amortization	23,548	22,662	590,041
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
	1,328,994	1,126,185	28,892,906
NET (LOSS)	$ (1,244,681)	$ (1,102,926)	$ (23,306,404)
BASIC AND DILUTED NET (LOSS) PER SHARE	$ (0.14)	$ (0.16)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	9,037,771	6,788,482	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Three months ended March 31, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003

(Unaudited)

	Three Months Ended March 31,		Cumulative period from August 29, 1996 (date of incorporation) to March 31,
	2003	2002	2003
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (1,244,681)	$ (1,102,926)	$ (23,306,404)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	23,548	22,662	590,041
Amortization of deferred unearned compensation			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	(4,085)	8,122	(145,272)
Due from licensee (Teva Pharmaceuticals USA, Inc.)	454,569		(65,494)
Accounts payable and accrued expenses	(514,836)	(211,850)	(234,107)
Due to licensor (Antares/Regents)	(186,512)	(37,663)	48,791
Due from SBI			(128,328)
Net cash used in operating activities	(1,471,997)	(1,321,655)	(17,387,938)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets		(16,633)	(1,021,817)
CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture			500,000
Proceeds from sales or conversion of shares		(1,250)	21,321,455
Net cash (used in) provided by financing activities		(1,250)	21,821,455
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(1,471,997)	(1,339,538)	3,411,700
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,883,697	4,502,387	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 3,411,700	$ 3,162,849	$ 3,411,700

SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	**$**	**$**	**$ 5,377,000**
Other net liabilities assumed			**(831,437)**
			4,545,563
Less: common stock issued therefor			**4,545,563**
	$	**$**	**$**
Income tax paid	**$**	**$**	**$**
Interest paid	**$**	**$**	**$**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB

MARCH 31, 2003

Notes To The Financial Statements (Unaudited)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of BioSante Pharmaceuticals, Inc. (the Company) as of March 31, 2003, the results of operations for the three months ended March 31, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003, and the cash flows for the three months ended March 31, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 4 to the financial statements, the Company s cash resources are limited and additional capital will need to be raised in the near future. The Company s recent activities in regard to this situation are also described in Note 4. The financial statements do not include any adjustments that might result from the success or failure of management to raise additional capital in the near future.

On May 31, 2002, the Company effected a one-for-ten reverse split of its issued and outstanding shares of common stock and class C stock. All share and per share stock numbers in this Form 10-QSB have been adjusted to reflect the reverse stock split.

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in the Company s Annual Report on Form 10-KSB for the year ended December 31, 2002.

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 the Company 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. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted the Company an exclusive license to nine United States patents owned by the University, including rights to sublicense such patents. The license agreement with the University of California requires the Company to

undertake various obligations, including but not limited to, the payment of royalties based on future net sales and the payment of minimum annual royalties.

On June 13, 2000, the Company entered into a license agreement with Antares Pharma Inc. covering four hormone therapy products for the treatment of men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain future events.

In August 2001, the Company 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 therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed the Company s estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin Labs Inc.), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, the Company received a $950,000 milestone payment pursuant to the Solvay sub-license agreement.

On October 1, 2001, the Company sub-licensed its BioVant™ 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 the Company milestone payments upon the achievement of certain milestones plus royalty payments on sales if and when vaccines are approved using BioVant™ and sold on a commercial basis. If Corixa sub-licenses vaccines that include BioVant™, the Company will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to BioVant™ for a variety of cancer, infectious and autoimmune disease vaccines.

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

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. under which Teva USA and the Company will collaborate on the development of a hormone therapy product for the U.S. market. Upon signing the U.S. development and license agreement, the Company received an upfront payment of $1.5 million. In addition, Teva will pay the Company development and sales-related milestone payments plus royalties on sales of the product commercialized in this collaboration. In exchange, the Company granted Teva exclusive rights to develop and market a certain hormone therapy product. Teva also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

4. FINANCING

The Company currently does not have sufficient resources to complete the commercialization of any of its proposed products. Therefore, the Company will need to raise additional capital in the near future to fund operations and may be unable to raise such funds when needed and on acceptable terms.

The Company cannot be certain that any financing will be available when needed. If the Company fails to raise additional financing as needed, it may have to delay or terminate product development programs or pass on opportunities to in-license or otherwise acquire new products that the Company believes may be beneficial to its business.

