BIOSANTE PHARMACEUTICALS INC
Form 10QSB
May 17, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended March 31, 2004

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

For the Transition Period From _____ To _____.

Commission file number 1-31812

BIOSANTE PHARMACEUTICALS, INC.

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

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

111 Barclay Boulevard
Lincolnshire, Illinois 60069

(Address of principal executive offices)
(847) 478-0500

(Issuer s telephone number)

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

State 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 14, 2004
Common stock, $0.0001 par value	17,771,774

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

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB
MARCH 31, 2004

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In this Form 10-QSB, references to BioSante, the company, we, our or us, unless the context otherwise requires, to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

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PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Balance Sheets
March 31, 2004 and December 31, 2003 (Unaudited)

	March 31, 2004	December 31, 2003
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 8,262,453	$ 9,134,327
Prepaid expenses and other sundry assets	153,783	183,316
	8,416,236	9,317,643
PROPERTY AND EQUIPMENT, NET	254,865	247,827
	$ 8,671,101	$ 9,565,470
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 375,759	$ 238,743
Accrued compensation	275,183	514,130
Other accrued expenses	452,739	110,467
Due to Antares	42,865	17,865
	1,146,546	881,205
COMMITMENTS		
STOCKHOLDERS EQUITY		
Capital stock		
Issued and Outstanding		
404,102 (2003-404,102) Class C special stock	404	404
14,461,429 (2003-13,548,875) Common stock	37,990,459	36,704,938
	37,990,863	36,705,342

Deficit accumulated during the development stage	**(30,466,308)**	**(28,021,077)**
	7,524,555	**8,684,265**
	$ 8,671,101	**$ 9,565,470**

See accompanying notes to the financial statements.

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ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Statements of Operations
Three months ended March 31, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2004
(Unaudited)

	Three Months Ended March 31,		Cumulative period from August 29, 1996 (date of incorporation) to March 31, 2004
	2004	2003	
REVENUE			
Licensing income	$	$ 65,494	$ 4,582,943
Grant income	7,316		7,316
	7,316	65,494	4,590,259
EXPENSES			
Research and development	1,456,523	803,153	16,361,077
General and administration	1,000,011	502,293	13,201,622
Depreciation and amortization	23,283	23,548	682,703
Loss on disposal of capital assets			157,545
Costs of acquisition of Structured Biologicals Inc.			375,219
Purchased in-process research and development			5,377,000
	2,479,817	1,328,994	36,155,166
OTHER - Interest income	27,270	18,819	1,098,599
NET (LOSS)	$ (2,445,231)	$ (1,244,681)	$ (30,466,308)
	$ (0.17)	$ (0.14)	

BASIC AND DILUTED NET (LOSS) PER SHARE		
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**14,387,175**	**9,037,771**

See accompanying notes to the financial statements.

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ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Statements of Cash Flows
Three months ended March 31, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2004
(Unaudited)

	Three Months Ended March 31,		Cumulative period from August 29, 1996 (date of incorporation) to March 31, 2003
	2004	2003	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$(2,445,231)	$(1,244,681)	$(30,466,308)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	23,283	23,548	682,703
Amortization of deferred unearned compensation			42,290
Repurchase of licensing rights			125,000
Employee compensation - noncash	293,916		637,916
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	29,533	(4,085)	(150,815)
Due from licensee (Teva Pharmaceuticals USA, Inc.)		454,569	-
Accounts payable and accrued expenses	240,341	(514,836)	409,041
Due to licensor (Antares/Regents)	25,000	(186,512)	42,865
Due from SBI			(128,328)
Net cash used in operating activities	(1,833,158)	(1,471,997)	(23,271,091)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(30,321)		(1,061,003)

CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture			**500,000**
Proceeds from sales or conversion of shares	**991,605**		**32,094,547**
Net cash provided by financing activities	**991,605**		**32,594,547**
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**(871,874)**	**(1,471,997)**	**8,262,453**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**9,134,327**	**4,883,697**	**-**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 8,262,453**	**$ 3,411,700**	**$ 8,262,453**
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	**$ 630**	**$**	**$ 2,625**
SIGNIFICANT NON-CASH TRANSACTIONS			
Fair value of common stock warrants issued in connection with the sale of capital stock	**$**	**$**	**$ 539,872**

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
FORM 10-QSB
MARCH 31, 2004

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, 2004, the results of operations for the three months ended March 31, 2004 and 2003 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2004, and the cash flows for the three months ended March 31, 2004 and 2003 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2004, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three months ended March 31, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004.

