

BIOSANTE PHARMACEUTICALS INC  
Form 10-Q  
May 01, 2007

**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, 2007**

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

**Commission File Number 001-31812**

**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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer:  Accelerated filer:  Non-accelerated filer:

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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 April 30, 2007, 23,084,663 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

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MARCH 31, 2007****TABLE OF CONTENTS**

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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<sup>®</sup>, Elestrin<sup>™</sup>, LibiGel<sup>®</sup>, Bio-E-Gel<sup>®</sup>, Bio-E/P-Gel<sup>™</sup>, LibiGel-E/T<sup>™</sup>, Bio-T-Gel<sup>™</sup>, The Pill-plus<sup>™</sup>, BioVant<sup>™</sup>, NanoVant<sup>™</sup>, CAP-Oral<sup>™</sup> and <sup>™</sup>. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.*

**BIOSANTE PHARMACEUTICALS, INC.****Balance Sheets****March 31, 2007 and December 31, 2006 (Unaudited)**

	March 31, 2007	December 31, 2006
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 11,290,742	\$ 7,653,852
Short-term investments	3,856,965	3,795,977
Accounts receivable	3,514,711	10,510,529
Prepaid expenses and other sundry assets	256,521	248,116
	<b>18,918,939</b>	<b>22,208,474</b>
<b>PROPERTY AND EQUIPMENT, NET</b>		
	<b>104,124</b>	<b>137,040</b>
<b>OTHER ASSETS</b>		
Security deposits	25,326	25,326
	<b>\$ 19,048,389</b>	<b>\$ 22,370,840</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 643,845	\$ 621,818
Due to licensor - Antares	875,000	2,625,000
Provision for contingencies	412,941	550,588
Accrued compensation	289,604	368,522
Other accrued expenses	175,236	65,500
Deferred revenue	34,091	68,182
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,430,717</b>	<b>4,299,610</b>
<b>STOCKHOLDERS' EQUITY</b>		
Capital stock		
Issued and Outstanding		
2007 - 391,286; 2006 - 391,286 Class		
C special stock	391	391
2007 - 23,027,540; 2006 - 22,975,040		
Common stock	65,331,346	64,967,887
	<b>65,331,737</b>	<b>64,968,278</b>
Accumulated deficit		
	(48,714,065)	(46,897,047)
	<b>16,617,672</b>	<b>18,071,231</b>
	<b>\$ 19,048,389</b>	<b>\$ 22,370,840</b>

See accompanying notes to the financial statements.



**BIOSANTE PHARMACEUTICALS, INC.****Statements of Operations****Three months ended March 31, 2007 and 2006 (Unaudited)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>REVENUE</b>		
Licensing revenue	\$ 34,091	\$ 34,091
Grant revenue	16,517	50,588
	<b>50,608</b>	<b>84,679</b>
<b>EXPENSES</b>		
Research and development	913,852	1,002,539
General and administration	771,589	1,520,344
Stock compensation expense	220,798	859,013
Depreciation and amortization	32,916	27,457
	<b>1,939,155</b>	<b>3,409,353</b>
OTHER - Interest income	146,529	96,179
<b>NET LOSS BEFORE INCOME</b>		
TAX EXPENSE	(1,742,018)	(3,228,495)
<b>INCOME TAX EXPENSE</b>		
	75,000	-
<b>NET LOSS</b>	<b>\$ (1,817,018)</b>	<b>\$ (3,228,495)</b>
<b>BASIC AND DILUTED NET LOSS</b>		
PER SHARE (Note 2)	\$ (0.08)	\$ (0.17)
<b>WEIGHTED AVERAGE NUMBER</b>		
<b>OF SHARES OUTSTANDING</b>	<b>23,367,493</b>	<b>19,426,895</b>
See accompanying notes to the financial statements.		