The Company is in the process of exploring alternatives for raising additional financing, which could include the issuance of shares of the Company s common stock, securities convertible into shares of the Company s common stock, shares of preferred stock, debentures, warrants and/or other equity or non-equity securities. If the Company is successful at raising additional capital, its expenses will increase as the Company accelerates product development. The Company currently has no commitments for additional funding, so the Company s ability to meet its liquidity needs is uncertain. If the Company raises additional funds through the issuance of equity securities, its stockholders may experience significant dilution. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to the Company or its stockholders. The Company is also exploring strategic alternatives, which could include selling some or all of its assets or entering into a business combination, but has not entered into any definitive agreements for such a strategic alternative.

5. COMMITMENTS

University of California License

The Company s license agreement with the University of California requires the Company to undertake various obligations, including:

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

Payment of minimum annual royalties on beginning for the year 2004 to be paid by February 28 of the following year 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, 2002 amounted to $12,240;

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 the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability related to this obligation.

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares. The Company expects to fund the development of the products, make milestone payments and once regulatory approval to market is received, pay royalties on the sales of products.

Wake Forest License

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

payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed.

Future minimum payments due under this agreement are as follows:

Year	Minimum Amount Due
2004	$ 10,000
2005	45,000
2006	80,000
2007	65,000
2008	90,000
2009	140,000
2010	90,000
2011	40,000
2012	140,000
2013	240,000
Thereafter	800,000
	$ 1,740,000

The Company has agreed to indemnify, hold harmless and defend Wake Forest University against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation.

6. STOCK BASED COMPENSATION

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

	March 31, 2003	March 31, 2002
Net loss		
As reported	**$ (1,244,681)**	$ (1,102,926)
Total stock-based employee compensation determined under fair value based method for all awards	**(138,966)**	(41,494)
Net loss, pro forma	**$ (1,383,647)**	$ (1,144,420)
Basic and diluted net loss per share		
As reported	**$ (0.14)**	$ (0.16)
Pro forma	**$ (0.15)**	$ (0.17)
Cumulative net loss		
As reported	**$ (23,306,404)**	
Total stock-based employee compensation determined under fair value based method for all awards	**(2,581,802)**	
Pro forma	**$ (25,888,206)**	

There were no options granted during the three months ended March 31, 2003. The weighted average fair value of the options at the date of grant for options granted during 2002 was $2.44. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2002
Expected option life (years)	10
Risk free interest rate	4.61%
Expected stock price volatility	45.47%
Dividend yield	

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue.

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 need to raise additional capital through future equity and other 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 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 Certain Important Factors below and those contained under the caption Certain Important Factors contained in BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002. 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 that is developing a pipeline of hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants or immune system boosters, drug delivery systems and the purification of the milk of transgenic animals.

Our hormone therapy products, most which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies 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-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), combinations of estradiol and testosterone and 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 therapy products, we paid Antares an upfront license fee of $1.0 million in June 2000. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, 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, which have been fully utilized, and a license for the combination estradiol plus testosterone gel product for all countries described above.

In August 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 therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed BioSante s estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin Labs Inc.), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, BioSante received a $950,000 milestone payment pursuant to the Solvay sub-license agreement. 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. As described further below, 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 17,361 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 therapy 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 were 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 $10.50 per share. In August 2001, BioSante exercised its right and declared the debenture converted in full. Accordingly, 47,619 shares of BioSante common stock were issued to Paladin in August 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 18,940 shares of its common stock to Paladin.

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

financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed.

In December 2002, we entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., under which we will collaborate with Teva USA on the development of a hormone therapy product for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA, future development and sales related milestone payments and royalties on sales of the commercialized product in exchange for rights to develop and market a hormone therapy product. Teva USA will also be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

Our strategy with respect to our hormone therapy product portfolio is to conduct human clinical trials of our proposed hormone therapy products, which are required to obtain approval from the FDA and to market the products in the United States.

We have initiated a Phase II clinical trial of our LibiGel for the treatment of female sexual dysfunction. The Phase II trial, being conducted in the United States, is a double-blind, placebo-controlled study that will enroll approximately 120 patients to determine the effect of LibiGel on a women s sexual desire and activity. We hope to initiate the one required pivotal Phase III clinical trial in 2003.