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, 2003.

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 for the three months ended March 31, 2004 does not include 1,267,634 outstanding options, with exercise prices ranging from $2.10 to $6.70 per share, and 3,089,753 outstanding common stock warrants with exercise prices ranging from $2.15 to $8.75 per share, because of their antidilutive effect on net loss per share. The computation of diluted net loss per share for the three months ended March 31, 2003, does not include 995,634 outstanding options, with exercise prices ranging from $2.30 to $9.10 per share, and 1,643,750 outstanding common stock warrants with exercise prices ranging from $3.00 to $8.75 per share, because of their antidilutive effect on net loss per share.

3. LICENSE AGREEMENTS

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

In June 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

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license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain events.

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

In August 2001, the Company entered into a 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), 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 for certain milestones achieved.

In October 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 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.

4. COMMITMENTS

University of California License

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

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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 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 Amount	Due Date
2004	$ 50,000	February 28, 2005
2005	100,000	February 28, 2006
2006	150,000	February 28, 2007
2007	200,000	February 28, 2008
2008	400,000	February 28, 2009
2009	600,000	February 28, 2010
2010	800,000	February 28, 2011
2011	1,500,000	February 28, 2012
2012	1,500,000	February 28, 2013
2013	1,500,000	February 28, 2014
Total	$6,800,000	

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 three months ended March 31, 2004 and 2003, amounted to $12,624 and $0, respectively;

Meeting performance milestones relating to:

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

Testing proposed products and obtaining government approvals;

Conducting clinical trials; and

Introducing products incorporating the licensed technology into the market;

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

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares. The Company expects to fund the development of the products, has made and will continue to

make milestone payments and once regulatory approval to market is received, pay royalties on the sales of products.

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Wake Forest License

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

Future minimum payments due under this agreement are as follows:

Year	Minimum Amount Due
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

The 2004 minimum payment was due during first quarter 2004.

The Company has agreed to indemnify, hold harmless and defend Wake Forest University against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation as no events occurred that would require indemnification.

5. STOCK-BASED COMPENSATION

The Company follows the provisions of APB Opinion No. 25, Accounting For Stock-Based Compensation (APB No. 25) which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the measurement date (generally the date of grant) and the amount the employee must pay to acquire the stock. As a result of the Company s application of APB No. 25, 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 stock-based 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.

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	Three Months Ended March 31, 2004	Three Months Ended March 31, 2003
Net loss		
As reported	**$ (2,445,231)**	$(1,244,681)
Stock-based compensation included in net loss as reported	**293,916**	
Total stock-based employee compensation determined under fair value based method for all awards	**(391,900)**	(138,966)
Net loss, pro forma	**$ (2,543,215)**	$(1,383,647)
Basic and diluted net loss per share		
As reported	**$ (0.17)**	$ (0.14)
Pro forma	**$ (0.18)**	$ (0.15)
Cumulative net loss		
As reported	**$(30,466,308)**	
Stock-based compensation included in net loss as reported	**637,916**	
Total stock-based employee compensation determined under fair value based method for all awards	**(3,895,887)**	
Pro forma	**$(33,724,279)**	

There were no options granted during the three month period ended March 31, 2004.

During the second quarter of 2003, the Company issued 285,000 options to certain officers of the Company, which were to vest upon the achievement of certain milestones in connection with the Company s evaluation of strategic alternatives. In March 2004, the vesting period related to these options was amended whereby the options now vest over a three year period from the date of grant. As a result of the amended option terms, $1,054,500 will be recognized over the remaining vesting period. For the three months ended March 31, 2004, the Company recorded approximately $293,000 of compensation expense related to these options.

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

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue. No warrants were issued as compensation for services rendered during the three months ended March 31, 2004.

