

BIOSANTE PHARMACEUTICALS INC  
Form 10-Q  
May 12, 2006

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark one)

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

**For the quarterly period ended March 31, 2006**

**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 registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**58-2301143**  
(IRS Employer Identification Number)

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

**(847) 478-0500**  
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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  NO

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES  NO

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of May 12, 2006, 19,160,694 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

## BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q  
MARCH 31, 2006

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*In this report, 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®EBGel/P-Gel™, LibiGel, LibiGel-E/T™ and Bio-T-Gel™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.*

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**BIOSANTE PHARMACEUTICALS, INC.**

(a development stage company)

**Balance Sheets****March 31, 2006 and December 31, 2005 (Unaudited)**

	March 31, 2006	December 31, 2005
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 70,189	\$ 310,643
Short-term investments	6,984,609	8,790,888
Prepaid expenses and other sundry assets	227,965	245,465
	<b>7,282,763</b>	<b>9,346,996</b>
<b>PROPERTY AND EQUIPMENT, NET</b>		
	<b>188,629</b>	<b>215,566</b>
<b>OTHER ASSETS</b>		
Security deposits	11,992	11,992
	<b>\$ 7,483,384</b>	<b>\$ 9,574,554</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,380,026	\$ 1,139,566
Accrual for contingencies	890,000	750,000
Accrued compensation	223,579	492,980
Other accrued expenses	104,794	147,125
Deferred revenue	136,363	136,363
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,734,762</b>	<b>2,666,034</b>
<b>LONG TERM LIABILITIES</b>		
Leasehold retirement liability	21,500	21,500
Deferred revenue	34,091	68,182
<b>TOTAL LONG TERM LIABILITIES</b>	<b>55,591</b>	<b>89,682</b>
<b>TOTAL LIABILITIES</b>	<b>\$ 2,790,353</b>	<b>\$ 2,755,716</b>
<b>STOCKHOLDERS' EQUITY</b>		
<b>Capital stock</b>		
Issued and Outstanding		
2006 - 391,286; 2005 - 391,286		
Class C special stock	398	398
	<b>57,668,032</b>	<b>56,653,219</b>

2006 - 19,160,694; 2005 -  
19,007,800 Common stock

	<b>57,668,430</b>	<b>56,653,617</b>
Deferred unearned compensation	<b>(58,584)</b>	<b>(146,459)</b>
Deficit accumulated during the development stage	<b>(52,916,815)</b>	<b>(49,688,320)</b>
	<b>4,693,031</b>	<b>6,818,838</b>
	<b>\$ 7,483,384</b>	<b>\$ 9,574,554</b>

See accompanying notes to the  
financial statements.

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**BIOSANTE PHARMACEUTICALS, INC.****(a development stage company)****Statements of Operations****Three months ended March 31, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2006****(Unaudited)**

	<b>Three Months Ended</b>		<b>Cumulative</b>
	<b>March 31,</b>		<b>period from</b>
	<b>2006</b>	<b>2005</b>	<b>August 29,</b>
			<b>1996</b>
			<b>(date of</b>
			<b>incorporation)</b>
			<b>to</b>
			<b>March 31,</b>
			<b>2006</b>
<b>REVENUE</b>			
Licensing income	\$ 34,091	\$ -	\$ 4,672,489
Grant income	50,588	28,677	299,370
Other Income	-	-	32,000
	<b>84,679</b>	<b>28,677</b>	<b>5,003,859</b>
<b>EXPENSES</b>			
Research and development	1,018,877	2,151,679	31,494,950
General and administration	2,223,019	720,495	20,555,320
Provision for contingencies	140,000	-	890,000
Depreciation and amortization	27,457	24,943	889,758
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
	<b>3,409,353</b>	<b>2,897,117</b>	<b>59,739,792</b>
OTHER - Interest income	96,179	97,947	1,819,118
<b>NET LOSS</b>	<b>\$ (3,228,495)</b>	<b>\$ (2,770,493)</b>	<b>\$ (52,916,815)</b>
<b>BASIC AND DILUTED NET LOSS</b>			
	<b>\$ (0.17)</b>	<b>\$ (0.14)</b>	

PER SHARE (Note  
2)

WEIGHTED  
AVERAGE  
NUMBER

OF SHARES

OUTSTANDING

**19,426,895**

**19,374,775**

See accompanying  
notes to the financial  
statements.