**BIOSANTE PHARMACEUTICALS, INC.****Statements of Cash Flows****Three months ended March 31, 2007 and 2006 (Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2007</b>	<b>2006</b>
<b>CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>		
Net loss	\$ (1,817,018)	\$ (3,228,495)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	32,916	27,457
Employee & director compensation - noncash	220,798	859,013
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other sundry assets	(8,405)	17,500
Accounts receivable	6,995,818	-
Accounts payable and accrued liabilities	(1,697,155)	(71,272)
Provision for contingencies	(137,647)	140,000
Deferred revenue	(34,091)	(34,091)
<b>Net cash provided by (used in) operating activities</b>	<b>3,555,216</b>	<b>(2,289,888)</b>
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>		
Redemption of short term investments	-	1,902,458
Purchase of short term investments	(60,988)	(96,179)
Purchase of capital assets	-	(520)
<b>Net cash (used in) provided by investing activities</b>	<b>(60,988)</b>	<b>1,805,759</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>		
Proceeds from sale or conversion of shares	142,662	243,675
<b>Net cash provided by financing activities</b>	<b>142,662</b>	<b>243,675</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		
	<b>3,636,890</b>	<b>(240,454)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>		
	<b>7,653,852</b>	<b>310,643</b>
	<b>\$ 11,290,742</b>	<b>\$ 70,189</b>

**CASH AND CASH  
EQUIVALENTS AT END OF  
PERIOD**

**SUPPLEMENTARY  
INFORMATION**

**Other information:**

Income tax paid	\$	75,000	\$	-
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See accompanying notes to the  
financial statements.



**BIOSANTE PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**MARCH 31, 2007**

**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, 2007, the results of operations for the three months ended March 31, 2007 and 2006, and the cash flows for the three months ended March 31, 2007 and 2006, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

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, 2006.

Certain 2006 amounts have been reclassified to conform to 2007 presentation.

**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, 2007 does not include options to purchase an aggregate of 1,371,788 shares of common stock, with exercise prices ranging from \$2.10 to \$6.70 per share, and warrants to purchase an aggregate of 2,534,210 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, 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 ranging from \$2.15 to \$7.00 per share, because of their antidilutive effect on net loss per share.

**3. LICENSE AGREEMENTS**

In November 2006, the Company entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin, our estradiol gel, in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of \$2.625 million. In addition, Bradley paid the Company \$7 million in the first quarter of 2007 triggered by the FDA approval of Elestrin in the U.S. and an additional \$3.5 million is due on the one-year anniversary of such approval during the fourth quarter of 2007. Upon receipt of the \$7 million payment, the Company paid Antares Pharma IPL AG ("Antares"), the Company's licensor of the transdermal estradiol gel formulation in Elestrin, 25 percent of such payment resulting in the Company receiving a net payment of \$5.25 million from Bradley and upon receipt of the additional \$3.5 million payment, the Company will be obligated to pay Antares 25 percent of such payment resulting in the Company receiving a net payment of \$2.625 million from Bradley. Bradley also has agreed to pay the Company additional sales-based milestone payments, plus royalties on sales of Elestrin. The Company will pay a portion of sales-based milestone payments and royalties to Antares. It is the Company's

understanding that Bradley is planning to commercially launch Elestrin in mid-2007.

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#### 4. CONTINGENCIES

In May 2006, the Company, certain officers, one of its directors and a former officer entered into a Settlement Agreement related to a personnel matter, under which the Company agreed to pay the former officer post-termination payments in the aggregate amount of \$780,000 in equal installments in accordance with the Company's regular payroll cycle through December 31, 2007, plus \$110,000 of legal fees incurred by the former officer. As required by the agreement, the payments are secured by an irrevocable letter of credit, which is supported by the Company's short-term investment account. The outstanding balance under the letter of credit and corresponding accrued liability was \$412,941 as of March 31, 2007 and will continue to decrease as payments are made through December 2007. In August 2006, the Company's employment practices liability carrier paid the Company \$500,000 in settlement of the Company's claim against the carrier for coverage in this matter. The costs of the Settlement Agreement and corresponding insurance payment receipt were included in general and administrative expenses in the statements of operations in 2006.

