

BIOSANTE PHARMACEUTICALS INC  
Form 10-Q  
August 14, 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 June 30, 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 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:

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 August 14, 2006, 22,973,672 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

---

**BIOSANTE PHARMACEUTICALS, INC.****FORM 10-Q****June 30, 2006****TABLE OF CONTENTS**

<u>Description</u>	<u>Page</u>
<b>PART I. FINANCIAL INFORMATION</b>	
<b>ITEM 1. Financial Statements</b>	
Balance Sheets as of June 30, 2006 and December 31, 2005	3
Statements of Operations for the three and nine months ended June 30, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006	4
Statements of Cash Flows for the nine months ended June 30, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006	5
Notes to the Financial Statements	6-11
<b>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	12-21
<b>ITEM 3. Quantitative and Qualitative Disclosure About Market Risk</b>	21
<b>ITEM 4. Controls and Procedures</b>	22
<b>PART II OTHER INFORMATION</b>	23
<b>ITEM 1. Legal Proceedings</b>	23
<b>ITEM 1A. Risk Factors</b>	23
<b>ITEM 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities</b>	23
<b>ITEM 3. Defaults upon Senior Securities</b>	23
<b>ITEM 4. Submission of Matters to a Vote of Security Holders</b>	23-24
<b>ITEM 5. Other Information</b>	24
<b>ITEM 6. Exhibits</b>	24
<b>SIGNATURE PAGE</b>	25
<b>Exhibit Index</b>	26

*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/E/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.*

---

**BIOSANTE PHARMACEUTICALS, INC.****(a development stage company)**

Balance Sheets

**June 30, 2006 and December 31, 2005 (Unaudited)**

	June 30, 2006	December 31, 2005
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 133,605	\$ 310,643
Short-term investments	4,371,626	8,790,888
Prepaid expenses and other sundry assets	207,678	245,465
	<b>4,712,909</b>	<b>9,346,996</b>
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>164,906</b>	<b>215,566</b>
<b>OTHER ASSETS</b>		
Security deposits	25,325	11,992
	<b>\$ 4,903,140</b>	<b>\$ 9,574,554</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 669,734	\$ 1,139,566
Accrual for contingencies	890,000	750,000
Accrued compensation	324,813	492,980
Other accrued expenses	282,713	147,125
Deferred revenue	136,363	136,363
<b>TOTAL CURRENT LIABILITIES</b>	<b>2,303,623</b>	<b>2,666,034</b>
<b>LONG TERM LIABILITIES</b>		
Leasehold retirement liability	21,500	21,500
Deferred revenue	-	68,182
<b>TOTAL LONG TERM LIABILITIES</b>	<b>21,500</b>	<b>89,682</b>
<b>TOTAL LIABILITIES</b>	<b>\$ 2,325,123</b>	<b>\$ 2,755,716</b>
<b>STOCKHOLDERS' EQUITY</b>		
Capital stock Issued and Outstanding		
2006 - 391,286; 2005 - 391,286		
Class C special stock	398	398
2006 - 19,160,694; 2005 - 19,007,800 Common stock	57,719,334	56,653,219
	<b>57,719,732</b>	<b>56,653,617</b>
Deferred unearned compensation	-	(146,459)

Deficit accumulated during the development stage	<b>(55,141,715)</b>		<b>(49,688,320)</b>
	<b>2,578,017</b>		<b>6,818,838</b>
	<b>\$ 4,903,140</b>	<b>\$</b>	<b>9,574,554</b>

See accompanying notes to the financial statements.

**BIOSANTE PHARMACEUTICALS, INC.****(a development stage company)****Statements of Operations****Three and six months ended June 30, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006 (Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006
	2006	2005	2006	2005	
<b>REVENUE</b>					
Licensing income	\$ 34,091	\$ -	\$ 68,182	\$ -	\$ 4,706,580
Grant income	86,160	45,596	136,748	74,273	385,530
Other Income	55,000	-	55,000	-	87,000
	<b>175,251</b>	<b>45,596</b>	<b>259,930</b>	<b>74,273</b>	<b>5,179,110</b>
<b>EXPENSES</b>					
Research and development	1,114,588	1,927,890	2,133,465	4,079,569	32,609,538
General and administration	1,328,612	775,174	3,551,631	1,495,669	21,883,932
Provision for contingencies	-	-	140,000	-	890,000
Depreciation and amortization	27,109	26,043	54,566	50,985	916,867
Loss on disposal of capital assets	-	-	-	-	157,545
Costs of acquisition of Structured Biologicals Inc. Purchased in-process research and development	-	-	-	-	5,377,000
	<b>2,470,309</b>	<b>2,729,107</b>	<b>5,879,662</b>	<b>5,626,223</b>	<b>62,210,101</b>
OTHER - Interest income	70,158	101,926	166,337	199,873	1,889,276
<b>NET LOSS</b>	<b>\$ (2,224,900)</b>	<b>\$ (2,581,585)</b>	<b>\$ (5,453,395)</b>	<b>\$ (5,352,077)</b>	<b>\$ (55,141,715)</b>
<b>BASIC AND DILUTED NET LOSS</b>					
	<b>\$ (0.11)</b>	<b>\$ (0.13)</b>	<b>\$ (0.28)</b>	<b>\$ (0.28)</b>	