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**BIOSANTE PHARMACEUTICALS, INC.**

(a development stage company)

**Statements of Cash Flows****Three months ended March 31, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2006****(Unaudited)**

	<b>Three Months ended March 31,</b>		<b>Cumulative period from August 29, 1996 (date of incorporation) to March 31, 2006</b>
	<b>2006</b>	<b>2005</b>	<b>2006</b>
<b>CASH FLOWS USED</b>			
<b>IN OPERATING</b>			
<b>ACTIVITIES</b>			
Net loss	\$ (3,228,495)	\$ (2,770,493)	\$ (52,916,815)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	27,457	24,943	889,758
Amortization of deferred unearned compensation	-	-	42,290
Repurchase of licensing rights	-	-	125,000
Employee & director compensation - noncash	859,013	87,875	2,127,054
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	17,500	104,859	(236,989)
Accounts payable and accrued liabilities	(71,272)	(96,106)	1,035,258
Accrual for contingencies	140,000	-	890,000
Deferred revenue	(34,091)	-	170,454
Due from SBI	-	-	(128,328)



<b>Net cash used in operating activities</b>	<b>(2,289,888)</b>	<b>(2,648,922)</b>	<b>(42,467,773)</b>
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**CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES**

Redemption of short term investments	<b>1,902,458</b>	<b>1,503,708</b>	<b>9,602,608</b>
Purchase of short term investments	<b>(96,179)</b>	<b>(97,947)</b>	<b>(16,587,217)</b>
Purchase of capital assets	<b>(520)</b>	<b>(27,852)</b>	<b>(1,201,822)</b>
<b>Net cash provided by (used in) investing activities</b>	<b>1,805,759</b>	<b>1,377,909</b>	<b>(8,186,431)</b>

**CASH FLOWS PROVIDED BY FINANCING ACTIVITIES**

Issuance of convertible debenture	-	-	<b>500,000</b>
Proceeds from sale or conversion of shares	<b>243,675</b>	<b>157,168</b>	<b>50,227,443</b>
Fractional share payout	-	-	<b>(3,050)</b>
<b>Net cash provided by financing activities</b>	<b>243,675</b>	<b>157,168</b>	<b>50,724,393</b>

**NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS**

	<b>(240,454)</b>	<b>(1,113,845)</b>	<b>70,189</b>
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**CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD**

	<b>310,643</b>	<b>1,170,025</b>	<b>-</b>
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**CASH AND CASH EQUIVALENTS AT END OF PERIOD**

	<b>\$ 70,189</b>	<b>\$ 56,180</b>	<b>\$ 70,189</b>
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**SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION**

Acquisition of SBI				
Purchased in-process research and development	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>5,377,000</b>
				<b>(831,437)</b>

Other net liabilities  
assumed

-	-	4,545,563
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Less: subordinate  
voting shares issued  
therefor

-	-	4,545,563
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\$ -	\$ -	\$ -
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Income tax paid	\$ -	\$ -	\$ -
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Interest paid	\$ -	\$ -	\$ 3,421
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**SIGNIFICANT  
NON-CASH  
TRANSACTIONS**

Fair value of common  
stock warrants issued in  
connection

with the sale of capital  
stock

\$ -	\$ -	\$ 1,053,423
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See accompanying  
notes to the financial  
statements.

**BIOSANTE PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**MARCH 31, 2006**  
**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, 2006, the results of operations for the three months ended March 31, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2006, and the cash flows for the three months ended March 31, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to March 31, 2006, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006.

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-K for the year ended December 31, 2005.

**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 special 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 is intended to reflect 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, the Company's outstanding options and warrants are antidilutive; accordingly, there is 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, 2006 does not include options to purchase an aggregate of 1,039,312 shares of common stock, with exercise prices ranging from \$2.10 to \$7.60 per share, and warrants to purchase an aggregate of 1,252,168 shares of common stock, with exercise prices of \$2.15 and \$7.00 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, 2005 does not include options to purchase an aggregate of 1,115,197 shares of common stock, with exercise prices ranging from \$2.10 to \$7.60 per share, and warrants to purchase an aggregate of 1,644,355 shares of common stock, with exercise prices ranging from \$2.15 to \$8.75 per share, because of their antidilutive effect on net loss per share.

**3. LICENSE AGREEMENTS**

In February 2006, the Company signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation ("MATC") for the use of the Company's calcium phosphate nanotechnology ("CaP") in the field of aesthetic medicine. Under the terms of the option and license agreement, MATC will use the Company's CaP technology to develop products for commercialization in the field of aesthetic medicine, specifically, the improvement and/or maintenance of the external appearance of the head, face, neck and body. Within the first 12 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to the Company of a license fee. The Company has the right to receive additional milestone payments upon approval by the U.S. Food and Drug Administration or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

#### 4. COMMITMENTS AND CONTINGENCIES

##### *Commitments*

The Company is a party to various licensing agreements, including agreements with the Regents of the University of California, Antares Pharma, Inc. and Wake Forest University. Certain of these agreements require the Company to indemnify the licensor for claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of the license agreement, including but not limited to, any product liability claim. The Company has no knowledge of events having occurred which would require indemnification by the Company, and has not recorded any liability in connection with these obligations as of March 31, 2006 or March 31, 2005.

