

BIOSANTE PHARMACEUTICALS INC  
Form 10-Q  
May 09, 2008  
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, 2008

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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer  Accelerated filer   
Non-accelerated filer (Do not check if smaller reporting company)   
Smaller reporting company

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

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

As of May 9, 2008, 26,798,607 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

---

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q  
MARCH 31, 2008

TABLE OF CONTENTS

Description	Page	
<b>PART I.</b>	<b>FINANCIAL INFORMATION</b>	
<b>ITEM 1.</b>	Condensed Financial Statements (unaudited)	
	Condensed Balance Sheets as of March 31, 2008 and December 31, 2007	3
	Condensed Statements of Operations for the three months ended March 31, 2008 and 2007	4
	Condensed Statements of Cash Flows for the three months ended March 31, 2008 and 2007	5
	Notes to the Condensed Financial Statements	6-13
<b>ITEM 2.</b>	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
<b>ITEM 3.</b>	Quantitative and Qualitative Disclosures About Market Risk	25
<b>ITEM 4.</b>	Controls and Procedures	26
<b>PART II.</b>	<b>OTHER INFORMATION</b>	27
<b>ITEM 1.</b>	Legal Proceedings	27
<b>ITEM 1A.</b>	Risk Factors	27
<b>ITEM 2.</b>	Unregistered Sales of Equity Securities and Use of Proceeds	28
<b>ITEM 3.</b>	Defaults Upon Senior Securities	28
<b>ITEM 4.</b>	Submission of Matters to a Vote of Security Holders	28
<b>ITEM 5.</b>	Other Information	28
<b>ITEM 6.</b>	Exhibits	28
<b>SIGNATURE PAGE</b>		29
<b>Exhibit Index</b>		30

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

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

BIOSANTE PHARMACEUTICALS, INC.  
Condensed Balance Sheets  
March 31, 2008 and December 31, 2007 (Unaudited)

	March 31, 2008	December 31, 2007
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 13,106,123	\$ 15,648,948
Short-term investments	14,472,050	15,005,976
Accounts receivable	30,218	14,566
Prepaid expenses and other assets	336,156	337,420
	27,944,547	31,006,910
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>59,748</b>	<b>54,896</b>
<b>OTHER ASSETS</b>		
Investment in MATC	140,000	140,000
Deposits	573,097	39,536
	\$ 28,717,392	\$ 31,241,342
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 2,301,248	\$ 710,575
Due to licensor - Antares	6,932	1,063
Accrued compensation	511,324	717,409
Other accrued expenses	102,750	77,712
Deferred revenue	4,545	9,091
	2,926,799	1,515,850
<b>STOCKHOLDERS' EQUITY</b>		
Capital stock		
Issued and outstanding		
2008 - 391,286; 2007 - 391,286 Class C special stock	391	391
2008 - 26,794,607; 2007 - 26,794,607 Common stock	84,500,322	84,206,583
	84,500,713	84,206,974
Accumulated other comprehensive loss	(602,000)	-
Accumulated deficit	(58,108,120)	(54,481,482)
	25,790,593	29,725,492
	\$ 28,717,392	\$ 31,241,342

See accompanying notes to the condensed financial statements.

BIOSANTE PHARMACEUTICALS, INC.  
Condensed Statements of Operations  
Three months ended March 31, 2008 and 2007 (Unaudited)

	Three Months Ended March 31,	
	2008	2007
<b>REVENUE</b>		
Licensing revenue	\$ 4,545	\$ 34,091
Grant revenue	25,648	16,517
Royalty revenue	15,404	-
Other revenue	17,400	-
	62,997	50,608
<b>EXPENSES</b>		
Research and development	2,677,946	987,470
General and administration	1,325,493	918,769
Depreciation and amortization	9,773	32,916
	4,013,212	1,939,155
OTHER - Interest income	323,577	146,529
<b>NET LOSS BEFORE INCOME TAX EXPENSE</b>		
TAX EXPENSE	(3,626,638)	(1,742,018)
INCOME TAX EXPENSE	-	75,000
<b>NET LOSS</b>	<b>\$ (3,626,638)</b>	<b>\$ (1,817,018)</b>
<b>BASIC AND DILUTED NET LOSS PER SHARE (Note 3)</b>		
	<b>\$ (0.13)</b>	<b>\$ (0.08)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>		
	27,185,893	23,367,493

See accompanying notes to the condensed financial statements.