6. STOCKHOLDERS EQUITY

During the three months ended March 31, 2004, 457,612 common stock warrants were exercised for total proceeds of $983,865.

During the three months ended March 31, 2004, 863,751 common stock warrants were exercised on a cashless basis, resulting in the issuance of 452,975 shares of common stock and the withholding of

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410,776 shares of common stock to pay the exercise price of such warrants. These warrants were originally issued in connection with a private placement of common stock as a non-cash financing transaction. The 410,776 shares of common stock withheld to pay the exercise price of the warrants were cancelled by the Company, and, as a result, reduced the number of outstanding shares of common stock, on a fully diluted basis.

7. SUBSEQUENT EVENTS

In April and May 2004, 221,200 common stock warrants were exercised for total proceeds of $656,205.

In April and May 2004, 255,313 common stock warrants were exercised on a cashless basis, resulting in the issuance of 139,124 shares of common stock and the withholding of 116,189 shares of common stock to pay the exercise price of such warrants. In May 2004, 75,000 common stock warrants with a $3.00 per share exercise price expired by their terms without the holder thereof exercising the warrants. These warrants were originally issued in connection with a private placement of common stock as a non-cash financing transaction. The 116,189 shares of common stock withheld to pay the exercise price of the warrants were cancelled by the Company and, as a result, reduced the number of outstanding shares of common stock, on a fully diluted basis. The expiration of the 75,000 common stock warrants also reduced the number of outstanding shares of common stock, on a fully diluted basis.

On May 14, 2004, the Company completed a private placement of 2,949,000 shares of its common stock and warrants to purchase 442,350 shares of its common stock at a purchase price of $6.00 per unit to certain institutional and other accredited investors. The private placement resulted in net proceeds to the Company of approximately $16.5 million, after deduction of transaction expenses. The Company also issued warrants to purchase 92,646 shares of common stock to its placement agent in this private placement and its placement agent in its prior August 2003 private placement. The exercise price of the warrants is $7.00 per share.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

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 nanotechnology, or CAP, for improved vaccines, drug delivery systems and the purification of the milk of transgenic animals.

Our Hormone Therapy Products. Our hormone therapy products, most of 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), 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, shoulders, abdomen or thighs, delivering the 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.

The following is a list of our hormone therapy gel products in development:

Bio-T-Gel once daily transdermal bioidentical testosterone gel in clinical development for treatment of hypogonadism, or testosterone deficiency, in men.

Bio-E-Gel once daily transdermal bioidentical estrogen gel in clinical development for treatment of menopausal symptoms in women.

LibiGel once daily transdermal bioidentical testosterone gel in clinical development for treatment of female sexual dysfunction (FSD).

Bio-E/P-Gel once daily transdermal combination gel of bioidentical estrogen and a progestogen in clinical development for treatment of menopausal symptoms in women.

LibiGel-E/T once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone in development for treatment of FSD in menopausal women.

Human clinical trials have begun on four of our hormone therapy products, which are required to obtain FDA approval to market the products. Our proposed Bio-E-Gel product is currently in a pivotal Phase III clinical trial. Our proposed LibiGel product is in a Phase II clinical trial. Our proposed Bio-T-Gel product also is currently in a clinical trial.

Our CAP Technology and Proposed Products. Our CAP technology, a portion of 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. We have identified three potential initial applications for our CAP technology:

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- 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 and allow for delivery of the vaccine via non-injectable routes of administration;

- the creation of oral and inhaled 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.

The following is a list of our CAP products in development:

BioVant - proprietary CAP adjuvant and delivery technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others including biodefense vaccines such as anthrax and ricin.

CAP-Oral - a delivery system using CAP technology for oral administration of proteins and other therapies that currently must be injected.

BioAir - a delivery system using CAP technology for inhalable versions of proteins and other therapies that currently must be injected.

CAP biotechnology production - use of CAP technology in a new patented process for purifying the milk of transgenic animals in order to extract therapeutic proteins.

Primary Sources and Uses of Our Cash. All of our revenue to date has been derived primarily from upfront and milestone payments earned on licensing and sub-licensing transactions, and most recently, from government grant revenue. We have not commercially introduced any products and do not expect to do so in the near future. To date, we have used primarily equity financing and licensing income to fund our ongoing business operations, and we expect to continue this practice for the foreseeable future. On May 14, 2004, we completed a private placement financing raising $16.5 million in net proceeds.