##### *Contingencies*

On November 30, 2005, the Company sent written notice to Leah M. Lehman, Ph.D., the Company's former Vice President, Product Development, that the Company was exercising its contractual right not to renew her employment agreement. As a result of this notice, Dr. Lehman's employment agreement expired by its terms on December 31, 2005. On February 15, 2006, the Company received notice that on February 10, 2006, Dr. Lehman had filed a complaint against the Company, the Company's President and Chief Executive Officer, the Company's Chief Financial Officer and one of the Company's directors, with the Occupational Safety and Health Administration under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") seeking reinstatement of her employment with back pay, interest and attorney's fees and claiming, among other things, wrongful termination. The Company believes that Dr. Lehman's allegations of wrongful termination and violations of the Sarbanes-Oxley Act are wholly without merit and intends to vigorously defend its position. On February 17, 2006, the Company filed a complaint against Dr. Lehman in the Circuit Court of Cook County, Illinois alleging breach of fiduciary duty, breach of contract in regard to her employment agreement with the Company, tortious interference with prospective economic advantage and abuse of process. The Company is seeking an unspecified amount of damages, punitive damages, declaratory judgment regarding a breach by Dr. Lehman of her employment agreement and the amount of severance pay, if any, to be owed to Dr. Lehman, reimbursement of the Company's legal fees and costs and such other relief as the Court may deem proper. In March 2006, Dr. Lehman filed a charge with the Equal Employment Opportunity Commission (the "EEOC") claiming sex discrimination and retaliation in violation of Title VII of the Civil Rights Act of 1964. The Company also believes that Dr. Lehman's charges with the EEOC are wholly without merit and intends to vigorously defend its position.

The Company has accrued \$890,000 in connection with this matter, \$140,000 of which was accrued during the three month period ended March 31, 2006. Although the Company believes that at least a portion of any liability resulting from this matter may be covered under its employment practices liability insurance policy, there can be no assurance that it will be so covered or that the ultimate resolution of this matter will not exceed the amount of the Company's accrual or will not otherwise result in a material adverse effect on the Company's business, financial condition or results of operations.

## 5. STOCK-BASED COMPENSATION

The Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" ("SFAS No. 123(R)") under the modified prospective method on January 1, 2006. Under the "modified prospective" method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS No. 123(R) for all share-based payments granted after that date, and based on the requirements of Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation" ("SFAS No. 123") for all unvested awards granted prior to the effective date of SFAS No. 123(R). SFAS No. 123(R) eliminates the intrinsic value measurement method of accounting in APB Opinion 25 and generally requires measuring the cost of the employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of the grant. The standard requires grant date fair value to be estimated using either an option-pricing model which is consistent with the terms of the award or a market observed price, if such a price exists. Such costs must be recognized over the period during which an employee is required to provide service in exchange for the award. The standard also requires estimating the number of instruments that will ultimately be issued, rather than accounting for forfeitures as they occur.

As of March 31, 2006, the Company maintained one share-based compensation plan, the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan, which is described below. The compensation cost that has been incurred by the Company in connection with this plan was \$859,013 and \$87,875 for the periods ended March 31, 2006 and 2005, respectively. No income tax benefit has been recognized in the Company's statement of operations for share-based compensation arrangements due to the Company's net loss position.

The BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the "Plan") permits the grant of stock options and stock awards to its employees, directors and consultants. As of March 31, 2006, 2 million shares of the Company's common stock were available for issuance under the Plan, subject to adjustment as provided in the plan. In April 2006, the Company's Board of Directors, upon recommendation of the Compensation Committee and subject to approval by the Company's stockholders, approved an amendment to the Plan to increase the number of shares of the Company's common stock available for issuance under the Plan from 2 million to 3 million. The Company believes that equity-based incentives, such as stock options and stock awards, align the interest of its employees with those of its stockholders. Options are generally granted with an exercise price equal to the market price of the Company's common stock on the date of the grant; outstanding employee stock options generally vest ratably over a period of time and have 10-year contractual terms. In certain instances, stock options have been granted to directors which were exercisable immediately. In these instances, compensation cost was recognized on the grant date in an amount equal to the fair value of the related options. No stock awards have been granted under the Plan. The Compensation Committee of the Board of Directors of the Company may at its sole discretion modify or accelerate the vesting of any stock option or stock award.

