BIOSANTE PHARMACEUTICALS INC
Form 10QSB
November 14, 2003

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the Quarterly Period Ended September 30, 2003

Commission file number 1-31812

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 x NOo

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

Class	Outstanding as of November 14, 2003
Common stock, $0.0001 par value	13,547,905

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

BIOSANTE PHARMACEUTICALS, INC.

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SEPTEMBER 30, 2003

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

PART I - FINANCIAL INFORMATION

ITEM 1 - FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
September 30, 2003 and December 31, 2002 (Unaudited)

	September 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,396,015	$ 4,883,697
Due from Teva Pharmaceuticals USA, Inc.		520,063
Prepaid expenses and other sundry assets	235,059	144,155
	10,631,074	5,547,915
PROPERTY AND EQUIPMENT, NET	266,370	331,889
	$ 10,897,444	$ 5,879,804
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 271,694	$ 470,871
Accrued compensation	168,258	313,287
Other accrued expenses	236,426	236,758
Due to Antares	23,750	235,303
	700,128	1,256,219
COMMITMENTS		
STOCKHOLDERS EQUITY		
Capital stock		
Issued and Outstanding		
466,602 (2002 - 466,602) Class C special stock	467	467
13,485,405 (2002 - 8,571,169) Common stock	36,558,258	26,684,841
	36,558,725	26,685,308
Deficit accumulated during the development stage	(26,361,409)	(22,061,723)
	10,197,316	4,623,585
	$ 10,897,444	$ 5,879,804

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and nine months ended September 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
	2003	2002	2003	2002	
REVENUE					
Licensing income	$	$ 950,000	$ 65,494	$ 950,000	$ 4,582,943
Interest income	25,399	12,556	55,708	42,527	1,040,448
	25,399	962,556	121,202	992,527	5,623,391
EXPENSES					
Research and development	960,205	1,326,556	2,702,482	2,958,478	13,915,616
General and administration	481,073	413,804	1,648,284	1,364,784	11,522,805
Depreciation and amortization	23,026	23,197	70,122	68,556	636,615
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
	1,464,304	1,763,557	4,420,888	4,391,818	31,984,800
NET LOSS	$ (1,438,905)	$ (801,001)	$ (4,299,686)	$ (3,399,291)	$ (26,361,409)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.12)	$ (0.11)	$ (0.43)	$ (0.49)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	12,022,673	7,375,017	10,056,709	6,986,096	

See accompanying notes to the financial statements.

ITEM 1 - FINANCIAL STATEMENTS (CONTINUED)

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Nine months ended September 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
(Unaudited)

	Nine Months Ended Sept. 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003
	2003	2002	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (4,299,686)	$ (3,399,291)	$ (26,361,409)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	70,122	68,556	636,615
Amortization of deferred unearned compensation			42,290
Repurchase of licensing rights			125,000
Employee compensation paid in shares of common stock			151,000
Director compensation paid in shares of common stock	189,000		189,000
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	(90,904)	(79,992)	(232,091)
Due from licensee (Teva Pharmaceuticals USA, Inc.)	520,063		
Accounts payable and accrued expenses	(316,991)	153,478	(36,262)
Due to licensor (Antares/Regents)	(211,553)	(388,425)	23,750
Due from SBI			(128,328)
Net cash used in operating activities	(4,139,949)	(3,645,674)	(20,055,890)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	(4,603)	(34,841)	(1,026,420)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture			500,000
Proceeds from sale of capital stock	9,656,870	4,435,844	30,978,325
Net cash provided by financing activities	9,656,870	4,435,844	31,478,325
NET INCREASE IN CASH AND CASH EQUIVALENTS	5,512,318	755,329	10,396,015
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,883,697	4,502,387	

CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 10,396,015**	**$ 5,257,716**	**$ 10,396,015**
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	**$**	**$**	**$**
Interest paid	**$ 1,995**	**$**	**$ 1,995**
SIGNIFICANT NON-CASH TRANSACTIONS			
Fair value of common stock warrants issued in connection with the sale of capital stock	**$ 539,872**	**$**	**$ 539,872**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-QSB
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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 September 30, 2003, the results of operations for the three and nine months ended September 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003, and the cash flows for the nine months ended September 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2003, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and nine month periods ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

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.