Our business operations consist mostly of research and development activities. We spent approximately $300,000 to $400,000 per month on research and development activities in 2003 and expect our research and development expenses to increase in 2004 based on our planned clinical development schedule. Our research and development expenses increased $653,370, or 81%, to $1,456,523 for the three month period ended March 31, 2004 from $803,153 for the three month period ended March 31, 2003 primarily as a result of increased expenses associated with the

clinical development of certain of our hormone therapy products. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds for research and development activities.

Our general and administrative expenses may fluctuate from quarter-to-quarter depending upon the amount of legal, public and investor relations and other fees and expenses incurred. Our general and administrative expenses for the three month period ended March 31, 2004 increased 99 percent compared to general and administrative expenses for the three month period ended March 31, 2003 primarily as a

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result of increased expenses related to investor relations efforts, a reserve for increased legal and other fees and expenses in connection with a personnel related issue and the recognition of a non-cash compensation expense during the three month period ended March 31, 2004.

Since our inception, we have experienced significant operating losses. We incurred a net loss of $2,445,231 for the three month period ended March 31, 2004 compared to a net loss of $1,244,681 for the three month period ended March 31, 2003. As of March 31, 2004, our accumulated deficit was $30,466,308. 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.

Results of Operations

The following table sets forth, for the periods indicated, our results of operations.

	Three Months Ended March 31,		Cumulative Period from August 29, 1996 (date of incorporation) to March 31, 2004
	2004	2003	
Revenue	$ 7,316	$ 65,494	$ 4,590,259
Expenses	2,479,817	1,328,994	36,155,166
Research and development	1,456,523	803,153	16,361,077
General and administrative	1,000,011	502,293	13,201,622
Interest income	27,270	18,819	1,098,599
Net (loss)	$(2,445,231)	$(1,244,681)	$(30,466,308)

Three Months Ended March 31, 2004 Compared to Three Months Ended March 31, 2003

We earned no licensing income during the three month period ended March 31, 2004 compared to licensing income of $65,494 during the three month period ended March 31, 2003, which consisted of the reimbursement by a licensee of certain clinical development expenses. We earned $7,316 in grant revenue during the three month period ended March 31, 2004 due to the reimbursement by Dynport Vaccine Company LLC (Dynport) of certain

development expenses related to our subcontract agreement with Dynport for the development of anthrax vaccines for delivery via alternative routes of administration.

Research and development expenses for the three month period ended March 31, 2004 increased 81 percent compared to research and development expenses for the three month period ended March 31,

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2003 primarily as a result of increased expenses associated with the clinical development of certain of our hormone therapy products.

General and administrative expenses for the three month period ended March 31, 2004 increased 99 percent compared to general and administrative expenses for the three month period ended March 31, 2003 primarily as a result of increased expenses related to investor relations efforts, increased legal and other fees and expenses in connection with a personnel related issue and the recognition of a non-cash compensation expense during the three month period ended March 31, 2004. The non-cash compensation expense was a result of an amendment to certain options to purchase an aggregate of 285,000 shares of common stock at an exercise price of $2.10 per share that were granted in the second quarter 2003 and were amended to change the vesting periods from milestone-based vesting schedules to time-based vesting schedules. The amended stock options now vest in three equal annual installments over a three year period from the date of grant as opposed to upon a change in control of the company. As a result of the stock option amendments, we will recognize a $1,054,500 compensation expense over a three year period beginning in the first quarter 2004.

Interest income for the three month period ended March 31, 2004 increased 45 percent compared to interest income during the three month period ended March 31, 2003 primarily as a result of higher invested cash balances during the three month period ended March 31, 2004.

The overall increase in net loss for the three month period ended March 31, 2004 compared to the three month period ended March 31, 2003 was primarily the result of higher expenses as described above.