## BIOSANTE PHARMACEUTICALS, INC.

## Condensed Statements of Cash Flows

Three months ended March 31, 2008 and 2007 (Unaudited)

	Three Months Ended March 31,	
	2008	2007
<b>CASH FLOWS (USED IN) PROVIDED BY OPERATING ACTIVITIES</b>		
Net loss	\$ (3,626,638)	\$ (1,817,018)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	9,773	32,916
Employee & director stock-based compensation	258,775	220,798
Stock warrant expense - noncash	34,964	-
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(532,297)	(8,405)
Accounts receivable	(15,652)	6,995,818
Accounts payable and accrued liabilities	1,409,626	(1,697,155)
Provision for contingencies	-	(137,647)
Due to licensor - Antares	5,869	-
Deferred revenue	(4,546)	(34,091)
Net cash (used in) provided by operating activities	(2,460,126)	3,555,216
<b>CASH FLOWS USED IN INVESTING ACTIVITIES</b>		
Purchase of short term investments	(68,074)	(60,988)
Purchase of capital assets	(14,625)	-
Net cash used in investing activities	(82,699)	(60,988)
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>		
Proceeds from sale or conversion of shares	-	142,662
Net cash provided by financing activities	-	142,662
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,542,825)</b>	<b>3,636,890</b>
<b>CASH AND CASH EQUIVALENTS</b>		
<b>AT BEGINNING OF PERIOD</b>	<b>15,648,948</b>	<b>7,653,852</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 13,106,123</b>	<b>\$ 11,290,742</b>
<b>SUPPLEMENTARY INFORMATION</b>		
Other information:		
Unrealized loss on available-for-sale securities, noncash	\$ 602,000	\$ -
Income tax paid	\$ -	\$ 75,000

See accompanying notes to the condensed financial statements.

BIOSANTE PHARMACEUTICALS, INC.  
FORM 10-Q  
MARCH 31, 2008

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited condensed 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, 2008, the results of operations for the three months ended March 31, 2008 and 2007, and the cash flows for the three months ended March 31, 2008 and 2007, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.

These unaudited interim condensed 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, 2007.

Correction of Prior Period Presentation

Subsequent to the issuance of the financial statements for the three months ended March 31, 2007 an error was identified in the presentation of expenses related to stock-based compensation, which had been presented as a separate line item on the face of the statements of operations, in order to include such amounts in the relevant statement of operations captions to which the stock compensation expense related. As a result, prior period statement of operations reclassifications have been made as follows:

For the three months ended March 31, 2007:

Account Description	As Previously Reported	Impact of Reclassification	As Corrected
Research and development expense	\$ 913,852	\$ 73,618	\$ 987,470
General and administrative expense	771,589	147,180	918,769
Stock compensation expense	220,798	(220,798)	—

2. COMPREHENSIVE LOSS

The components of the Company's comprehensive loss in the periods presented are:

Three Months Ended March	
2008	2007
31,	

Net loss	\$ 3,626,638	\$ 1,817,018
Other Comprehensive Loss:		
Unrealized Loss on Available for Sale Securities	602,000	-
Comprehensive Loss	\$ 4,228,638	\$ 1,817,018



### 3. 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, 2008 does not include options to purchase an aggregate of 1,901,441 shares of common stock with exercise prices ranging from \$2.10 to \$6.70 per share, and warrants to purchase an aggregate of 2,655,652 shares of common stock with exercise prices of \$2.15 to \$8.00 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, 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 ranging from \$2.15 to \$7.00 per share, because of their antidilutive effect on net loss per share.

### 4. LICENSE AGREEMENTS

In November 2006, the Company entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. ("Bradley") for the marketing of Elestrin, the Company's estradiol gel, in the United States. Effective February 21, 2008, Nycomed US Inc. ("Nycomed") completed its acquisition of Bradley. As a result, all references to Bradley have been changed to Nycomed in these condensed financial statements and the notes hereto. Upon execution of the sublicense agreement, the Company received an upfront payment of \$3.5 million. In addition, Nycomed paid the Company \$7.0 million and \$3.5 million in the first and fourth quarters of 2007, respectively, both triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter of 2006. The Company licenses the transdermal estradiol gel formulation that is used in Elestrin from Antares Pharma IPL AG ("Antares"). Under its license agreement with Antares, the Company is obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that the Company may receive. The aggregate \$14.0 million received from Nycomed (consisting of the following amounts paid by Nycomed to the Company: \$3.5 million in the fourth quarter of 2006, \$7.0 million in the first quarter of 2007 and \$3.5 million in the fourth quarter of 2007) was recognized as revenue in 2006 since the entire \$14.0 million was non-refundable, the Company had a contractual right to receive such payments, the contract price was fixed, the collection of the resulting receivable was reasonably assured and the Company had no further performance obligations under the license agreement. Nycomed also agreed to pay the Company additional payments of up to \$40 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. The Company is obligated to pay 25 percent of any sales-based milestone payments and a specified portion of royalties to Antares, which the Company recognizes as these payments are triggered, based on reported levels of Elestrin sales.

Nycomed commercially launched Elestrin in June 2007. The Company recognized \$15,404 and \$69,353 in royalty revenue from sales of Elestrin during the three months ended March 31, 2008 and the year ended December 31, 2007, respectively, which represent the gross royalty revenue received from Bradley and not the Company's corresponding obligation to pay Antares a portion of the royalties received. No royalty revenue was recorded for the three months ended March 31, 2007 as Elestrin was not launched by Nycomed until the second quarter of 2007. Considering the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, the Company recently approached Nycomed and currently is in discussions with Nycomed regarding Nycomed's promotion of Elestrin and the Company's alternatives going forward, including the possibility that the Company may reacquire the U.S. marketing rights to the product.