New Financial Accounting Standards Board (FASB) Interpretation

In November 2002, the FASB Emerging Issues Task Force (EITF) issued FASB Interpretation (FIN) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (FIN45), which elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements of FIN 45 became effective for financial statements of interim and annual periods ending after December 15, 2002, while the initial recognition and measurement provisions of FIN 45 became effective for all for guarantees issued or modified after December 31, 2002. The Company does not believe that the adoption of FIN 45 will have a material impact on the Company s financial position, cash flow or results of operations.

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 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 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 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 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 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. 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 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
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 year ended December 31, 2002 and the nine months ended September 30, 2003 amounted to $12,240 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.

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 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

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 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.

	Nine Months Ended Sept. 30, 2003	**Nine Months Ended Sept. 30, 2002**
Net loss		
As reported	**$ (4,299,686)**	$ (3,399,291)
Stock based compensation included in net loss as reported	**187,500**	
Total stock-based employee compensation determined under fair value based method for all awards	**(581,108)**	(295,741)
Net loss, pro forma	**$ (4,693,294)**	$ (3,695,032)
Basic and diluted net loss per share		
As reported	**$ (0.43)**	$ (0.49)
Pro forma	**$ (0.47)**	$ (0.53)
Cumulative net loss		
As reported	**$ (26,361,409)**	
Stock based compensation included in net loss as reported	**265,500**	
Total stock-based employee compensation determined under fair value based method for all awards	**(3,477,163)**	
Pro forma	**$ (29,573,072)**	

	Three Months Ended Sept. 30, 2003	Three Months Ended Sept. 30, 2002
Net loss		
As reported	**$ (1,438,905)**	$ (801,001)
Stock based compensation included in net loss as reported	**7,500**	
Total stock-based employee compensation determined under fair value based method for all awards	**(106,171)**	(31,890)
Net loss, pro forma	**$ (1,537,576)**	$ (832,891)
Basic and diluted net loss per share		
As reported	**$ (0.12)**	$ (0.11)
Pro forma	**$ (0.13)**	$ (0.11)

There were 0 and 22,000 options granted during the three and nine month periods ended September 30, 2003, respectively. The 22,000 options granted during the nine month period ended September 30, 2003 had a weighted average fair value at the date of grant of $1.57. 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:

	2003
Expected option life (years)	10
Risk free interest rate	3.98%
Expected stock price volatility	64.17%
Dividend yield	

In addition, during the second quarter of 2003, BioSante issued 285,000 options to certain officers of BioSante which vest only upon the achievement of certain milestones in connection with BioSante s evaluation of strategic alternatives.

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 in 2002.

6. STOCKHOLDERS EQUITY

Each of BioSante s non-employee directors are paid a $10,000 annual retainer to be paid in shares of our common stock and $1,000 for each board or committee meeting attended in person and $500 for each board or committee meeting attended via telephone to be paid in shares of BioSante s common stock. In addition, a portion of each of BioSante s executive officers annual bonus is typically paid in shares of BioSante s common stock.

In June 2003, BioSante issued 119,613 shares of common stock to its officers and directors as partial payment of the officers 2002 annual bonus (approximately $78,000) and payment of fees to BioSante s directors for their significant involvement during 2002 and 2003 for director-related services rendered, including attendance at board and committee meetings (approximately $180,000). The 2002 officer bonuses of approximately $78,000 had been previously accrued at December 31, 2002. However,

as BioSante had historically not paid fees to directors, the $180,000 of fees paid to directors was expensed in the three month period ended June 30, 2003. The number of shares issued was determined by dividing the dollar amount of bonus or director fees owed to the officer or director, respectively, by the closing market price of BioSante s common stock on the date of issuance. The share price used in computing the number of shares to issue was approximately $2.16. Shares were issued in lieu of cash in order to conserve the cash funds of BioSante.