Liquidity and Capital Resources

Sources of Cash

All of our revenue to date has been derived primarily from upfront and milestone payments earned on licensing and sub-licensing transactions, and most recently, from government grant revenue. To date, we have used primarily equity financing and licensing income to fund our ongoing business operations, and we expect to continue this practice for the foreseeable future. Since our inception through March 31, 2004, we raised net proceeds of approximately $32.6 million from equity financings, class A and class C stock conversions, warrant exercises and the issuance of a $500,000 convertible debenture, and have received $4.6 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash and cash equivalents were $8,262,453 and $3,411,700 at March 31, 2004 and March 31, 2003, respectively. The increase in our cash balance was primarily due to the closing of a $10.3 million ($9.7 million net of transaction costs) private placement financing in August 2003, coupled with approximately $1 million received from warrant exercises in February and March 2004. We received an additional $656,205 in April and May 2004 as a result of warrant exercises and may receive additional funds in May 2004 from additional exercises of warrants, the amount of funds depending upon how many warrants are exercised for cash as opposed to on a cashless basis.

On May 14, 2004, we completed a private placement of 2,949,000 shares of our common stock and warrants to purchase 442,350 shares of our common stock at a purchase price of $6.00 per unit to certain institutional and other accredited investors. The private placement resulted in net proceeds to us of approximately $16.5 million, after deduction of transaction expenses. We also issued warrants to purchase 92,646 shares of common stock to our placement agent in this private placement and our placement agent in our prior August 2003 private placement. The exercise price of the warrants is $7.00 per share.

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Uses of Cash and Cash Flow

We used cash in operating activities of $1,833,158 for the three month period ended March 31, 2004 versus cash used in operating activities of $1,471,997 for the three month period ended March 31, 2003. The increase in cash used in operating activities largely reflects the increased net loss. The $25,000 increase in Due to Antares during the three month period ended March 31, 2004 represents expenses related to formulation services provided by Antares Pharma, Inc. We used $30,321 in net cash in investing activities for the three month period ended March 31, 2004 for the purchase of laboratory equipment and computers versus using no net cash in investing activities for the three month period ended March 31, 2003. Our financing activities provided us $991,605 in net cash for the three month period ended March 31, 2004 versus no cash provided or used by financing activities for the three month period ended March 31, 2003.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of March 31, 2004. We have, however, several potential 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, 2004:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 191,841	$191,841	$	$	$
Commitments Under License Agreement with UCLA	6,800,000	50,000	250,000	600,000	5,900,000
Commitments Under License Agreement with Wake Forest	1,730,000	45,000	145,000	230,000	1,310,000
Total Contractual Cash Obligations	$8,721,841	$286,841	$395,000	$830,000	$7,210,000

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 marketing partners to 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;

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

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

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

Off-Balance Sheet Arrangements

Except for operating leases entered in the ordinary course of business, we do not have any material off-balance sheet arrangements.

Outlook

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash resources and commitments, including the net proceeds from our recent private placement, we believe we should be able to maintain our current planned development activities and our corresponding level of expenditures through December 2006. Unexpected increases in general and administrative expenses and research and development expenses may cause us to need additional financing prior to such time.

Critical Accounting Policies

The discussion and analysis of the financial statements and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The SEC has defined a company s most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified certain of our accounting policies as critical

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accounting policies. Our critical accounting policies are described in Item 6. Management s Discussion and Analysis or Plan of Operation section of our annual report on Form 10-KSB. There have been no changes to the critical accounting policies described in our annual report on Form 10-KSB. Although we believe that our estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

Quantitative and Qualitative Disclosure About Market Risk

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

Forward-Looking Statements

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

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

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to BioSante. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described below in this section and also contained under the caption Item 1. Description of Business Forward-Looking Statements in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated

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in the forward-looking statements and from historical results, due to the risks and uncertainties described above, as well as others that we may consider immaterial or do not anticipate at this time. The foregoing risks and uncertainties are not exclusive and further information concerning the company and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-QSB and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

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 Item 1. Description of Business Forward-Looking Statements in our Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003:

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 $2,445,231 for the three month period ended March 31, 2004, and as of March 31, 2004, our accumulated deficit was $30,466,308.