PER SHARE (Note  
2)

WEIGHTED  
AVERAGE  
NUMBER  
OF SHARES

OUTSTANDING	<b>19,551,980</b>	<b>19,385,086</b>	<b>19,488,094</b>	<b>19,379,457</b>
-------------	-------------------	-------------------	-------------------	-------------------

See accompanying notes to the financial statements.

4

---

**BIOSANTE PHARMACEUTICALS, INC.**

(a development stage company)

**Statements of Cash Flows**

six months ended June 30, 2006 and 2005 and the cumulative

period from August 29, 1996 (date of incorporation) to June 30, 2006 (Unaudited)

	Six Months ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006
	2006	2005	
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>			
Net loss	\$ (5,453,395)	\$ (5,352,077)	\$ (55,141,715)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	54,566	50,985	916,867
Amortization of deferred unearned compensation	-	-	42,290
Repurchase of licensing rights	-	-	125,000
Employee & director compensation - noncash	975,222	175,750	2,243,263
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, deposits and other sundry assets	24,454	131,130	(230,035)
Accounts payable and accrued liabilities	(502,411)	(356,059)	604,119
Accrual for contingencies	140,000	-	890,000
Deferred revenue	(68,182)	-	136,363
Due from SBI	-	-	(128,328)
<b>Net cash used in operating activities</b>	<b>(4,829,746)</b>	<b>(5,350,271)</b>	<b>(45,007,631)</b>
<b>CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>			
Redemption of short term investments	4,585,599	4,605,576	12,285,749
Purchase of short term investments	(166,337)	(199,873)	(16,657,375)



Purchase of capital assets	(3,906)	(43,703)	(1,205,208)
<b>Net cash provided by (used in) investing activities</b>	<b>4,415,356</b>	<b>4,362,000</b>	<b>(5,576,834)</b>

### CASH FLOWS PROVIDED BY FINANCING ACTIVITIES

Issuance of convertible debenture	-	-	500,000
Proceeds from sale or conversion of shares	237,352	197,769	50,221,120
Fractional share payout	-	-	(3,050)
<b>Net cash provided by financing activities</b>	<b>237,352</b>	<b>197,769</b>	<b>50,718,070</b>

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

	(177,038)	(790,502)	133,605
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>310,643</b>	<b>1,170,025</b>	<b>-</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 133,605</b>	<b>\$ 379,523</b>	<b>\$ 133,605</b>

### SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION

Acquisition of SBI				
Purchased in-process research and development	\$ -	\$ -	\$ -	5,377,000
Other net liabilities assumed	-	-	-	(831,437)
-				4,545,563
Less: subordinate voting shares issued therefor	-	-	-	4,545,563
	\$ -	\$ -	\$ -	-
Income tax paid	\$ -	\$ -	\$ -	-
Interest paid	\$ -	\$ -	\$ -	3,421

### SIGNIFICANT NON-CASH TRANSACTIONS

Fair value of common stock warrants issued in connection with the sale of capital stock	\$ -	\$ -	\$ -	1,053,423
---	------	------	------	-----------

See accompanying notes to the financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**  
**FORM 10-Q**  
**JUNE 30, 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 June 30, 2006, the results of operations for the three and six months ended June 30, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006, and the cash flows for the six months ended June 30, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2006, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 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 and six months ended June 30, 2006 does not include options to purchase an aggregate of 1,039,312 and 1,037,979 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 and six months ended June 30, 2005 does not include options to purchase an aggregate of 1,099,530 and 1,107,364 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 June 30, 2006 or June 30, 2005.