## 5. STOCK-BASED COMPENSATION

The BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the “1998 Plan”) permits the grant of stock options and stock awards to its employees, directors and consultants. As of March 31, 2008, 3,000,000 shares of the Company’s common stock were authorized for issuance under the 1998 Plan and 735,086 remained available for future grants, in each case, subject to adjustment as provided in the 1998 Plan. In March 2008, the Company’s Board of Directors, subject to approval of the Company’s stockholders, adopted the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the “2008 Plan”). If approved by the Company’s stockholders, the 2008 Plan will replace the 1998 Plan, which will be terminated with respect to future grants upon the effectiveness of the 2008 Plan. The number of shares of the Company’s common stock authorized for issuance under the 2008 Plan is 2,000,000, subject to adjustment as provided in the 2008 Plan. None of the shares of the Company’s common stock remaining available for grant under the 1998 Plan at the time of its termination will be carried forward for issuance under the 2008 Plan.

The Company believes that equity-based incentives, such as stock options, align the interest of its employees, directors and consultants with those of its stockholders. Options are 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. Certain of the Company’s stock options have performance condition-based vesting provisions which will result in expense when such performance conditions have been satisfied. 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.

The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan was \$258,775 and \$220,798 for the three months ended March 31, 2008 and 2007, respectively. No income tax benefit was recognized in the Company’s statement of operations for stock-based compensation arrangements due to the Company’s net loss position.

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 options granted during the three months ended March 31, 2008 and 2007.

	Three Months Ended March 31,	
	2008	2007
Expected life in years	6.01 years	10 years
Annualized volatility	67.65%	71.00%
Discount rate – bond equivalent yield	3.62%	4.82%
Expected dividend yield	0.00%	0.00%

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 NASDAQ Global Market (or The American Stock Exchange prior to November 5, 2007). Since the Company has a limited history with option exercises, the expected life was set to the entire life of the option grant through the fourth quarter of 2007. Beginning with options granted during the fourth quarter 2007, the Company began estimating the expected life of its options in a manner consistent with SAB 107, and SAB 110 beginning January 1, 2008, which allows companies to use a simplified method to estimate the life of options meeting certain criteria. The Company believes that the use of the simplified method provides a reasonable term for purposes of determining compensation costs for these grants, and expects to use the simplified method to estimate the expected life of future options for eligible grants. 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 1998 Plan during the three months ended March 31, 2008 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2007	1,427,191	\$ 3.50
Granted	474,250	3.52
Exercised	-	-
Forfeited or expired	-	-
Outstanding March 31, 2008	1,901,441	\$ 3.51
(weighted average contractual term)	7.9 years	
Exercisable at March 31, 2008	979,193	\$ 3.37
(weighted average contractual term)	6.42 years	

The aggregate intrinsic values of the Company's outstanding and exercisable options as of March 31, 2008 and 2007 were \$1,190,018 and \$2,193,323, respectively.

A summary of the 1998 Plan's non-vested options at December 31, 2007 and activity under the Plan during the three months ended March 31, 2008 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2007	656,333	\$ 3.65
Granted	474,250	3.52
Vested	(208,337)	3.27
Forfeited	-	-
Non-Vested at March 31, 2008	922,246	\$ 3.65

As of March 31, 2008, there was \$2,044,968 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the 1998 Plan. The cost is expected to be recognized over a remaining weighted-average vesting period of 2.35 years.

There were no options exercised under the 1998 Plan for the three months ended March 31, 2008.

The following table summarizes the stock-based compensation expense for employees and non-employees recognized in the Company's statements of operations for each period:

	Three Months Ended March	
	2008	2007
Stock-Based Compensation Expense:		
Research and development	\$ 84,382	\$ 73,618
General and administrative	174,393	147,180
Total stock-based compensation expense	\$ 258,775	\$ 220,798

The first quarter of 2007 column in the above table has been corrected to reflect the reclassification described in Note 1 to our condensed financial statements for the three months ended March 31, 2007.

In July 2007, the Company issued warrants to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrants are exercisable at an exercise price equal to \$8.00 per share with 50 percent of the warrants becoming exercisable on July 19, 2008 and the remainder becoming exercisable on July 19, 2009. The warrants are exercisable through and including July 18, 2010. The Company uses the Black-Sholes pricing model to value this warrant consideration and remeasures the award each quarter until the measurement date is established. During the three months ended March 31, 2008, the Company recorded \$34,964 in non-cash general and administrative expense pertaining to these warrants.

## 6. RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("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 are separately disclosed by level within the fair value hierarchy. SFAS 157 was effective for the Company January 1, 2008. See Note 8, Fair Value Measurements, for disclosure of the Company's adoption of SFAS 157.

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 was effective for the Company beginning January 1, 2008. The Company did not elect the fair value option for any of its existing financial assets and liabilities, and therefore the adoption of SFAS 159 did not have an impact on the Company's current results of operations or financial condition. The future impact, if any on the Company's results of operations or financial condition of electing the fair value option for future financial assets and liabilities, is not known.