The fair value of each option grant has been estimated on the date of grant using the Black-Scholes option-pricing-model using the assumptions in the table below:

	<b>Three Months Ended</b>	
	<b>March, 31</b>	
	<b>2006</b>	<b>2005</b>
Expected life in years	10	10
Annualized volatility	73.94%	73.91%
Discount rate - bond equivalent yield	4.10%	3.96%
	0.0%	0.0%

Expected  
dividend yield

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The Company uses a volatility rate calculation based on the closing price for its common stock at the end of each calendar month as reported by the American Stock Exchange. Since the Company has a limited history with option exercises, the expected life was set to the entire life of the option grant. The discount rate used is as published in *The Wall Street Journal* as of the grant date. The Company has not in the past issued a dividend, nor does it have any current plans to do so in the future; therefore, an expected dividend yield of 0 was used.

A summary of activity under the Plan during the three months ended March 31, 2006 is presented below:

<b>Options</b>	<b>Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding December 31, 2005	1,425,530	\$ 3.41
Granted	362,500	3.87
Exercised	152,894	2.51
Forfeited or expired	593,157	3.58
Outstanding March 31, 2006 <i>(weighted average contractual term)</i>	1,041,979	\$ 3.61  8.0 years
Exercisable at March 31, 2006 <i>(weighted average contractual term)</i>	720,312	\$ 3.63  7.6 years

The aggregate intrinsic values of the Company's outstanding and exercisable options as of March 31, 2006 were \$822,453 and \$557,524, respectively.

A summary of the Plan's non-vested options at December 31, 2005 and activity under the Plan during the three months ended March 31, 2006 is presented below:

<b>Options</b>	<b>Shares</b>	<b>Weighted Average Grant Date Fair-Value</b>
Outstanding December 31, 2005	398,000	\$ 3.61
Granted	362,500	3.11
Vested	263,333	3.15
Forfeited	179,056	3.49
Non-Vested at March 31, 2006	318,111	\$ 3.58

As of March 31, 2006, there was \$691,627 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. The cost is expected to be recognized over a weighted-average

period of 2.36 years.

Cash received from option exercises under the Plan for the three months ended March 31, 2006 was \$243,675. The intrinsic value of options exercised during the three months ended March 31, 2006 was \$218,613. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position.

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<b>March 31, 2006</b>	<b>Three Months Ended March 31, 2006</b>	<b>Three Months Ended March 31, 2005</b>
Net loss		
As reported	<b>\$ (3,228,495)</b>	\$ (2,770,493)
Stock-based compensation included in net loss as reported	<b>859,013</b>	87,875
Total stock-based employee compensation determined under fair value based method for all awards	<b>(859,013)</b>	(402,568)
Net loss, pro forma	<b>\$ (3,228,495)</b>	\$ (3,085,186)
Basic and diluted net loss per share		
As reported	<b>\$ (0.17)</b>	\$ (0.14)
Pro forma	<b>\$ (0.17)</b>	\$ (0.16)

## 6. STOCKHOLDERS' EQUITY

During the three months ended March 31, 2006, options to purchase an aggregate of 91,849 shares of common stock were exercised for total cash proceeds of \$243,675. In addition, options to purchase an aggregate of 61,045 shares of common were exercised on a cashless basis, for which 91,768 shares were withheld and subsequently cancelled by the Company in payment for the exercised options, thus reducing the number of shares outstanding on a fully diluted basis.

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

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the caption "Forward-Looking Statements" below. The following discussion of the results of operations and financial condition of BioSante should be read in conjunction with our 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 primarily vaccine adjuvants or immune system boosters and drug delivery systems.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so until early 2007 at the earliest depending upon the timing of the decision by the U.S. Food and Drug Administration, or FDA, on our New Drug Application, or NDA, for our Bio-E-Gel product, which we submitted in February 2006, and the potential approval of such application.

To date, we have used primarily equity financing and licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. For the three months ended March 31, 2006, we received approximately \$244,000 from option exercises. Our cash, cash equivalents and short-term investments were \$7,054,798 as of March 31, 2006. We currently do not have sufficient resources on a long-term basis to complete the commercialization of any of our proposed products. Based on our current cash resources and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be made that we will not need additional cash prior to such time.

Our business operations to date have consisted mostly of research and development activities, and we expect this to continue for the immediate future. If and when our Bio-E-Gel or other proposed products receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the product ourselves.