##### *Contingencies*

In November 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 and that the agreement, consequently, would expire by its terms on December 31, 2005. In February 2006, Lehman 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 seeking reinstatement of her employment with back pay, interest and attorney's fees and claiming, among other things, wrongful termination. The Company subsequently filed a complaint against 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 sought an unspecified amount of damages, punitive damages, declaratory judgment regarding a breach by Lehman of her employment agreement and the amount of severance pay, if any, to be owed to Lehman, reimbursement of the Company's legal fees and costs and such other relief as the Court may have deemed proper. In March 2006, Lehman filed a charge with the Equal Employment Opportunity Commission claiming sex discrimination and retaliation in violation of Title VII of the Civil Rights Act of 1964. In May 2006, the Company, its President and Chief Executive Officer, its Chief Financial Officer, Treasurer and Secretary, one of its directors, and Dr. Lehman entered into a Confidential Settlement Agreement. Under the Settlement Agreement, the parties thereto agreed to voluntarily withdraw and dismiss any and all charges, claims and pending litigation with prejudice and execute mutual releases and covenants not to sue. The Company agreed to pay Lehman post-termination installment payments in the aggregate amount of \$780,000 in equal installments in accordance with the Company's regular payroll cycle through December 31, 2007 and to secure such payments with an irrevocable letter of credit. The Company also agreed to pay the legal fees incurred by Lehman in the amount of \$110,000. In exchange for the payments, Lehman agreed, among other things, to honor through June 30, 2007, non-competition and non-solicitation obligations as provided in her employment agreement. The Company has accrued \$890,000 in connection with this matter.

To secure payments under the Settlement Agreement described above, on May 26, 2006, the Company entered into an irrevocable letter of credit with UBS AG in the amount of \$780,000 supported by the Company's short term investment account with UBS AG. The outstanding balance under the letter of credit will decrease as payments are made through December 2007.

In July 2006, the Company reached an agreement with its employment practices liability insurance carrier pursuant to which the carrier has agreed to pay the Company \$500,000 in settlement of the Company's claim against the carrier for coverage in this matter (see note 7 to our financial statements entitled "Subsequent Events").

## 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 June 30, 2006, 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 \$975,222 and \$175,750 for the six months ended June 30, 2006 and 2005, 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 June 30, 2006, 3,000,000 shares of the Company's common stock were available for issuance under the Plan, 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 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, 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 using the assumptions in the table below:

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2006</b>	<b>2005</b>
Expected life in years	10	10
Annualized volatility	73.94%	76.58%
Discount rate - bond equivalent yield	4.10%	3.96%
	0.0%	0.0%

Expected  
dividend  
yield

8

---

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

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 cash 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 six months ended June 30, 2006 is presented below:

<b>Options</b>	<b>Option 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	597,157	3.65
Outstanding June 30, 2006 <i>(weighted average contractual term)</i>	1,037,979	\$ 3.61 <i>7.9 years</i>
Exercisable at June 30, 2006 <i>(weighted average contractual term)</i>	788,478	\$ 3.49 <i>7.4 years</i>

The aggregate intrinsic values of the Company's outstanding and exercisable options as of June 30, 2006 were \$51,458 and \$51,458, respectively.

A summary of the Plan's non-vested options at December 31, 2005 and activity under the Plan during the six months ended June 30, 2006 is presented below:

<b>Options</b>	<b>Option Shares</b>	<b>Weighted Average Grant Date Fair-Value</b>
Outstanding December 31, 2005	398,000	\$ 3.61
Granted	362,500	3.87
Vested	331,944	3.56
Forfeited	179,055	3.49
Non-Vested at June 30, 2006	249,501	\$ 3.58

As of June 30, 2006, there was \$610,846 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 2.27 years.

As a result of March 2006 issuance of stock options with immediate vesting to the non-employee members of our Board of Directors, \$746,616 of non-cash, stock based compensation expense was recorded in the six months ended June 30, 2006.

9

---

Cash received from option exercises under the Plan for the six months ended June 30, 2006 was \$243,675. The intrinsic value of options exercised during the six months ended June 30, 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.