In June 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 is effective for the Company prospectively for new contractual arrangements entered into beginning January 1, 2008. The adoption of EITF 07-3 did not have an impact on the Company's results of operations or financial condition.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133" ("SFAS 161") which is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after January 1, 2009, with early application encouraged. The adoption of SFAS 161 is not expected to have an impact on the Company's results of operations or financial condition.

## 7. STOCKHOLDERS' EQUITY

During the three months ended March 31, 2008, no options or warrants to purchase shares of common stock were granted or exercised, other than the grant of options to purchase an aggregate of 474,250 shares to certain employees of the Company and the Company's non-employee directors.

## 8. FAIR VALUE MEASUREMENTS

On January 1, 2008, the Company adopted the fair value methods required under SFAS No. 157 to value its financial assets and liabilities. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Financial assets recorded at fair value as of March 31, 2008 are classified in the table below in one of the three categories described above:

Description	March 31, 2008 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available for Sale Securities	\$ 14,472,050	\$ 1,074,050		\$ 13,398,000
Total	\$ 14,472,050	\$ 1,074,050		\$ 13,398,000

The Company's money market fund investment is classified as based on level 1 inputs, as the fair value is based on the quoted security prices in active market. The Company's auction rate securities investments are classified as based on level 3 inputs, due to the lack of currently observable market quotes, generally those obtained or corroborated through the auction process. The Company determines the fair value using unobservable inputs based on expected cash flows and collateral values, including assessments of counterparty credit quality, default risk underlying the security, overall capital market liquidity, and expectations of early redemption of the securities. Factors that may impact the Company's valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, counterparty risk and ongoing strength and quality of market credit and liquidity.

At January 1, 2008, the value of the auction rate securities were based on observable prices in active markets and as such would have been considered based on level 1 inputs. Due to the failure of auctions during first quarter 2008, the auction rate securities are valued based on level 3 inputs at March 31, 2008. As a result of the temporary declines in fair value of the Company's auction rate securities, which the Company attributes to liquidity issues affecting the credit markets associated with the securities rather than counterparty credit issues, the Company has recorded an unrealized loss of \$602,000 to Accumulated other comprehensive loss. The table below presents a reconciliation of the auction rate securities balance at March 31, 2008.

	Fair Value Measurements Using Significant Unobservable Inputs Auction Rate Securities
January 1, 2008	\$ -
Total gains or losses (realized/unrealized)	
Included in earnings	-
Included in other comprehensive loss	(602,000)
Purchases, Issuances or Settlements	-
Transfers in and/or out of Level 3	14,000,000



March 31, 2008 \$ 13,398,000

No gains or losses (realized or unrealized) were included in earnings for the quarter ended March 31, 2008.

12

---

The Company's securities for which auctions have failed will continue to accrue interest at the contractual rate and will be subject to auctions every 7 or 28 days, depending upon the securities, until the auction process succeeds, the issuers redeem the securities or the underlying debt instruments mature. If the Company determines that an issuer of the securities is unable to successfully close future auctions or redeem or refinance the obligations, the Company might be required to reclassify the investments from a current asset to a non-current asset. If an issuer's financial stability or credit rating deteriorates or adverse developments occur in the bond insurance market, the Company might be required to adjust the carrying value of its auction rate securities through a future impairment charge. The Company continues to monitor the market for auction rate securities and to consider its impact (if any) on the fair market value of the Company's investments. The Company currently believes the market values of our auction rate securities are not other than temporarily impaired and the Company expects to be able to recover the full par value of its investments, primarily due to government agency backing of the underlying securities, the investment-grade credit rating of each auction rate security in the Company's portfolio, the credit worthiness of the issuers, recent market developments and expectations regarding redemption or tender of these securities. As a result of the temporary declines in fair value of the Company's auction rate securities, which the Company attributes to liquidity issues affecting the related credit markets of the securities rather than counterparty credit issues, the Company has recorded an unrealized loss of \$602,000 to Accumulated other comprehensive loss.

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. The Management's Discussion and Analysis of Financial Condition and Results of Operations has been corrected to reflect the reclassification described in Note 1, Summary of Significant Accounting Policies to our condensed financial statements for the three months ended March 31, 2008.

Business Overview

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. Our primary products are gel formulations of testosterone and estradiol. Our key products include:

- LibiGel – once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD).
- Elestrin – once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause and marketed in the U.S.
- Bio-T-Gel – once daily transdermal gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.
- The Pill-Plus (triple hormone contraceptive) – once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

With respect to LibiGel, we believe based on discussions, meetings and agreements with the FDA, including a Special Protocol Assessment (SPA) received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD). The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel. The SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD. These SPA trials use our validated instruments to measure the clinical endpoints.