We have completed a Phase II/III clinical trial of Bio-E-Gel , a topical gel for the treatment of menopausal symptoms, including hot flushes. The trial, conducted in the United States and Canada, was a double-blind placebo-controlled study of 161 patients. The data from the Phase II/III Bio-E-Gel clinical trial have been analyzed. The objective of the Phase II/III clinical trial was to identify an effective dose of Bio-E-Gel to study in Phase III development. The Phase II/III trial demonstrated that Bio-E-Gel effectively reduces the severity and frequency of moderate-to-severe hot flushes in menopausal women, according to Food and Drug Administration (FDA) guidances for development of estrogen products.

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 and to purify the milk of transgenic animals, among other uses. We have identified three potential initial applications for our CAP technology:

the creation of improved versions of current vaccines and of new 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.

6. STOCK BASED COMPENSATION 23

The trial was completed in October 2000. The results showed that there was no apparent difference in side effect profile between CAP and placebo.

In October 2001, we licensed our 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.

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

Our goal is to develop and commercialize our portfolio of hormone therapy 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:

Continue the development of our hormone therapy products;

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

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

License or otherwise acquire other drugs that will add value to our current product portfolio and consider the sub-license of certain hormone therapy products.

All of our revenue to date has been derived from interest earned on invested funds and upfront and milestone 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 $3,810,690 for the year ended December 31, 2002, resulting in an accumulated deficit of $22,061,723. We incurred a

net loss of $1,244,681 for the three months ended March 31, 2003, and as of March 31, 2003, our accumulated deficit was $23,306,404. 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 making necessary regulatory filings and obtaining approvals; and

the timing and cost of obtaining third party reimbursement.

Critical Accounting Policies

Revenue Recognition

We recognize revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees. Revenue is recognized when cash is received and we have completed all of our obligations under our licensing arrangement which are required for the payment to be non-refundable. Revenue also includes reimbursement for certain research and development expenses which we recognize as both revenue and expense at the time the expense is incurred. Any ancillary payment related to the products being licensed, such as royalties to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized. Interest income on invested cash balances is recognized on the accrual basis as earned.

Research and Development

Research and development costs are charged to expenses as incurred. Research and development costs are capitalized only when FDA approval has occurred. To date, no research and development expenses have been capitalized.

Results of Operations

Three Months Ended March 31, 2003 Compared to Three Months Ended March 31, 2002

We earned licensing income of $65,494 during the three month period ended March 31, 2003 due to the reimbursement by a licensee of certain clinical development expenses. There was no licensing income during the three month period ended March 31, 2002. Interest income decreased from $23,259 during the three month period ended March 31, 2002 to $18,819 during the three month period ended March 31, 2003 as a result of lower interest rates coupled with lower invested cash balances during the three months ended March 31, 2003.

Research and development expenses increased from $644,394 during the three month period ended March 31, 2002 to $803,153 during the three month period ended March 31, 2003. This overall increase is the result of increased expenses during the three month period ended March 31, 2003 associated with the clinical development of certain of our hormone therapy products. We expect that our research and development expenses will continue to be significant in future periods as a result of human clinical trials of certain of our hormone therapy products. We 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) available resources; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

General and administrative expenses increased 23% from $459,129 during the three month period ended March 31, 2002 to $502,293 during the three month period ended March 31, 2003. This increase is the result of an increase in expenses for expenses related to our efforts to raise additional capital, strategic

alternative consulting and investor relations during the three month period ended March 31, 2003 compared to the same period last year.

We incurred a net loss of $1,244,681 for the three month period ended March 31, 2003, compared to a net loss of $1,102,926 for the three month period ended March 31, 2002. The increase in net loss is largely the result of increased expenses associated with the clinical development of our hormone therapy product portfolio during the three month period ended March 31, 2003 compared to the same period last year. We anticipate that our operating losses will continue 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 $17.3 million from equity financings, class A and class C stock conversions, warrant exercises and the issuance of a $500,000 convertible debenture. Since inception, we have received $4.6 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash and cash equivalents were $3,411,700 and $4,883,697 at March 31, 2003 and December 31, 2002, respectively. We used cash in operating activities of $1,471,997 for the three month period ended March 31, 2003 versus cash used in operating activities of $1,321,655 for the three month period ended March 31, 2002. The increase in cash used in operating activities largely reflects an increase in cash expenditures during the three month period ended March 31, 2003 related to the clinical development of our hormone therapy product portfolio. The $186,512 reduction of the Due to Licensor account during the three month period ended March 31, 2003, which represents expenses related to manufacturing and formulation services provided by Antares, partially offset the increase in cash used in operating activities. There was no net cash used in investing activities for the three month period ended March 31, 2003 versus $16,633 used in investing activities for the three month period ended March 31, 2002. The uses of cash in investing activities during the three month period ended March 31, 2002 were capital expenditures for the purchase of computer equipment. There was no net cash used in financing activities during the three months ended March 31, 2003 compared to net cash used in financing activities of $1,250 for the three months ended March 31, 2002. The net cash used in financing activities during the three month period ended March 31, 2002 reflects the transaction costs associated with a previous financing.