	<b>Three Months Ended June 30, 2006</b>	Three Months Ended June 30, 2005
Net loss		
As reported	\$ (2,224,900)	\$ (2,581,585)
Stock-based compensation included in net loss as reported	116,209	87,875
Total stock-based employee compensation determined under fair value based method for all awards	(116,209)	(178,892)
Net loss, pro forma	\$ (2,224,900)	\$ (2,672,602)
Basic and diluted net loss per share		
As reported	\$ (0.11)	\$ (0.13)
Pro forma	\$ (0.11)	\$ (0.14)
	<b>Six Months Ended June 30, 2006</b>	Six Months Ended June 30, 2005
Net loss		
As reported	\$ (5,453,395)	\$ (5,352,077)
Stock-based compensation included in net loss as reported	975,222	175,750
Total stock-based employee compensation determined under fair value based method for all awards	(975,222)	(370,735)
Net loss, pro forma	\$ (5,453,395)	\$ (5,547,062)
Basic and diluted net loss per share		
As reported	\$ (0.28)	\$ (0.28)
Pro forma	\$ (0.28)	\$ (0.29)

## 6. STOCKHOLDERS' EQUITY

During the six months ended June 30, 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 options were withheld by the Company in payment of the exercise price for the exercised options, thus reducing the number of shares outstanding on a fully diluted basis.



## 7. SUBSEQUENT EVENTS

On July 21, 2006, the Company closed a private placement of 3,812,978 shares of its common stock and associated warrants to purchase 1,334,542 shares of its common stock at a purchase price of \$2.00 per share to certain institutional and other accredited investors for gross proceeds of approximately \$7.6 million. The private placement resulted in net proceeds to the Company of approximately \$7.2 million, after deduction of transaction expenses. The warrants are exercisable for a period of four years and nine months, beginning January 22, 2006, at an exercise price of \$2.75 per share. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities.

Also subsequent to the end of the Company's second quarter 2006, in July 2006, the Company reached an agreement with its employment practices liability insurance carrier pursuant to which the carrier has agreed to pay the Company \$500,000 in settlement of the Company's claim against the carrier for coverage in the personnel related matter described in more detail in note 4 to these financial statements. This settlement amount is expected to be received by the Company during the third quarter of 2006.

## **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 development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat both 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.

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., are gel formulations for transdermal administration that deliver bioidentical estradiol, testosterone, 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 U.S. Food and Drug Administration, or FDA approval to market the products. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted our New Drug Application, or NDA with the FDA in February 2006. We hope to commercially launch our Bio-E-Gel product upon 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 by year-end 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.

We also are developing our CaP technology, several of whose issued patents we license on an exclusive basis from the University of California, for novel vaccines, including avian flu and biodefense vaccines for toxins such as anthrax and ricin, and drug delivery systems. Our strategy with respect to CaP is to continue development of our CaP technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. We have entered into an agreement with the U.S. Army's Medical Research Institute of Infectious Disease for the development of non-injected biodefense vaccines, including anthrax, staph and ricin, and an agreement 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. We have also entered into 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, a subcontract with the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration, and 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.

## 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 until 2007 at the earliest depending upon the timing of the decision by the FDA on our 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 six months ended June 30, 2006, we received approximately \$244,000 from option exercises. Our cash, cash equivalents and short-term investments were \$4,505,231 as of June 30, 2006. On July 21, 2006, we completed a private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock at a purchase price of \$2.00 per share. The private placement resulted in net proceeds of approximately \$7.2 million, after deduction of transaction expenses. 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, including the net proceeds we received from our July 2006 private placement, 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 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, however, at this time we are seeking a sales/marketing partner to launch Bio-E-Gel if and when approved.

We spent an average of approximately \$350,000 per month on research and development activities during the six months ended June 30, 2006. Our research and development expenses decreased \$813,302 or 42 percent, to \$1,114,588 for the three months ended June 30, 2006 from \$1,927,890 for the same period ended June 30, 2005, and decreased \$1,946,104 or 48 percent to \$2,133,465 in the six months ended June 30, 2006 from \$4,079,569 for the same period in 2005. This reduction is primarily as a result of the completion of the Phase III clinical trial of Bio-E-Gel 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 remain at approximately the same level as the first six months of 2006 until the commencement of our LibiGel Phase III clinical program, which we expect to commence by year-end 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. We were in compliance with this requirement as of June 30, 2006.

Our general and administrative expenses increased \$553,438 or 71 percent, to \$1,328,612 for the three months ended June 30, 2006 from \$775,174 for the same period ended June 30, 2005, and increased \$2,055,962 or 137 percent to \$3,551,631 in the six months ended June 30, 2006 from \$1,495,669 in the same period in 2005. This increase was primarily as a result of increased legal expenses incurred due to a personnel-related matter and recognition of \$975,222 in non-cash, stock-based compensation expense during the six months ended June 30, 2006 compared to \$175,750 for the six months ended June 30, 2005 as a result of our adoption of SFAS No. 123(R) "Share-Based Payment" ("SFAS 123"). \$746,616 of the non-cash, stock-based compensation expense recorded in the six months ended June 30, 2006 related to a March 2006 issuance of stock options with immediate vesting to the non-employee members of our 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 \$2,224,900 and \$5,453,395 for the three and six months ended June 30, 2006, respectively, resulting in an accumulated deficit of \$55,141,715 as of June 30, 2006. 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; and
  - the cost of sales and marketing activities.