On March 28, 2007, the Company received notice that the staff of the Securities and Exchange Commission's Division of Enforcement (the "Staff") is conducting an inquiry arising out of allegations contained in a complaint made by the former officer with whom the Company entered into the above-described settlement agreement to the U.S. Department of Labor, Occupational Safety & Health Administration ("OSHA") in February 2006 under the "whistleblower" provision of the Sarbanes-Oxley Act of 2002 ("SOX"). Immediately upon notice of the former officer's intent to file the SOX complaint in January 2006, the Board of Directors of the Company directed that an investigation be made into the allegations of securities and other law violations contained in the former officer's SOX complaint. The results of the investigation led to the conclusion by the Company and the Company's outside legal counsel that the allegations in the SOX complaint were without merit. OSHA closed its investigation into the SOX complaint in August 2006. The Staff has informed the Company that the Staff's investigation into the matter should not be construed as an indication by the SEC or the Staff that any violation of law has occurred. The Company intends to fully cooperate with the Staff. In this regard, the Company's legal counsel recently met with members of the Staff to discuss the matter, including the background of the personnel matter and the fact that the Company had previously conducted an investigation into the allegations contained in the SOX complaint.

#### 5. STOCK-BASED COMPENSATION

The Company adopted Statement of Financial Accounting Standards ("SFAS") 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 Accounting Principles Board 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, 2007, the Company maintained one stock-based compensation plan, the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan, which is described below. The non-cash, stock-based compensation cost that has been incurred by the Company in connection with this plan was \$220,798 and \$859,013 for the three months ended March 31, 2007 and 2006, respectively. No income tax benefit has been recognized in the Company's statement of operations for stock-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, 2007, 3,000,000 shares of the Company's common stock were reserved for issuance under the Plan, and 1,317,820 shares remained available for issuance, in each case, subject to adjustment as provided in the Plan. The Company believes that equity-based incentives, such as stock options and stock awards, align the interest of its employees, directors and consultants 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 which were exercisable immediately. In these instances, stock-based compensation expense 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 at any time but may not reprice any outstanding options without obtaining stockholder approval.

The fair value of each option grant has been estimated on the date of grant using the Black-Scholes option-pricing-model. The assumptions in the table below reflect the weighted average of all stock option grants during the first quarter ended March 31, 2007 and 2006.

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2007</b>	<b>2006</b>
Expected life in years	10	10
Annualized volatility	71.00%	73.94%
Discount rate - bond equivalent yield	4.82%	4.10%
Expected dividend yield	0.0%	0.0%

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 the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company has not in the past issued a cash dividend, nor does it have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

A summary of activity under the Plan during the three months ended March 31, 2007 is presented below:

<b>Options</b>	<b>Option Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding December 31, 2006	1,011,479	\$ 3.61
Granted	455,000	2.98
Exercised	0	0
Forfeited or expired	(94,691)	4.99
Outstanding March 31, 2007	1,371,788	\$ 3.31
<i>(weighted average contractual term)</i>	8.45	<i>years</i>
Exercisable at March 31, 2007	810,753	\$ 3.41
<i>(weighted average contractual term)</i>	6.2	<i>years</i>

The aggregate intrinsic values of the Company's outstanding and exercisable options as of March 31, 2007 were \$3,657,619 and \$2,090,855, respectively.

A summary of the Plan's non-vested options at December 31, 2006 and activity under the Plan during the three months ended March 31, 2007 is presented below:

<b>Options</b>	<b>Option Shares</b>	<b>Weighted Average Grant Date Fair-Value</b>
Outstanding December 31, 2006	207,833	\$ 3.65
Granted	455,000	2.98
Vested	(77,145)	3.95
Forfeited	(24,668)	4.99
Non-Vested at March 31, 2007	561,020	\$ 3.14

As of March 31, 2007, there was \$1,269,312 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan. The cost is expected to be recognized over a weighted-average period of 2.35 years.

There were no options exercised under the Plan for the three months ended March 31, 2007.

## **6. ADOPTION OF FIN 48**

The company adopted the provisions of Financial Accounting Standards Board (“FASB”) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* (“FIN 48”) on January 1, 2007. FIN 48 requires companies to determine whether it is “more likely than not” that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. The adoption of FIN 48 did not have an impact on our results of operations or financial condition.

## **7. STOCKHOLDERS’ EQUITY**

During the three months ended March 31, 2007, a warrant to purchase 52,500 shares of common stock was exercised for total cash proceeds of \$144,375.

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## **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.