We spent an average of approximately \$300,000 to \$350,000 per month on research and development activities during the three months ended March 31, 2006. Our research and development expenses decreased \$1,132,802 or 53 percent, to \$1,018,877 for the three months ended March 31, 2006 from \$2,151,679 for the same period ended March 31, 2005, primarily as a result of the completion of the Phase III clinical trial of our Bio-E-Gel product in March 2005, partially offset by the costs associated with the preparation of the Bio-E-Gel NDA. We expect our research and development expenses to be significantly lower in 2006 until the commencement of our LibiGel Phase III trial, which we expect to commence sometime during 2006. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) resources available; (2) our development schedule, including the timing of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our proposed products; and (5) 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 increased \$1,502,524 or 209%, to \$2,223,019 for the three months ended March 31, 2006 from \$720,495 for the same period ended March 31, 2005, primarily as a result of increased legal expenses incurred due to pending litigation of a personnel-related matter and recognition of \$859,013 in non-cash compensation expense during the three months ended March 31, 2006 compared to \$87,875 for the three months ended March 31, 2005 as a result of our adoption of SFAS No. 123(R) "Share-Based Payment" ("SFAS 123"). \$746,616 of the expenses recorded in the three months ended March 31, 2006 related to a March 2006 issuance of options with immediate vesting to the non-employee members of the Company's Board of Directors which were fully expensed on the grant date due to the terms of those awards. Our general and administrative expenses may fluctuate from year-to-year depending upon the amount of legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

Since our inception, we have experienced significant operating losses. We incurred a net loss of \$3,228,495 for the three months ended March 31, 2006, resulting in an accumulated deficit of \$52,916,815. 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 or sublicensing of our products;
- the timing and cost of making necessary regulatory filings and obtaining approvals;
  - the timing and cost of obtaining third party reimbursement;
  - the cost of sales and marketing activities; and
- the costs of pending and any future litigation of which we may be subject.

**Hormone Therapy Products.** Our hormone therapy products address a variety of hormone therapies for symptoms that affect both men and women. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen. Our hormone therapy products include Bio-E-Gel, LibiGel, Bio-E/P-Gel, Bio-E/T-Gel and Bio-T-Gel. We have conducted human clinical trials on several of our hormone therapy products, which are required to obtain FDA approval to market the products. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted an NDA with the FDA in February 2006. We hope to commercially launch our Bio-E-Gel product after obtaining FDA approval, which we hope to receive in late 2006 or early 2007. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials which we hope to begin during 2006. We have not received FDA or any other government approval for any of our products and thus have not commercialized any of them in the United States or elsewhere.

Under the terms of our license agreement with Antares Pharma, Inc., we acquired exclusive marketing rights, with the right to grant sublicenses, to the single active ingredient products containing testosterone and estradiol for all therapeutic indications in the U.S. and several foreign countries. We acquired exclusive marketing rights, with the right to grant sublicenses, for the combination estradiol and progestogen product in the U.S. and Canada. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, pay royalties to Antares on sales of the products if and when the products are brought to market.

In August 2001, we entered into a sublicense 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 sublicenses our 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. Solvay has been responsible for all costs of development to date.

We have sublicensed the marketing rights to our portfolio of hormone therapy products (other than the estrogen/progestogen combination product) in Canada to Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made.

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 obtained an option to license the patents for triple hormone contraception. The financial terms of the license include an upfront payment by us in exchange for exclusive rights to the license, and regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed. In July 2005, we exercised the option for an exclusive license for the three U.S. patents for triple hormone contraception. The financial terms of this license include an upfront payment, regulatory milestone payments, 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., pursuant to which Teva USA agreed to develop our proposed Bio-T-Gel 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 and royalties on sales of the commercialized product upon approval in exchange for rights to develop and market Bio-T-Gel. Teva USA is also responsible under the terms of this agreement for continued development, regulatory filings and all manufacturing and marketing associated with the product. Teva USA has discontinued development of Bio-T-Gel and indicated to us a desire to formally terminate this agreement. Accordingly, we are in the process of exploring various alternatives with respect to our Bio-T-Gel product, including licensing the product to another third party or continuing the development of the product ourselves. We believe the decision by Teva to discontinue the development of Bio-T-Gel is based on strategic decisions by Teva.

Bio-E-Gel and LibiGel are both non-partnered products; and therefore, we can control better the timing and future development and commercialization of these products, subject to customary and inevitable uncertainties associated with the product development process, regulatory approvals and market acceptance of such products. Those products we have licensed to others, such as Bio-E/P-Gel and Bio-T-Gel, are reliant on our partners for timely development, obtaining required regulatory approvals, commercialization and an ongoing commitment to the products, subject to regulatory and market conditions. From time to time, based on various circumstances including market analysis or a change in the strategic plan of the partner, a partner may elect to restructure its arrangement which may result in entering into a revised agreement or a mutual termination. Any restructuring or termination of these agreements by such partners as Solvay Pharmaceuticals, B.V. or Teva Pharmaceuticals USA, Inc. could adversely affect the development and marketing of our licensed products if we are unable to license the proposed products to another qualified partner or continue the development and future commercialization of the proposed products ourselves. Unfortunately, the market for progestogen containing hormone therapy products has declined dramatically in the last several years and the market for testosterone in men may change in the next couple of years since a generic testosterone gel already has been approved. We will continue to monitor these developments carefully.