On August 6, 2003, BioSante closed a private placement, raising approximately $10.3 million, ($9.7 million net of estimated transaction costs) upon the issuance of units, which consisted of an aggregate of approximately 4.8 million shares of common stock and five-year warrants to purchase an aggregate of approximately 2.8 million shares of common stock (includes placement agent warrants issued in conjunction with the financing). The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $2.15. The exercise price of the warrants is $2.15 per share. The estimated fair value of the warrants issued to the placement agent represents a non cash financing activity.

In September 2003, BioSante issued 2,641 shares of common stock to its directors as payment of fees to BioSante s directors for their involvement during the third quarter ended September 30, 2003 for director-related services rendered, including attendance at board and committee meetings ($7,500). The number of shares issued was determined by dividing the dollar amount of director fees owed to the directors by the closing market price of BioSante s common stock on the date of issuance. The share price used in computing the number of shares issued was between $2.70 and $2.90. Shares were issued in lieu of cash in order to conserve the cash funds of BioSante.

In November 2003, 62,500 shares of common stock were issued pursuant to a conversion of class C special stock to common stock at a conversion price of $2.50 per share. Accordingly, BioSante raised $156,250 on the conversion.

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

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.

Forward-Looking Statements

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 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 existing cash and whether and how long these funds will be sufficient to fund our operations; and
- our need to raise additional capital through future equity and other financings.

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 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.

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), and 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 U.S. Food and Drug Administration 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 ongoing 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 have completed a Phase II/III clinical trial of Bio-E-Gel, a topical gel for the treatment of menopausal symptoms, including hot flashes. 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 flashes in menopausal women, according to FDA guidances for development of estrogen products.

In October 2003, we announced that a blinded interim analysis of an ongoing Phase II trial of LibiGel (topical testosterone gel) for the treatment of female sexual dysfunction (FSD) showed statistically significant results for the primary endpoints of the study. In the U.S.-based, double-blind, placebo-controlled study to determine the effect of LibiGel on women s sexual activity and desire, after three months of treatment there was a 130 percent increase from baseline ($p<0.01$) in the frequency of satisfying sexual events as measured by individual patient diaries. In addition, there was a 136 percent increase from baseline ($p<0.01$) in sexual desire as measured by the Brief Index of Sexual Functioning for Women (BISF-W). The interim analysis reports on the first 28 patients who have completed the study, without breaking the blind as to dose of LibiGel or placebo. The data indicate an effective LibiGel dose for the treatment of hypoactive sexual desire disorder (HSDD) in women, and that LibiGel was well tolerated during the course of the trial.

We have initiated the one required pivotal Phase III Bio-E-Gel clinical trial for the treatment of moderate-to-severe hot flashes and vaginal atrophy in menopausal women. The Phase III trial is being conducted in the United States and Canada and is a randomized, double-blind, placebo-controlled study of symptomatic menopausal women. This trial follows successful completion of a Phase II/III clinical study and two dose-ranging Phase II clinical trials, which demonstrated that Bio-E-Gel topical gel successfully delivers therapeutic doses of bioidentical estradiol and statistically significantly reduces the frequency and

severity of hot flashes. Current FDA requirements for approval of new estradiol products include one 12-week Phase III clinical trial. The clinical endpoints of the required Phase III trial include a significant reduction in the severity and frequency of hot flashes at week 4 and week 12 of treatment as compared to placebo. The Bio-E-Gel Phase III clinical trial will test two doses of Bio-E-Gel to maximize the safety profile by identifying the lowest effective dose.

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. 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.

In June 2003, we announced the signing of another CRADA with the U.S. Army s Medical Research Institute of Infectious Disease (USAMRIID) for the development of biodefense vaccines, including anthrax, staph and ricin. The USAMRIID has agreed to grant us an exclusive license to any U.S. patent application or issued patent as a result of the work under the CRADA.

In September 2003, we announced that we were awarded a $100,000 Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) to support our development of formulations for the oral delivery of insulin using our proprietary calcium phosphate particulate (CAP) technology. We did not recognize any revenue for this grant in our September 30, 2003 interim financial statements as the grant funds had not yet been received.

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:

- Actively manage 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 $4,299,686 for the nine months ended September 30, 2003, and as of September 30, 2003, our accumulated deficit was $26,361,409. 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.