### **Business Overview**

We are a biopharmaceutical company that licenses and develops hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for vaccine adjuvants or immune system boosters and drug delivery systems.

Our hormone therapy products are gel formulations of testosterone, estradiol, and various combinations of estrogens, progestogens and androgens. Our hormone therapy products include Elestrin, LibiGel, Bio-E/P-Gel, LibiGel-E/T, Bio-T-Gel and triple hormone contraceptives. We license the technology underlying our hormone therapy products, except Bio-T-Gel and triple hormone contraceptives, from Antares Pharma IPL AG. Bio-T-Gel was developed and is fully-owned by us. Our license agreement with Antares required us to pay an up-front license fee to Antares, certain development and regulatory milestone payments and to pay royalties to Antares based on a percentage of the net sales of any products we or our sublicensees sell incorporating the licensed technology. We license the technology underlying our proposed triple hormone contraceptives from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center. The financial terms of this license include an upfront license fee, regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed.

We have entered into several sublicense agreements covering our hormone therapy products, including an agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product, a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA agreed to develop our proposed Bio-T-Gel product for the U.S. market and an agreement with Paladin Labs Inc. covering Canadian rights to certain of our hormone therapy products. The financial terms of these agreements generally include an upfront license fee, milestone payments, and royalty payments to us if a product incorporating the licensed technology gets approved and subsequently marketed.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of \$2.625 million. In addition, in March 2007, Bradley paid us \$5.25 million which was triggered by FDA approval of Elestrin in the U.S. and has agreed to pay us an additional \$2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. Bradley also has agreed to pay us additional sales-based milestone payments, plus royalties on sales of Elestrin. It is our understanding that Bradley is planning to commercially launch Elestrin in mid-2007.

We completed our pivotal Phase III clinical trial of Elestrin in April 2005, submitted an NDA for Elestrin with the FDA in February 2006 and received FDA approval for Elestrin in December 2006. The Elestrin FDA approval is a non-conditional and full approval with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel.

In April 2007, we announced that a new patent has issued covering the formulations used in Elestrin™ (estradiol gel), our newly approved treatment for moderate to severe vasomotor symptoms associated with menopause and LibiGel® (testosterone gel), which recently moved into Phase III clinical development for the treatment of female sexual dysfunction. The patent, which was issued on April 3, 2007 covering both Elestrin and LibiGel, will expire on June 25, 2022.

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. For example, under a subcontract with DynPort Vaccine Company LLC, we provided BioVant, our vaccine adjuvant, and DynPort provided recombinant antigens to be used in potential vaccines against anthrax. The objective was 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. We have completed this subcontract and recorded approximately \$300,000 in revenue over the life of the subcontract with \$1,806 and \$82,985 recognized in 2007 and 2006, respectively. Currently, we are seeking additional funding from government sources or potential partners for our anthrax program.

## **Financial Overview**

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 in the foreseeable future, although Bradley, our marketing partner for Elestrin, expects to commercially launch Elestrin in mid-2007, at which point we will then be entitled to receive royalties on any net sales of Elestrin and additional milestone payments upon the achievement of certain sales-based milestones.

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. In 2006, we recognized \$14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in December 2006. Upon execution of the Bradley agreement, we received an upfront payment of \$2.625 million. In addition, in March 2007, Bradley paid us \$5.25 million and has agreed to pay us an additional \$2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. Our cash, cash equivalents and short-term investments were \$15,147,707 as of March 31, 2007.



Our business operations to date have consisted mostly of licensing and research and development activities, and we expect this to continue for the immediate future. If and when our proposed products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves. We currently do not have sufficient resources on a long-term basis to complete the commercialization of any of our proposed products for which we have not entered into marketing relationships. Based on our current cash resources, including the net proceeds we received from the additional sublicensing payments we recently received from Bradley, and our current 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 or seek additional cash prior to such time. As an alternative to raising additional financing, we may be able to license LibiGel to a third party who would finance the continued development and if approved, commercialization of LibiGel.