**CaP Technology and Proposed Products.** Our CaP technology, several of whose issued patents 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. Our strategy with respect to CaP is to continue development of our nanoparticle technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. In addition to continuing our own product development in the potential commercial applications of our CaP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CaP technology. We believe these collaborations may enable us to accelerate the development of potential improved vaccines and vaccines that can be delivered other than by injection as well as delivery by non-injected routes products that now must be injected.

In June 2003, we announced the signing of a CRADA with the U.S. Army’s Medical Research Institute of Infectious Disease (USAMRIID) for the development of non-injected 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. The USAMRIID will cover all costs associated with the CRADA.

In January 2004, we announced the signing of a subcontract with DynPort Vaccine Company LLC for the development of anthrax vaccines for delivery via alternative routes of administration, including nasal, oral and needle-free transcutaneous routes. Under the subcontract, we provide BioVant and DynPort provides recombinant antigens to be used in potential vaccines against anthrax. The objective is to assess the immunogenic potential of BioVant when used in anthrax vaccines versus the immunogenic response of anthrax vaccines that use alum as the vaccine adjuvant. The subcontract is in support of the U.S. Department of Defense Joint Vaccine Acquisition Program. The subcontract is valued at approximately up to \$658,000. We have successfully completed the first year of this contract which should conclude in the second half of 2006. Revenue related to this contract of \$30,345 was recorded in the three months ended March 31, 2006.

In September 2005, we signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products. The partner company will fund its development of potential products for the treatment of conditions including rhinitis, asthma, conjunctivitis, dermatitis, and allergic gastrointestinal diseases. Under the terms of the agreement, we received a nonrefundable \$250,000 upfront payment. We are recognizing revenue from this agreement on a pro rata basis over the term of the agreement. The remainder of the upfront payment is recorded as deferred revenue. If the option is exercised and the parties enter into an exclusive license agreement, we will receive a one-time license fee, annual maintenance payments, milestone payments upon the achievement of regulatory milestones and royalties on commercial sales of any allergy product that is developed using CaP. Revenue related to this contract of \$34,091 was recorded in the three months ended March 31, 2006.

In December 2005, we were awarded a subcontract by the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration. The subcontract was awarded to us as part of the University’s five year \$10 million grant entitled “GMP Recombinant FIX for IV and Oral Hemophilia B Therapy” from the National Institutes of Health. Our subcontract is for the first year of the grant, and if warranted, we can apply to renew the subcontract in subsequent years. The first year of the subcontract is valued at approximately \$250,000. We believe this subcontract leverages our expertise in alternative routes of drug administration, specifically buccal and pulmonary administration using our proprietary CaP BioOral and BioAir technologies. Revenue related to this subcontract of \$20,243 was recorded in the three months ended March 31, 2006.

In February 2006, we signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation, or MATC, for the use of our CaP technology in the field of aesthetic medicine. Under the terms of the option and license agreement, MATC will use our CaP technology to develop products for commercialization in the field of aesthetic medicine, specifically, the improvement and/or maintenance of the external appearance of the head, face, neck and body. Within the first 12 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

## Results of Operations

### *Three Months Ended March 31, 2006 Compared to Three Months Ended March 31, 2005*

The following table sets forth our results of operations for the three months ended March 31, 2006 and 2005.

	Three Months Ended March 31,				%
	2006	2005	\$	Change	Change
Revenue	\$ 84,679	\$ 28,677	\$	56,002	195.3%
Expenses					
Research and development	1,018,877	2,151,679		(1,132,802)	(52.6)%
General and administrative	2,223,019	720,495		1,502,524	208.5%
Interest income	96,179	97,947		1,768	(1.8)%
Net loss	\$ (3,228,495)	\$ (2,770,493)	\$	458,002	16.5%

We earned \$34,091 in licensing income during the three months ended March 31, 2006 due to the CaP option and material transfer agreement we entered into in September 2005 and no licensing income during the same period in 2005. We earned \$50,588 and \$28,677 in grant revenue during the three months ended March 31, 2006 and 2005, respectively. This increase is due to a subcontract we entered into with the University of Nebraska in December 2005, for the development of alternative routes of delivery of Factor IX formulations for Hemophilia B therapy.