New Financial Accounting Standards Board (FASB) Interpretation

In November 2002, the FASB Emerging Issues Task Force (EITF) issued FASB Interpretation (FIN) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (FIN45), which elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements of FIN 45 became effective for financial statements of interim and annual periods ending after December 15, 2002, while the initial recognition and measurement provisions of FIN 45 became effective for all for guarantees issued or modified after December 31, 2002. We do not believe that the adoption of FIN 45 will have a material impact on our financial position, cash flow or results of operations.

Results of Operations

Three Months Ended September 30, 2003 Compared to Three Months Ended September 30, 2002

We earned no licensing income during the three month period ended September 30, 2003 compared to $950,000 licensing income earned during the same three month period in 2002. As described earlier, we received the $950,000 milestone payment pursuant to our sublicense agreement with Solvay Pharmaceuticals. Interest income increased from $12,556 during the three month period ended September 30, 2002 to $25,399 during the three month period ended September 30, 2003 as a result of higher invested cash balances during the three months ended September 30, 2003.

Research and development expenses decreased from $1,326,556 during the three month period ended September 30, 2002 to $960,205 during the three month period ended September 30, 2003. This overall decrease is the result of decreased expenses 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 16% from $413,804 during the three month period ended September 30, 2002 to $481,073 during the three month period ended September 30, 2003. This increase is largely the result of filing fees and legal expenses related to our common stock being accepted for listing on the American Stock Exchange during the three month period ended September 30, 2003.

We incurred a net loss of $1,438,905 for the three month period ended September 30, 2003, compared to a net loss of $801,001 for the three month period ended September 30, 2002. The increase in net loss is largely the result of the aforementioned $950,000 Solvay milestone payment recognized during

the three month period ended September 30, 2002. We anticipate that our operating losses will continue for the foreseeable future.

Nine Months Ended September 30, 2003 Compared to Nine Months Ended September 30, 2002

We earned licensing income of $65,494 during the nine month period ended September 30, 2003 due to the reimbursement revenue from a licensee for certain clinical development expenses. We earned $950,000 licensing income during the nine month period ended September 30, 2002 due to the receipt of the aforementioned Solvay milestone payment. Interest income increased from $42,527 during the nine month period ended September 30, 2002 to $55,708 during the nine month period ended September 30, 2003 as a result of higher invested cash balances during the nine month period ended September 30, 2003.

Research and development expenses decreased from $2,958,478 during the nine month period ended September 30, 2002 to $2,702,482 during the nine month period ended September 30, 2003. This overall decrease is the result of decreased expenses associated with the clinical development of certain of our hormone therapy products.

General and administrative expenses increased 21% from $1,364,784 during the nine month period ended September 30, 2002 to $1,648,284 during the nine month period ended September 30, 2003. This increase is the combined result of filing fees and legal expenses related to our common stock being accepted for a listing on the American Stock Exchange and BioSante common stock paid to our directors as compensation during the nine month period ended September 30, 2003 compared to no similar expenses in the same period last year.

We incurred a net loss of $4,299,686 for the nine month period ended September 30, 2003, compared to a net loss of $3,399,291 for the nine month period ended September 30, 2002. The increase in net loss is largely the result of the receipt of the $950,000 Solvay milestone and resulting licensing income recognition in the nine month period ended September 30, 2002, which did not reoccur in 2003.

Liquidity and Capital Resources

As of September 30, 2003, 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 $31.0 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 $10,396,015 and $4,883,697 at September 30, 2003 and December 31, 2002, respectively. We used cash in operating activities of $4,139,949 for the nine month period ended September 30, 2003 versus cash used in operating activities of $3,645,674 for the nine month period ended September 30, 2002. The increase in cash used in operating activities largely reflects the increased net loss and associated decrease in accounts payable and accrued expenses, offset by payments received from a licensee related to reimbursement of clinical development costs of a product within our hormone therapy product portfolio. The $211,553 reduction in Due to Antares during the nine month period ended September 30, 2003 represents expenses related to a development milestone paid to, and manufacturing and formulation services provided by, Antares Pharma. There was $4,603 net cash used in investing activities for the nine month period ended September 30, 2003 versus $34,841 used in investing activities for the nine month period ended September 30, 2002 which was used for the purchase of computer equipment and filing cabinets. There was $9,656,870 net cash provided by financing activities as a result of our private placement which closed during the nine months ended September 30,

2003, compared to net cash provided by financing activities of $4,435,844 for the nine months ended September 30, 2002 as a result of a financing which closed in September 2002.