We spent an average of approximately \$300,000 to \$350,000 per month on research and development activities in the first quarter of 2007. Our research and development expenses decreased \$88,687 or 9 percent, to \$913,852 for the three months ended March 31, 2007 from \$1,002,539 for the three months ended March 31, 2006, primarily as a result of the filing of the NDA for Elestrin in February 2006. We expect our research and development expenses to be higher for the remainder of 2007 and beyond compared to the first three months of 2007 as a result of the commencement of our Phase III clinical development program for LibiGel, which began in December 2006. Specifically, we expect our research and development expenses to increase to approximately \$600,000 to \$800,000 per month beginning in the third quarter of 2007. 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.

Our general and administrative expenses for the three months ended March 31, 2007 decreased \$748,755 or 49 percent, compared to the three months ended March 31, 2006. This decrease was due to higher legal and business development costs during the previous period, including costs associated with a personnel-related matter. 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.

Although we recognized net income of \$2,791,273 for the year ended December 31, 2006 primarily due to recognizing \$14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in 2006, we have incurred losses in recent years and expect to incur substantial and continuing losses for the foreseeable future. As of March 31, 2007, our accumulated deficit was \$48,714,065. Although we expect Bradley to commercially launch Elestrin in mid-2007 for which we will be entitled to receive royalties on the net sales of Elestrin as well as sales-based milestone payments, 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 or continue, including in particular the Phase III clinical trial program for our LibiGel product which commenced in December 2006. 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 timing and cost of obtaining necessary regulatory approvals;

- the commercial success and net sales of Elestrin, on which we will receive royalties and potential sales-based milestone payments; and
- the costs of licensure or acquisition of new products.

## Results of Operations

### *Three Months Ended March 31, 2007 Compared to Three Months Ended March 31, 2006*

The following table sets forth our results of operations for the three months ended March 31, 2007 and 2006.

	Three Months Ended March 31,		\$ Change	% Change
	2007	2006		
Revenue	\$ 50,608	\$ 84,679	\$ (34,071)	(40.2)%
Expenses				
Research and development	913,852	1,002,539	(88,687)	(8.8)%
General and administrative	771,589	1,380,344	(608,755)	(44.1)%
Stock compensation expense	220,798	859,013	(638,215)	(74.3)%
Interest income	146,529	96,179	50,350	52.4%
Net loss	\$ (1,817,018)	\$ (3,228,495)	\$ (1,411,477)	(43.7)%

Revenue decreased \$34,071 primarily as a result of the completion of the company's activities under the Dynport subcontract which terminated in December 2006.

Research and development expenses for the three months ended March 31, 2007 decreased 9 percent compared to the three months ended March 31, 2006 primarily as a result of the submission of our NDA for Elestrin in February 2006, and the subsequent reduction in Elestrin-related expenditures following that submission.

General and administrative expenses for the three months ended March 31, 2007 decreased 44 percent compared to the three months ended March 31, 2006 primarily as a result of legal fees incurred and related provisions recorded in the first quarter of 2006 in connection with a personnel-related matter.

Stock compensation expense decreased 74% as a result of the recognition of \$220,798 in non-cash stock-based compensation expense during the three months ended March 31, 2007 compared to \$859,013 for the three months ended March 31, 2006. A portion of the expense related to a March 2007 grant of options with immediate vesting to a non-employee consultant of the Company, which was fully expensed on the grant date due to the term of the award. 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, 2007 increased 52 percent compared to interest income for the three months ended March 31, 2006 as a result of higher average invested cash balances and higher average interest rates on invested cash balances during the first three months of 2007 compared to the same period in 2006.

## 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 from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future, although our marketing partner for our Elestrin product, Bradley Pharmaceuticals, Inc., expects to commercially launch Elestrin in mid-2007, at which point we will then be entitled to receive royalties on any net sales of Elestrin and milestone payments upon the achievement of certain sales-based milestones. Our cash, cash equivalents and short-term investments available to fund current operations were \$15,147,707 and \$11,449,829 at March 31, 2007 and December 31, 2006, respectively. The increase in our cash and short-term investment balances was primarily due to our receipt during the first quarter of 2007 of a net payment of \$5.25 million as a result of our sublicense agreement with Bradley, partially offset by our use of cash to fund operations. We do not have any outstanding debt.