Research and development expenses for the three months ended March 31, 2006 decreased 53 percent compared to research and development expenses for the three months ended March 31, 2005 primarily as a result of completion of clinical development of certain of our hormone therapy products, including the Phase III clinical trial of our Bio-E-Gel product, which was completed at the end of March 2005, partially offset by the expenses related to the New Drug Application for Bio-E-Gel, which was submitted to the FDA in February 2006. We expect our research and development expenses to remain at approximately the same level as our first quarter 2006 until we commence our LibiGel Phase III trials, which we plan to commence in 2006.

General and administrative expenses for the three months ended March 31, 2006 increased 209 percent compared to general and administrative expenses for the three months ended March 31, 2005, primarily as result of additional legal costs incurred due to pending litigation of a personnel-related matter combined with the recognition of \$859,013 in non-cash stock-based compensation expense during the three months ended March 31, 2006 compared to \$87,875 for the three months ended March 31, 2005 as a result of our adoption of SFAS No. 123(R) "Share-Based Payment" ("SFAS 123"). Of the expenses recorded in the three months ended March 31, 2006, \$746,616 related to a March 2006 grant of options with immediate vesting to the non-employee members of the Company's Board of Directors, which were fully expensed on the grant date due to the terms of those awards. The Company's other stock option grants have remaining service lives of one to ten years and will be amortized over that period. Certain of the Company's stock option grants also have milestone provisions, which will result in recognition of expense when such milestones are probable of being reached.

Interest income for the three months ended March 31, 2006 decreased 2 percent compared to interest income during the three months ended March 31, 2005, primarily as a result of lower invested cash balances, offset by higher interest rates on invested cash balances in first quarter 2006.

The overall increase in net loss for the three months ended March 31, 2006 compared to the three months ended March 31, 2005 was primarily the impact of adopting SFAS 123(R) and increases in general and administrative expenses, partially offset by reductions in research and development expense and an increase in revenue, as described above.

## **Liquidity and Capital Resources**

### ***Working Capital***

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and most recently, from a subcontract. To date, we have used primarily equity financing and received licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. Since inception, we have raised net proceeds of approximately \$50.7 million from equity financings, class A and class C stock conversions, warrant and option exercises and the issuance of a \$500,000 convertible debenture, and have received \$4.7 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash, cash equivalents and short-term investments available to fund current operations were \$7,054,798 and \$9,101,531 at March 31, 2006 and December 31, 2005, respectively. We expect our cash balance to decrease as we continue to use cash to fund our operations. We do not have any debt for borrowed money.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash balance and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be given that we will not need additional cash prior to such time. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;

- the cost, timing and outcome of regulatory reviews;
  - the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses, including legal expenses incurred in connection with pending and any future litigation of which we may be subject, and if we receive FDA approval of any of our proposed products, the amount of resources we devote to sales and marketing capabilities;
  - our ability to sublicense our products;
  - the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

If we raise additional funds through the issuance of equity securities, our stockholders may experience dilution, which could be significant. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. If financing is not available when required or is not available on acceptable terms, we may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the development of our proposed products, commercial introduction of our products or restrict us from acquiring new products that we believe may be beneficial to our business.

#### ***Uses of Cash and Cash Flow***

We used cash in operating activities of \$2,289,888 for the three months ended March 31, 2006 versus cash used in operating activities of \$2,648,922 for the three months ended March 31, 2005. The decrease in cash used in operating activities primarily reflects the increase in non-cash stock-based compensation expense during the three months ended March 31, 2006 as a result of our adoption of SFAS No. 123(R) "Share-Based Payment", partially offset by an increase in our net loss over the same three month period. We received \$1,806,279 and \$1,405,761 from the net sale of auction rate securities for the three months ended March 31, 2006 and 2005, respectively. We used \$520 for the purchase of computer equipment during the three months ended March 31, 2006 and \$27,852 for the purchase of computer, lab and office equipment during the three months ended March 31, 2005. Net cash provided by financing activities was \$243,675 for the three months ended March 31, 2006 versus \$157,168 for the three months ended March 31, 2005, which during both periods consisted of cash received due to option exercises, and in the case of the first quarter 2005, due to warrant exercises.

#### ***Commitments and Contractual Obligations***

We did not have any material commitments for capital expenditures as of March 31, 2006. We have, however, several potential financial commitments, including product development milestone payments to the licensor 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. We refer you to the table summarizing the timing of these future contractual obligations and commitments contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. There has been no material change in this information.



We expect to continue to spend capital on:

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- general administrative expenses, involving investor relations, legal and accounting fees and expenses;
- establishment of our own marketing capabilities or a search for third party sales and marketing partners to sell and market our products for us; and
  - the licensure or acquisition of new products or sublicensing of our 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;
  - new collaborative, licensing and other commercial relationships that we may establish; and
  - costs incurred in connection with pending and any future litigation of which we may be subject.