All of our revenue to date has been derived from up front and milestone payments earned on sub-licensing transactions and grant revenue earned from a government grant. 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 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 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

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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, 2004 was $8,262,453. On May 14, 2004, we completed a private placement financing raising approximately $16.5 million in net proceeds. We believe our cash, including the proceeds from our recent private placement, will be sufficient to fund our operations through December 2006. 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. Unexpected increases in general and administrative expenses and research and development expenses may cause us to need 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 cannot be certain that any financing will be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

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

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

- the absence of an operating history;
- the lack of commercialized products;
- insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- limited experience in dealing with regulatory issues;
- 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.

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

Our proposed products are in the research and development stages and will require further research and development, preclinical 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 product or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management s credibility, the value of our company and our operating results and liquidity would be adversely affected.

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

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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 (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed hormone therapy products differ from the products used in the Women s Health Initiative study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment. 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 many of our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors 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 currently are developing or will develop.

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

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

We have licensed two of our proposed hormone therapy products to third parties and any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect our business.

We have licensed two of our proposed hormone therapy product to third parties that have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. Any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect our business if we are unable to license the proposed products to another party on substantially the same or better terms or continue the work ourselves.

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

We do not have a manufacturing facility that can be used for production of our products. In addition, at this time, we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions and in the course of our development program, we will likely be required to enter into additional arrangements with other companies or universities or clinical investigators for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If our licensees breach their obligations under our license agreements to perform these functions or we are otherwise 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.

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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 have 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 we cannot use our technology as claimed under our patent. Competitors may also contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

We are in the 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 those patents.

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

It also is unclear whether our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

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

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States until the patents are issued and also are maintained in secrecy for a period of time outside the United States. Accordingly, we can conduct only limited searches to determine whether our technology infringes any patents or patent applications of others. Any claims of patent infringement would be time-consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development delays;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

Item 3. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Controls

There was no change in our internal control over financial reporting that occurred during our quarter ended March 31, 2004 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II - OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

Sales of Unregistered Securities

During the three months ended March 31, 2004, we issued an aggregate of 375,296 shares of BioSante common stock as a result of the cashless exercise of warrants at an exercise price of $3.00 per share. The following directors and officers of BioSante exercised common stock warrants, resulting in the issuance of the following shares: Stephen M. Simes trust, 6,641 shares of common stock upon the cashless exercise of a warrant; Fred Holubow, 6,641 shares of common stock upon the cashless exercise of a warrant; Victor Morgenstern, 39,844 shares of common stock upon the cashless exercise of a warrant; Victor Morgenstern, through an affiliated trust and entity, an aggregate of 26,562 shares of common stock upon the cashless exercise of warrants; and Ross Mangano, through an affiliated entity, 184,322 shares of common stock upon the cashless exercise of a warrant.

During the three months ended March 31, 2004, we issued an aggregate of 77,679 shares of BioSante common stock as a result of the cashless exercise of warrants at an exercise price of $2.15 per share and an aggregate of 457,612 shares of BioSante common stock as a result of the cash exercise of warrants at an exercise price of $2.15 per share.

No underwriting commissions or discounts were paid with respect to the sales of the unregistered securities described above. In addition, all of the above sales were made in reliance on either Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. In all such transactions, certain inquiries were made by BioSante to establish that such sales qualified for such exemption from the registration requirements. In particular, BioSante confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) all offers of sales and sales were made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) each investor made representations that he or she was sophisticated in relation to this investment (and BioSante has no reason to believe that such representations were incorrect), (iii) each purchaser gave assurance of investment intent and the certificates for the shares bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

Small Business Issuer Purchase of Equity Securities

Except for holders of warrants who exercised their warrants on a cashless basis by using an aggregate of 473,450 shares underlying shares of common stock to pay the exercise price, we did not purchase any shares of our common stock or other securities during the three month period ended March 31, 2004 and our board of directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other securities on the open market or otherwise.

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ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

10.1 First Amendment to Lease, dated February 26, 2004, between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association.

31.1 Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14.

31.2 Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14.

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

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

(b) Reports on Form 8-K:

On March 9, 2004, BioSante furnished a current report on Form 8-K to announce its results of operations for the year ended December 31, 2003.

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SIGNATURES

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

May 17, 2004

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)

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