Currently, two Phase III safety and efficacy clinical trials are underway in addition to a separate Phase III cardiovascular safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III cardiovascular safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months at which time we intend to submit an NDA to the FDA. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years. 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. Alternatively, we may choose to sublicense LibiGel or another product for development and commercialization, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

We license the technology underlying many of our products, except Bio-T-Gel and The Pill-Plus, from Antares Pharma, Inc. Bio-T-Gel was developed and is fully-owned by us. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the licensed technology and required us to pay an up-front license fee. We license the technology underlying our proposed triple hormone contraceptives from Wake Forest University Health Sciences 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 is subsequently marketed.

We have entered into several sublicense agreements covering our products, including a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA agreed to develop our male testosterone gel, Bio-T-Gel, for the U.S. market, an agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal gel product and an agreement with Paladin Labs Inc. covering Canadian rights to certain of our products. We believe that our estrogen/progestogen combination transdermal hormone therapy gel product which we have sub-licensed to Solvay is not in active development by Solvay, and we do not expect its active development to occur at any time in the near future. 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 is subsequently marketed and a portion of any payments received from subsequent successful out-licensing efforts.

In November 2006, we entered into an exclusive sublicense agreement with Nycomed for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, we received an upfront payment of \$3.5 million. In addition, Nycomed paid us \$10.5 million in milestone payments during 2007 as a result of the FDA approval of Elestrin in the U.S., which occurred in December 2006. The Elestrin FDA approval was a non-conditional and full approval with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. Nycomed also agreed to pay us additional payments of up to \$40.0 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. We license the transdermal estradiol gel formulation that is used in Elestrin from Antares Pharma, Inc. Under our license agreement with Antares, we are obligated to pay Antares 25 percent of all licensing-related milestones and a portion of any future associated royalties. Nycomed commercially launched Elestrin in June 2007. We recognized \$15,404 and \$69,353 in royalty revenue from sales of Elestrin during the three months ended March 31, 2008 and the year ended December 31, 2007, respectively, which represent the gross royalty revenue received from Bradley and not our corresponding obligation to pay Antares a portion of the royalties received. No royalty revenue was recorded for the three months ended March 31, 2007 as Elestrin was not launched by Nycomed until the second quarter of 2007. Considering the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, we recently approached Nycomed and currently are in discussions with Nycomed regarding Nycomed's promotion of Elestrin and our alternatives going forward, including the possibility that we may reacquire the U.S. marketing rights to the product.

Our strategy with respect to our CaP technology 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, in November 2007, we signed a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial filler in aesthetic medicine. Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received an ownership position in MATC of approximately five percent of the common stock of MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

One of our strategic goals for 2008 is to continue to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. We continually evaluate various strategic alternatives with respect to our products and our company. Therefore, as a matter of course from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company.

#### Financial Overview

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. To date, we have used primarily equity financing, licensing income and interest income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future.

We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our marketing sublicensee for Elestrin, commercially launched Elestrin in June 2007. As a result, since such date, we have received royalties on net sales of Elestrin. However, such royalties have been minimal. In addition, as a result of the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, we expect that any future royalties we receive from Nycomed will be minimal as well. We recently approached Nycomed and currently are in discussions with Nycomed regarding Nycomed's promotion of Elestrin and our alternatives going forward, including the possibility that we may reacquire the U.S. marketing rights to the product. We recognized royalty revenue from Nycomed's net sales of Elestrin of \$15,404 during the quarter ended March 31, 2008. The royalty revenue presented in our statements of operations represents the gross royalty revenue to be received from Nycomed. Our corresponding obligation to pay Antares a portion of the royalties received which equaled \$6,932 for the quarter ended March 31, 2008, is recorded within general and administrative expenses.

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 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 12 months irrespective of our ability to obtain liquidity from our auction rate securities. (See “—Liquidity and Capital Resources” section) No assurance can be provided that we will not need or seek additional cash prior to such time. As an alternative to raising additional financing, we may license LibiGel or another product to a third party who may finance a portion or all of the continued development and if approved, commercialization of LibiGel or the other product, or we may elect to sell certain assets or rights we have under our existing license agreements.

We incurred expenses of approximately \$900,000 per month on research and development activities in the first quarter of 2008. Our research and development expenses increased \$1,690,476 or 171 percent, to \$2.7 million for the first quarter of 2008 from \$1.0 million for the first quarter of 2007, primarily as a result of the conduct of the two LibiGel Phase III safety and efficacy clinical studies and the LibiGel Phase III cardiovascular safety study. We expect our monthly research and development expenses to be approximately \$1.1 million per month for the foreseeable future. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) our development schedule, including the timing of our clinical trials; (2) resources available; (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 first quarter of 2008 increased \$406,724 or 44 percent, compared to the first quarter of 2007. This increase was due primarily to an increase in business development costs and other personnel-related costs. Our general and administrative expenses may fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense, legal, public and investor relations, business development, accounting and corporate governance and other fees and expenses incurred.

Our non-cash, stock-based compensation and consideration expense for the first quarter of 2008 increased \$72,941 or 33 percent, compared to the first quarter of 2007. The primary reason for this increase was the grant of options to purchase an aggregate of 474,250 shares of our common stock to new and certain existing employees and our non-employee directors in the first quarter of 2008.