On August 4, 2003, BioSante closed a private placement, raising approximately $10.3 million, ($9.7 million net of estimated transaction costs) upon the issuance of units, which consisted of an aggregate of approximately 4.8 million shares of common stock and five-year warrants to purchase an aggregate of approximately 2.8 million shares of common stock (includes placement agent warrants issued in conjunction with the financing). The price of each unit, which consisted of one share of common stock plus a warrant to purchase one-half share of common stock was $2.15. The exercise price of the warrants is $2.15 per share.

We did not have any material commitments for capital expenditures as of September 30, 2003. 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 September 30, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 198,768	$ 170,028	$ 28,740	$	$
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	10,000	125,000	155,000	1,450,000
Total Contractual Cash Obligations	$ 8,738,768	$ 180,028	$ 303,740	$ 505,000	$ 7,750,000

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;
- 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.

Our cash on hand as of September 30, 2003 was $10,396,015. We believe our cash on hand will be sufficient to fund our operations through December 2004. We have based this estimate, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. We currently do not have sufficient resources to complete the commercialization of any of our proposed products. 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.

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 $4,299,686 for the nine month period ended September 30, 2003, and as of September 30, 2003, our accumulated deficit was $26,361,409.

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 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 September 30, 2003 was $10,396,015. We believe our cash on hand will be sufficient to fund our operations through December 2004. We have based this estimate, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. We currently do not have sufficient resources to complete the commercialization of any of our proposed products. 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 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 interest rate exposure.

ITEM 4. CONTROLS AND PROCEDURES

As of September 30, 2003, the end of the period covered by 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 was no change in our internal control over financial reporting that occurred during our quarter ended September 30, 2003 that has materially affected, or is reasonably likely to materially effect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 2 - CHANGES IN SECURITIES AND USE OF PROCEEDS

During the three months ended September 30, 2003, we issued to 37 accredited investors, including existing stockholders, some of our executive officers and several members of our board of directors, an aggregate of 4,791,982 shares of common stock and five-year warrants to purchase an aggregate of 2,767,366 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase one-half share of common stock was $2.15, the approximate price of BioSante s common stock less a slight discount at closing. The exercise price of the warrant is $2.15 per full share. Proceeds of the financing were approximately $9.7 million, net of transaction costs related to the private placement.

We filed with the Securities and Exchange Commission a registration statement on Form SB-2 on September 5, 2003 registering the offering and resale of 7,584,348 shares of our common stock, including the 4,791,982 outstanding shares of common stock and 2,767,366 shares of common stock issuable upon exercise of the warrants we issued in our private placement in August 2003 and 25,000 shares of common stock issuable upon exercise of the warrants we issued to a consultant in June 2000. This registration statement was declared effective by the SEC on September 22, 2003.

ITEM 6 - EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

31.1 Certification of CEO Pursuant to SEC Rule 13a-14.

31.2 Certification of CFO Pursuant to SEC Rule 13a-14.

32.1 Certification of CEO 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 CFO 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 August 6, 2003, BioSante filed a current report on Form 8-K to announce the completion of a private placement.

On August 19, 2003, BioSante filed a current report on Form 8-K/A to announce the amount of its stockholders equity as a result of the closing of its August 2003 private placement.

On September 25, 2003, BioSante filed a current report on Form 8-K to announce that on the evening of September 24, 2003, BioSante Pharmaceuticals, Inc. received a notice that its common stock was approved for listing on the American Stock Exchange and that it expected that its common stock will begin trading on the American Stock Exchange under the ticker symbol BPA at the opening of trading on October 1, 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.

November 14, 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)