Our business operations to date have consisted mostly of licensing and research and development activities, and we expect this to continue for the immediate future. If and when our proposed products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves. We currently do not have sufficient resources to obtain regulatory approval of our other proposed products or to complete the commercialization of any of our proposed products. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we may need to raise substantial additional capital to fund our operations or alternatively, we may choose to sublicense another product for development and commercialization or enter into other business collaborations or combinations.

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. During the three months ended March 31, 2007, we also received \$144,375 in cash proceeds from a warrant exercise.

We believe that our cash and short-term investments as of March 31, 2007, together with payments we expect to receive from Bradley under our sublicense agreement with Bradley, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, we may seek to obtain additional financing prior to that 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 commercial success and net sales of Elestrin, on which we will receive royalties and potential sales-based milestone payments;
  - the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
  - our general and administrative expenses;
  - 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, or additional sublicense agreements are not signed, 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 received cash from operating activities of \$3,555,216 for the three months ended March 31, 2007 versus cash used in operating activities of \$2,289,888 for the three months ended March 31, 2006. Net cash was provided by operations in the first quarter ended March 31, 2007 primarily due to the receipt of a net payment of \$5,250,000 from Bradley under the licensing agreement for Elestrin. Cash used in operating activities for the first three months of 2006 was primarily the result of the net loss for that period. Net cash used in investing activities was \$60,988 for the three months ended March 31, 2007 versus cash provided by investing activities of \$1,805,759 for the three months ended March 31, 2006. Redemption of short-term investments provided \$1,902,458 in cash during the first three months of 2006. Net cash provided by financing activities during the three months ended March 31, 2007 was \$142,662, which resulted from a warrant exercise. Net cash provided by financing activities during the three months ended March 31, 2006 was \$243,675 and was the result of option exercises.

We recorded and paid \$75,000 in income tax expense during the quarter ended March 31, 2007 as we were subject to the corporate alternative minimum tax provision.

### *Commitments and Contractual Obligations*

We did not have any material commitments for capital expenditures as of March 31, 2007. We have, however, several potential financial commitments, including product development milestone payments to the licensors of our hormone therapy products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments. We refer you to our most recently filed annual report on Form 10-K for further details regarding our contractual obligations. 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; and
- the licensure or acquisition of new products, general business development including out-licensing of our products in our territories.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our pre-clinical studies and clinical trials;
  - time and cost necessary to obtain regulatory approvals;
- time and cost necessary to seek 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. 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.

Under the terms of the license agreements with the University of California and Wake Forest University Health Sciences and Cedars-Sinai Medical Center, we have the right to terminate the license agreements for any reason, with our only obligation being the payment of monies owed at the date of termination.

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

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these 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, 2006. There have been no changes to the critical accounting policies described in our quarterly Report on Form 10-Q for the period ended March 31, 2007.

### **Recent Accounting Pronouncements**

The company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. FIN 48 requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. The adoption of FIN 48 did not have an impact on our results of operations or financial condition.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* (“SFAS 157”). The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. The statement will be effective for us January 1, 2008 though early adoption is permitted. We have not yet determined the impact, if any, that the implementation of SFAS 157 will have on our results of operations or financial condition.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115* (“SFAS 159”). SFAS 159 permits an entity to elect fair value as the initial and subsequent measurement attribute for many financial assets and liabilities. Entities electing the fair value option are required to recognize changes in fair value in earnings. SFAS 159 also requires additional disclosures to compensate for the lack of comparability that will arise from the use of the fair value option. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The adjustment to reflect the difference between the fair value and the carrying amount would be accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. We have not yet determined the impact, if any, that the adoption of SFAS 159 will have on our results of operations or financial condition.