We recognized a net loss for the first quarter of 2008 of \$3.6 million compared to a net loss of \$1.8 million for the first quarter of 2007. This increase was primarily due to the increased LibiGel clinical development expenses discussed above. We expect to incur substantial and continuing losses for the foreseeable future. This is true especially as our own product development programs expand and various clinical trials commence or continue, including in particular the Phase III clinical trial program for LibiGel and other trials and studies associated with LibiGel. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the progress, timing and cost of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
  - the timing and cost of obtaining necessary regulatory approvals for our proposed products;
- the commercial success and net sales of Elestrin, on which we currently receive royalties and potentially sales-based milestones, Nycomed’s willingness to continue promotion of the product or our ability to reacquire the product and sell it ourselves or relicense it to another third party;



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- the timing and cost of various cash and non-cash general and administrative items;
- the timing and cost of obtaining third party reimbursement for our products; and
- the progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions with entities that have businesses or technologies complementary to our business.

### Results of Operations

Three Months Ended March 31, 2008 Compared to Three Months Ended March 31, 2007

The following table sets forth our results of operations for the three months ended March 31, 2008 and 2007.

	Three Months Ended March 31,		\$ Change	% Change
	2008	2007		
Revenue	\$ 62,997	\$ 50,608	\$ 12,389	24.5%
Expenses				
Research and development	2,677,946	987,470	1,690,476	171.2%
General and administrative	1,325,493	918,769	406,724	44.3%
Interest income	323,577	146,529	177,048	120.8%
Net loss	\$ (3,626,638)	\$ (1,817,018)	\$ 1,809,620	99.6%

Revenue increased \$12,389 primarily as a result of the recognition of royalty revenue from Nycomed on Elestrin sales, partially offset by a reduction in deferred revenue related to a license associated with our CaP technology.

Research and development expenses for the three months ended March 31, 2008 increased 171 percent compared to the three months ended March 31, 2007 primarily as a result of the conduct of the two LibiGel Phase III safety and efficacy clinical studies and the LibiGel Phase III cardiovascular safety study.

General and administrative expenses for the three months ended March 31, 2008 increased 44 percent compared to the three months ended March 31, 2007 primarily as a result of an increase in business development and other personnel-related costs.

Non-cash, stock-based compensation expense increased as a result of the recognition of \$293,739 in non-cash stock-based compensation and consideration expense during the three months ended March 31, 2008 compared to \$220,798 for the three months ended March 31, 2007 due to an increase in the number of stock options granted and the number of stock options and warrants outstanding during the three months ended March 31, 2008 compared to the same period in 2007. Our outstanding stock options and warrants have remaining lives of one to ten years and will be amortized over the respective remaining vesting periods. Certain of our outstanding stock options have performance condition-based vesting provisions, which will result in recognition of expense when such performance conditions have been satisfied.

Interest income for the three months ended March 31, 2008 increased 121 percent compared to interest income for the three months ended March 31, 2007 as a result of higher average invested cash balances and higher average interest rates on invested cash balances during the three months ended March 31, 2008 compared to the same period in 2007.





## Liquidity and Capital Resources

### Working Capital

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our marketing sublicensee for Elestrin, commercially launched Elestrin in June 2007. As a result, since such date, we have received royalties on net sales of Elestrin. However, such royalties have been minimal. In addition, as a result of the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, we expect that any future royalties we receive from Nycomed will be minimal as well. We recently approached Nycomed and currently are in discussions with Nycomed regarding Nycomed's promotion of Elestrin and our alternatives going forward, including the possibility that we may reacquire the U.S. marketing rights to the product.

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 or if we reacquire the U.S. marketing rights to Elestrin from Nycomed and choose not to enter into a marketing relationship with another third party, 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 establish our own sales and marketing function, obtain regulatory approval of our other proposed products or complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. 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. Alternatively, we may choose to sublicense LibiGel or another product for development and commercialization, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

To date, we have used primarily equity financings, licensing income and interest 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 March 31, 2008, we had \$13.1 million of cash and cash equivalents and an additional \$14.5 million of short-term investments. We expect our cash balance to decrease as we continue to use cash to fund our operations. We do not have any outstanding debt.

Our cash and cash equivalents are invested in highly-rated, investment grade financial instruments consisting primarily of commercial paper. Our short-term investments consist primarily of money market investments and investment-grade auction rate securities, the underlying assets of which are portfolios of student loans backed by the federal government. Although such securities typically have been very liquid, such liquidity recently has been reduced as a result of events in the credit markets, including the market for these auction rate securities. Although we expect the markets for auction rate securities to recover in the near term and believe we will be able to restructure, redeem or liquidate our investments in our auction rate securities without any loss, the timing of such an outcome is uncertain. Currently there is no liquid market for these securities. Based on our expected cash expenditures, our cash and cash equivalents balance and other potential sources of cash, including our anticipated ability to borrow using these securities as collateral, we do not anticipate that the potential lack of liquidity of these investments in the near term will adversely affect our ability to execute our current business plan. However, no assurance can be provided that it will not do so.