We did not have any material commitments for capital expenditures as of March 31, 2003. We have, however, several financial commitments, including product development milestone payments to the licensors of our hormone therapy products, payments under our license agreements with the University of California and Wake Forest University, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of March 31, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 97,635	$ 97,635	$	$	$
Commitments Under License Agreement with UCLA	6,800,000		150,000	350,000	6,300,000
Commitments Under License Agreement with Wake Forest	1,740,000		200,000	230,000	1,310,000

Total Contractual Cash Obligations	$ 8,637,635	$ 97,635	$ 350,000	$ 580,000	$ 7,610,000

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

enter into additional leases for new facilities and capital equipment;

enter into additional licenses and collaborative agreements; and

incur additional expenses associated with being a public company.

Our cash on hand as of March 31, 2003 was $3,411,700. We currently project that we have adequate cash resources to meet our planned expenditures through December 2003; however, we do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will need to raise substantial additional capital to fund our operations. 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 in the process of exploring alternatives for raising additional financing, which could include the issuance of shares of our common stock, securities convertible into shares of our common stock, shares of preferred stock, debentures, warrants and/or other equity or non-equity securities. If we are successful at raising additional capital, our expenses will increase as we accelerate product development. We currently have no commitments for additional funding, so our ability to meet our liquidity needs is uncertain. If we raise

additional funds through the issuance of equity securities, our stockholders may experience significant dilution. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. We are also in the process of exploring strategic alternatives, which could include selling some or all of our assets or entering into a business combination, but we have not entered into any definitive agreements for such a strategic alternative.

Certain Important 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, 2002:

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 $1,244,681 for the three month period ended March 31, 2003, and as of March 31, 2003, our accumulated deficit was $23,306,404.

All of our revenue to date has been derived from interest earned on invested funds and upfront and milestone 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 proposed products or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

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

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will need to raise substantial additional capital to fund our operations sometime in the future. 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.

Our cash on hand as of March 31, 2003 was $3,411,700. We believe this cash will be sufficient to fund our operations through December 2003. We have based this estimate 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. We are in the process of exploring alternatives for raising additional financing, which could include the issuance of shares of our common stock, securities convertible into shares of our common stock, shares of preferred stock, debentures, warrants and/or other equity or non-equity securities. Any additional equity financings may be dilutive to our existing stockholders and involve the issuance of securities that may have rights, preferences or privileges senior to those possessed by our current stockholders. A debt financing, if available, may involve restrictive covenants on our business which could limit our operational and financial flexibility, and the amount of debt incurred could make us more vulnerable to economic downturns and limit our ability to compete. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. 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.

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 some 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.

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.

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 or safety;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the trading price of our shares.

In July 2002, the National Institutes of Health released data from its Women s Health Initiative study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The National Institutes of Health announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up

period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed hormone therapy products differ from the products used in the Women s Health Initiative study and the primary products observed in the National Cancer Institute and United Kingdom studies. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

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 most of the technology underlying our proposed hormone therapy products and most of our CAP technology from third parties and may lose the rights to license them.

We license most of the technology underlying our proposed hormone therapy products from Antares Pharma, Inc. and most of our CAP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California s license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license the technology underlying our proposed hormone therapy products or CAP technology could harm our business and future operating results. For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone therapy products 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 CAP 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 develop 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. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States until the patents are issued and 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.

ITEM 4. CONTROLS AND PROCEDURES

Within the 90 days prior to the filing date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 13a-15 under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of our evaluation.

PART II - OTHER INFORMATION

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

99.1 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K

No reports on Form 8-K were filed during the quarter ended March 31, 2003.

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 13, 2003

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)

CERTIFICATIONS

I, Stephen M. Simes, certify that:

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

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

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

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

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

(b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

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

I, Phillip B. Donenberg certify that:

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

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

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

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

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

(b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 13, 2003

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