## Results of Operations

### *Three Months Ended June 30, 2006 Compared to Three Months Ended June 30, 2005*

The following table sets forth our results of operations for the three months ended June 30, 2006 and 2005.

	Three Months Ended June 30,				% Change
	2006	2005	\$	Change	
Revenue	\$ 175,251	\$ 45,596	\$	129,655	284.4%
Expenses					
Research and development	1,114,588	1,927,890		(813,302)	(42.2)%
General and administrative	1,328,612	775,174		553,438	71.4%
Interest income	70,158	101,926		(31,768)	(31.1)%
Net loss	\$ (2,224,900)	\$ (2,581,585)	\$	356,685	13.8%

We earned \$34,091 in licensing income during the three months ended June 30, 2006 due to the CaP option and material transfer agreement we entered into in September 2005 compared to no licensing income during the same period in 2005. We earned \$86,160 and \$45,596 in grant revenue during the three months ended June 30, 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.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Research and development expenses for the three months ended June 30, 2006 decreased 42 percent compared to research and development expenses for the three months ended June 30, 2005 primarily as a result of completion of the Phase III clinical trial of Bio-E-Gel in March 2005 and submission of our NDA for Bio-E-Gel in February 2006.

General and administrative expenses for the three months ended June 30, 2006 increased 71 percent compared to general and administrative expenses for the three months ended June 30, 2005, primarily as result of additional legal costs incurred due to a personnel-related matter.

Interest income for the three months ended June 30, 2006 decreased 31 percent compared to interest income during the three months ended June 30, 2005, as a result of lower invested cash balances, partially offset by higher interest rates on invested cash balances in 2006.

The overall decrease in net loss for the three months ended June 30, 2006 compared to the three months ended June 30, 2005 was primarily due to the reductions in research and development expense and an increase in revenue, partially offset by increased legal expenses, as described above.

***Six Months Ended June 30, 2006 Compared to Six Months Ended June 30, 2005***

The following table sets forth our results of operations for the six months ended June 30, 2006 and 2005.

	<b>Six Months Ended June 30,</b>				%
	<b>2006</b>	<b>2005</b>	<b>\$</b>	<b>Change</b>	<b>Change</b>
Revenue	\$ 259,930	\$ 74,273	\$	185,657	250.0%
Expenses					
Research and development	2,133,465	4,079,569		(1,946,104)	(47.7)%
General and administrative	3,551,631	1,495,669		2,055,962	137.5%
Interest income	166,337	199,873		(33,536)	(16.8)%
Net loss	\$ (5,453,395)	\$ (5,352,077)	\$	(101,318)	(1.9)%

We earned \$68,182 in licensing income during the six months ended June 30, 2006 due to the CaP option and material transfer agreement we entered into in September 2005 compared to no licensing income during the same period in 2005. We earned \$136,748 and \$74,273 in grant revenue during the six months ended June 30, 2006 and 2005, respectively. This increase is due to a subcontract we entered into with the University of Nebraska in December 2005.

Research and development expenses for the six months ended June 30, 2006 decreased 48 percent compared to research and development expenses for the six months ended June 30, 2005 primarily as a result of completion of the Phase III clinical trial of Bio-E-Gel in March 2005 and submission of our NDA for Bio-E-Gel in February 2006.

General and administrative expenses for the six months ended June 30, 2006 increased 137 percent compared to general and administrative expenses for the six months ended June 30, 2005, primarily as result of additional legal costs incurred due to a personnel-related matter and the recognition of \$975,222 in non-cash, stock-based compensation expense during the six months ended June 30, 2006 compared to \$175,750 for the six months ended June 30, 2005 as a result of our adoption of SFAS No. 123(R) "Share-Based Payment" ("SFAS 123"). Of the non-cash, stock-based compensation expense recorded in the six months ended June 30, 2006, \$746,616 related to a March 2006 grant of stock options with immediate vesting to the non-employee members of our Board of Directors, which were fully expensed on the grant date due to the terms of those awards. Our other stock option grants have remaining service lives of one to ten years and will be amortized over that period. Certain of our stock option grants also have milestone provisions, which will result in recognition of expense upon such milestones being reached.