Our securities for which auctions have failed will continue to accrue interest at the contractual rate and will be subject to auctions every 7 or 28 days, depending upon the securities, until the auction process succeeds, the issuers redeem the securities or the underlying debt instruments mature. If we determine that an issuer of the securities is unable to successfully close future auctions or redeem or refinance the obligations, we might be required to reclassify the investments from a current asset to a non-current asset. If an issuer's financial stability or credit rating deteriorates or adverse developments occur in the bond insurance market, we might be required to adjust the carrying value of our auction rate securities through a future impairment charge. We continue to monitor the market for auction rate securities and to consider its impact (if any) on the fair market value of our investments. We currently believe the market values of our auction rate securities are not other than temporarily impaired and we expect to be able to recover the full par value of our investments, primarily due to government agency backing of the underlying securities, the investment-grade credit rating of each auction rate security in our portfolio, the credit worthiness of the issuers, recent market developments such as the JPMorgan Chase tender offer described below and expectations regarding redemption or tender of these securities. As a result of the temporary declines in fair value of our auction rate securities, which we attribute to liquidity issues affecting the related credit markets of the securities rather than counterparty credit issues, we have recorded an unrealized loss of \$602,000 to Accumulated other comprehensive loss.

On April 22, 2008, JPMorgan Chase Bank, National Association commenced a tender offer to purchase any and all of the outstanding student loan asset-backed auction rate notes of each of the following securitization trusts: Collegiate Funding Services Education Loan Trust 2003-A, Collegiate Funding Services Education Loan Trust 2003-B and Collegiate Funding Services Education Loan Trust 2004-A. We own \$2.0 million in principal amount of such notes and have tendered all of such notes to JPMorgan. The offer is scheduled to expire at 5 p.m. (Eastern Time) on Tuesday, May 20, 2008, unless extended or earlier terminated. Each registered owner who validly tenders any or all of the owner's auction rate notes by the deadline will receive, subject to the terms and conditions of the tender offer, \$1,000 for each \$1,000 principal amount of the auction rate notes validly tendered, plus accrued and unpaid interest from the last applicable distribution date to, but not including, the settlement date, which is expected to be May 21, 2008.

We believe that our cash, cash equivalents and short-term investments as of March 31, 2008 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months irrespective of our ability to obtain liquidity from auction rate securities. However, we may seek to obtain additional financing prior to that time. In addition to our ability to liquidate our auction rate securities, our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;
  - the cost, timing and outcome of regulatory reviews of our proposed products;
  - the commercial success and net sales of Elestrin, on which we currently receive royalties and potentially sales-based milestones, Nycomed's willingness to continue promotion of the product or our ability to reacquire the product and sell it ourselves or re-license it to another third party;

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- the timing and cost of obtaining third party reimbursement for our products;
- the progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions with entities that have businesses or technologies complementary to our business.
  - our ability to license LibiGel or other products for development and commercialization;
    - the rate of technological advances;
  - ongoing determinations of the potential markets for and 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 and commercial introduction of our products.

### Uses of Cash and Cash Flow

We used cash in operating activities of \$2,466,050 for the three months ended March 31, 2008 versus receiving cash from operating activities of \$3,555,216 for the three months ended March 31, 2007. Cash used in operating activities for the three months ended March 31, 2008 was primarily the result of the net loss for that period, and to a lesser extent, an increase in prepaid expenses and other assets, offset primarily by an increase in accounts payable and accrued liabilities. Net cash provided by operations in the three months ended March 31, 2007 was due primarily to the receipt of a net payment of \$5,250,000 from Nycomed under the licensing agreement for Elestrin, offset primarily by the net loss and a decrease in accounts payable and other accrued liabilities.

Net cash used in investing activities was \$76,775 for the three months ended March 31, 2008 and \$60,988 for the three months ended March 31, 2007 and in each period consisted primarily of purchases of short-term investments. There was no net cash provided by or used in financing activities during the three months ended March 31, 2008. During the three months ended March 31, 2007, net cash provided by financing activities was \$142,662, which resulted from a warrant exercise.

We recorded and paid \$75,000 in income tax expense during the three months ended March 31, 2007 as we were subject to the corporate alternative minimum tax provision. Pursuant to further review and tax advice, we recorded and filed for a tax refund for that same amount. The \$75,000 tax refund was received in October 2007.

## Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of March 31, 2008. We have, however, several potential financial commitments, including product development milestone payments to the licensors of certain of our products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of March 31, 2008:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating Leases	\$ 154,110	\$ 154,110	\$ —	\$ —	\$ —
Obligation under License Agreement with Antares	6,932	6,932	—	—	—
Commitments Under License Agreement with Wake Forest	720,000	130,000	230,000	160,000	200,000
Total Contractual Cash Obligations	\$ 881,042	\$ 291,042	\$ 230,000	\$ 160,000	\$ 200,000

## 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 condensed financial statements and results of operations are based upon our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed 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, 2007. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2007.