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 based on annual usage and subject to cancellation upon our request, 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.

Under the terms of the license agreements with the University of California and Wake Forest University, we have the right to terminate the license agreements for any reason, with our only obligation being the payment of monies owed to the date of termination.

### **Off-Balance Sheet Arrangements**

Except for operating leases entered in the ordinary course of business and customary indemnification obligations under our license, financing and other agreements, we do not have any off-balance sheet arrangements.

### **Critical Accounting Policies**

The discussion and analysis of our 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 Securities and Exchange Commission 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 requires 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 accounting policies. Our critical accounting policies are described in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2005. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, other than our adoption of SFAS No. 123(R), as described herein. 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.

### **Forward-Looking Statements**

This quarterly report on Form 10-Q 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, as amended, and are subject to the safe harbor created by those sections. 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. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "could," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "approximate," "contemplate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained in the notes to our financial statements and elsewhere in this report, including under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our forward-looking statements generally relate to:

- the timing of the commencement and completion of our clinical trials and other regulatory status of our proposed products;

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

Forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors that affect all businesses operating in a global market as well as matters specific to us. These uncertainties and factors are difficult to predict and many of them are beyond our control. The following are some of the uncertainties and factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements:

- Failure to obtain and maintain required regulatory approvals for our proposed products in a timely and cost-effective manner or at all;
  - FDA requirements regarding size and duration of clinical trials required to obtain and maintain regulatory approvals for our proposed products;
    - Failure of our proposed products to perform as expected in clinical trials;
- Slow patient enrollment in our clinical trials, untimely completion of clinical site protocol approval and obtaining informed consent form subjects, longer treatment time required to demonstrate efficacy or safety of our proposed products, adverse medical events or side effects in patients treated with our proposed products, lack of effectiveness of our proposed product and other risks associated with clinical trials;
- Failure of our proposed products if commercially introduced to obtain market acceptance and generate any revenues;
- Uncertainties associated with the impact of published studies and research regarding the adverse health effects of certain forms of hormone therapy;
- Highly competitive nature of the markets in which we intend to sell our products and the introduction of competing products;
  - Failure to maintain our rights to license our licensed technology;
    - Exposure to assertions of intellectual property claims and failure to protect our intellectual property;
- Our lack of experience and dependence upon others for clinical testing and manufacturing and sales and marketing functions;
  - Failure to obtain additional capital when needed or on acceptable terms;
    - Failure to comply with applicable laws and regulations;

- Failure to retain senior management and other key personnel or replace lost senior management or key personnel;
  - Effects of litigation, including threatened or pending litigation;
    - Adverse changes in applicable laws or regulations;
    - Changes in generally accepted accounting principles; or
- Conditions and changes in pharmaceutical industry or in general economic and business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2005 under the heading "Part I - Item 1A. Risk Factors" on pages 22 through 34 of such report.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. 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 in the forward-looking statements and from historical results, due to the uncertainties and factors described above, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown uncertainties and factors, including those described above. The risks and uncertainties described above are not exclusive and further information concerning us 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, amend or clarify 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 annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

### **ITEM 3. 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.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to reasonably 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. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated can provide only reasonable assurance of achieving the desired control objectives and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. 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-Q. 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 to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that material information relating to our company and our consolidated subsidiaries is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

### **Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during our quarter ended March 31, 2006 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

A description of our legal proceedings in note 5 of our financial statements included within this report is incorporated herein by reference.

**ITEM 1A. RISK FACTORS**

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. The significant factors known to us that could materially adversely affect our business, financial condition or operating results are described in our Annual Report on Form 10-K for the year ended December 31, 2005 under the heading "Part I - Item 1A. Risk Factors." There has been no material change in those risk factors.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Recent Sales of Unregistered Equity Securities**

During the three months ended March 31, 2006, we did not issue any equity securities that were not registered under the Securities Act of 1933, as amended.

**Issuer Purchases of Equity Securities**

Other than the withholding of 91,768 shares of our common stock in connection with the cashless net exercise of stock options, we did not purchase any shares of our common stock or other equity securities during the three months ended March 31, 2006, and our board of directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

The following exhibits are being filed or furnished with this quarterly report on Form 10-Q:

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10.1 Third Amendment to Lease dated as of January 27, 2006, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago

31.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)

31.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

May 12, 2006

**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, Treasurer and Secretary

(principal financial and accounting officer)



**BIOSANTE PHARMACEUTICALS, INC.  
 QUARTERLY REPORT ON FORM 10-Q  
 EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
10.1	Third Amendment to Lease dated as of January 27, 2006, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K dated January 27, 2006 (SEC File No. 001-31812)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
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	Furnished herewith
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	Furnished herewith