### **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;
  - the timing of the commercialization of our Elestrin product
  - the future market and market acceptance of our products;
- our belief as to the merits of the allegations of violations of law contained in a “whistleblower” complaint filed by a former officer of our company under the Sarbanes-Oxley Act of 2002 and the effect on our business of the pending investigation regarding such allegations by the staff of the SEC’s Enforcement Division;

- the effect of new accounting pronouncements;
- 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, ability and expected timing of any actions 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:

- lack of market acceptance of Elestrin and our other hormone therapy products if and when they are commercialized
  - failure to obtain additional capital when needed or on acceptable terms;
  - failure of products to be commercially introduced for several years or at all;
  - failure to obtain and maintain required regulatory approvals on a timely basis or at all;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- our dependence upon Bradley Pharmaceuticals, Inc, for the marketing and sale of our Elestrin product and our dependence upon other sub-licensees for the development, marketing and sale of certain of our other hormone therapy products;
- our dependence upon the maintenance of our licenses with Antares Pharma IPL AG, Wake Forest University Health Sciences and Cedars-Sinai Medical Center and the University of California - Los Angeles;
  - patient recruitment and enrollment in our current and future clinical trials;
  - the scope, timing and results of our clinical trials and other uncertainties associated with clinical trials;
  - our ability to compete in a competitive industry;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
  - our dependence upon key employees;
  - our ability to maintain effective internal controls over financial reporting;
- effect of any potential litigation and the pending investigation by the staff of the SEC's Enforcement Division;
- adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
  - changes in generally accepted accounting principles; or
  - conditions and changes in the biopharmaceutical industry or in general economic or 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, 2006 under the heading “Part I - Item 1A. Risk Factors” on pages 22 through 32 of such report and “Part II — Item 1A. Risk Factors” included elsewhere in this 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 and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 under the heading “Part I - Item 1A. Risk Factors”, 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 and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 under the heading “Part I - Item 1A. Risk Factors”. 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, 2007 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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## **PART II - OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We refer you to the description under the heading “Contingencies” in note 4 of our consolidated financial statements included within this report, which 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. In addition to the other information set forth in this report, including the additional risk factor below, careful consideration should be taken of the factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2006 under the heading “Part I - Item 1A. Risk Factors,” which could materially adversely affect our business, financial condition or operating results.

The staff of the Securities and Exchange Commission’s Division of Enforcement is conducting an investigation arising out of allegations contained in a complaint made by a former officer of our company to the U.S. Department of Labor, Occupational Safety & Health Administration (“OSHA”) in February 2006 under the “whistleblower” provision of the Sarbanes-Oxley Act of 2002, which complaint was subsequently closed by OSHA in August 2006. Although we believe the allegations in the complaint are without merit, it is possible that the staff of the SEC’s Division of Enforcement may disagree with our conclusion.

On March 28, 2007, we received notice that the staff of the Securities and Exchange Commission’s Division of Enforcement (the “Staff”) is conducting an investigation arising out of allegations contained in a complaint made by a former officer of our company to the U.S. Department of Labor, Occupational Safety & Health Administration (“OSHA”) in February 2006 under the “whistleblower” provision of the Sarbanes-Oxley Act of 2002 (“SOX”). Immediately upon notice of the former officer’s intent to file the SOX complaint in January 2006, the Board of Directors of our company directed that an investigation be made into the allegations of securities and other law violations contained in the former officer’s SOX complaint. The results of the investigation led to the conclusion by us and our outside legal counsel that the allegations in the SOX complaint were without merit. OSHA closed its investigation into the SOX complaint in August 2006. The Staff has informed us that the Staff’s inquiry into the matter should not be construed as an indication by the SEC or the Staff that any violation of law has occurred. We intend to fully cooperate with the Staff. In this regard, our legal counsel recently met with members of the Staff to discuss the matter, including the background of the personnel matter and the fact that we had previously conducted an investigation into the allegations contained in the SOX complaint. Although we believe the allegations in the complaint are without merit, it is possible that the Staff may disagree with our conclusion.

### **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, 2007, we did not issue any unregistered equity securities.

### **Issuer Purchases of Equity Securities**

We did not purchase any shares of our common stock or other equity securities during the three months ended March 31, 2007, 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:

- 10.1 Fourth Amendment to Lease dated as of March 7, 2007, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago
- 10.2 Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended
- 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 1, 2007

**BIOSANTE PHARMACEUTICALS, INC.**

By: /s/ Stephen M. Simes

Stephen M. Simes

Vice Chairman, 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	Fourth Amendment to Lease dated as of March 7, 2007, 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 the registrant's current report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2007
10.2	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Incorporated by reference to Exhibit 10.1 to the registrant's annual report on Form 10-K for the fiscal year ended December 31, 2006
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