Interest income for the six months ended June 30, 2006 decreased 17 percent compared to interest income during the six months ended June 30, 2005, as a result of lower invested cash balances, partially offset by higher interest rates on invested cash balances in 2006.

The overall increase in net loss for the six months ended June 30, 2006 compared to the six months ended June 30, 2005 was primarily the impact of our adoption of 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. As of June 30, 2006, 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 \$4,505,231 and \$9,101,531 at June 30, 2006 and December 31, 2005, respectively. We do not have any debt for borrowed money.

On July 21, 2006, we completed a private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock at a purchase price of \$2.00 per share. The private placement resulted in net proceeds of approximately \$7.2 million, after deduction of transaction expenses.

Also subsequent to the end of our second quarter 2006, in July 2006, we reached an agreement with our employment practices liability insurance carrier pursuant to which the carrier has agreed to pay us \$500,000 in settlement of our claim against the carrier for coverage in the personnel related matter described in more detail in notes 4 and 7 to our financial statements.

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, including the net proceeds we received from our July 2006 private placement, 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 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 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 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 \$4,829,746 for the six months ended June 30, 2006 versus cash used in operating activities of \$5,350,271 for the six months ended June 30, 2005. The decrease in cash used in operating activities primarily reflects the increase in non-cash, stock-based compensation expense during the six months ended June 30, 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 six month period. We received \$4,585,599 and \$4,605,576 from the net sale of auction rate securities for the six months ended June 30, 2006 and 2005, respectively. We used \$3,906 for the purchase of computer equipment during the six months ended June 30, 2006 and \$43,703 for the purchase of computer, lab and office equipment during the six months ended June 30, 2005. We entered into an irrevocable letter of credit with UBS AG in the amount of \$780,000 supported by our short term investment account with UBS AG. The outstanding balance under the letter of credit will decrease as payments are made to a former executive officer pursuant to a settlement agreement through December 2007. Net cash provided by financing activities was \$237,352 for the six months ended June 30, 2006 versus \$197,769 for the six months ended June 30, 2005, which during both periods consisted of cash received due to option exercises, and in the case of the six months ended June 30, 2005, due to warrant exercises as well.

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

We did not have any material commitments for capital expenditures as of June 30, 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, other than the entering into of a settlement agreement with a former executive officer pursuant to we agreed to pay the former executive post-termination installment payments in the aggregate amount of \$780,000 in equal installments in accordance with our regular payroll cycle through December 31, 2007.



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; and
  - new collaborative, licensing and other commercial relationships that we may establish

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

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (FIN 48), which clarifies the accounting for uncertainty in tax positions. This Interpretation requires that we recognize in our financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

### **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, including approval of our Bio-E-Gel NDA and the commencement of our Phase III clinical trials for LibiGel;
- 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 any litigation of which we may be subject, 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 June 30, 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 4 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. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2005 under the heading "Part I - Item 1A. Risk Factors," which could materially adversely affect our business, financial condition or operating results.

**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 June 30, 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**

We did not purchase any shares of our common stock or other equity securities during the three months ended June 30, 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**

(a) The Annual Meeting of Stockholders of BioSante was held on June 6, 2006.

(b) The results of the stockholder votes were as follows:

	<b>For</b>	<b>Against/ Withheld</b>	<b>Abstain</b>	<b>Broker Non-Vote</b>
<b>1. Election of Directors</b>				
Fred Holubow	14,404,525	393,258	0	0
Peter Kjaer	14,310,271	487,512	0	0
Ross Mangano	14,404,864	392,919	0	0
Victor Morgenstern	14,312,049	485,734	0	0
Edward C. Rosenow	14,402,861	394,922	0	0
Stephen M. Simes	14,304,799	492,984	0	0
Louis W. Sullivan	14,402,975	394,808	0	0
<b>2. Amendment to the Amended and Restated 1998 Stock Plan</b>				
	8,227,833	562,627	116,461	5,890,862
<b>3. Ratification of Appointment of Independent Registered Public Accounting Firm</b>				
	14,789,182	7,810	791	0

**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 BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan

10.2 Confidential Settlement Agreement effective as of May 26, 2006 among BioSante Pharmaceuticals, Inc., Leah Lehman and the other parties thereto 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.

August 14, 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**

Exhibit No.	Description	Method of Filing
10.1	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.2	Confidential Settlement Agreement effective as of May 26, 2006 among BioSante Pharmaceuticals, Inc., Leah Lehman and the other parties thereto as amended	Filed herewith
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