## Recent Accounting Pronouncements

We refer you to the information contained in Note 5 to our condensed financial statements for the effect of recent accounting pronouncements on our results of operations and 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 condensed 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, enrollment and completion of our clinical trials and other regulatory status of our proposed products;
  - the future market and market acceptance of our products;
- the amount of royalty revenue we expect to receive from Nycomed on net sales of Elestrin and the future of our relationship with Nycomed;
  - the effect of new accounting pronouncements;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;
- collaborating, merging or acquiring entities that have businesses or technologies complementary to our business;
  - whether and how long our existing cash will be sufficient to fund our operations;
- valuation, expected returns and ability to liquidate investments in our investment portfolios based on risks affecting underlying securities or the markets in which they are bought and sold.
- 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 products if and when they are commercialized;
- our dependence upon Nycomed for the marketing and sale of Elestrin and Nycomed's willingness to continue promotion of Elestrin especially in light of its focus on dermatology and our ability to reacquire the U.S. marketing rights to Elestrin and either sell Elestrin ourselves or re-license the marketing rights to another third party on a timely basis or on substantially the same terms;
- our failure to obtain liquidity for our auction rate securities on a timely basis or obtain additional capital when needed or on acceptable terms;
- our failure to recover the carrying value of our investment in auction rate securities may be limited or non-existent in the near term;
  - our ability to realize the par value and accrued interest of our investment in auction rate securities;
    - the failure of our products to be commercially introduced for several years or at all;
    - our 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 other sublicensees, other than Nycomed, for the development, marketing and sale of certain of our other 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, including in particular our Phase III clinical trial program for LibiGel;
  - 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 implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;
- 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;
- 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, 2007 under the heading “Part I – Item 1A. Risk Factors” on pages 23 through 34 of such report and elsewhere in this report, including under the heading “Part II – Item 1A. Risk Factors.”

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, 2007 under the heading “Part I – Item 1A. Risk Factors” and included elsewhere in this report, including under the heading “Part II – 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, 2007 under the heading “Part I – Item 1A. Risk Factors” and included elsewhere in this report, including under the heading “Part II – 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 DISCLOSURES ABOUT MARKET RISK

We are exposed to interest rate risk on the investments of our excess cash and short-term investments, 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 typically have invested in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically have invested in short-term securities with maturities of less than one year.



At March 31, 2008, we held investments in \$13.4 million of investment-grade auction rate securities, the underlying assets of which are student loans backed by the federal government. As a result of the temporary declines in fair value of our auction rate securities, which we attribute to liquidity issues affecting the credit markets associated with these securities rather than counterparty credit issues, we have recorded an unrealized loss of \$602,000 to Accumulated other comprehensive loss. Although such securities typically have been very liquid, such liquidity recently has been impacted as a result of recent events in the credit markets, including the markets for these securities, and currently there is no liquid market for these securities. Although we believe we will be able to liquidate our investments in our auction rate securities in the near term without any loss, the timing of such an outcome is uncertain. Therefore, we are exposed to market risk related to our investments in auction rate securities. For further details, see “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations–Liquidity and Capital Resources.”

#### 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 officer and principal financial officer, 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 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, 2008 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

Not applicable.

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, 2007 under the heading “Part I – Item 1A. Risk Factors” which could materially adversely affect our business, financial condition or operating results. Other than as set forth below, there have been no material changes to such disclosures.

We are party to an exclusive sublicense agreement with Nycomed for the marketing of Elestrin in the United States as a result of which we are dependent upon Nycomed for the marketing and sale of Elestrin. Considering the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed’s focus in dermatology, we recently approached Nycomed and currently are in discussions regarding Nycomed’s promotion of Elestrin and our alternatives going forward, including the possibility that we may reacquire the U.S. marketing rights to the product.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States pursuant to which we received an upfront license payment, certain regulatory milestone payments and have the right to receive certain sales-based milestone payments, plus royalties on sales of Elestrin. Effective February 21, 2008, Nycomed US Inc. completed its acquisition of Bradley. We recognized \$15,404 and \$69,353 in royalty revenue from sales of Elestrin during the three months ended March 31, 2008 and the year ended December 31, 2007, respectively, which represent the gross royalty revenue received from Nycomed and not our corresponding obligation to pay Antares a portion of the royalties received. We, therefore, have not received any meaningful royalty revenue from Nycomed’s sales of Elestrin. Considering the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed’s focus in dermatology, we recently approached Nycomed and currently are in discussions with Nycomed regarding Nycomed’s promotion of Elestrin and our alternatives going forward, including the possibility that we may reacquire the U.S. marketing rights to the product. If Nycomed decides to retain its marketing rights to the product, we cannot assure you that Nycomed will remain focused on the commercialization of the product or will not otherwise breach the terms of our agreement, especially if Nycomed’s Elestrin sales do not increase significantly. If our agreement with Nycomed is not terminated and if Nycomed breaches its obligations under our agreement, our royalty revenue from Nycomed will continue to be adversely affected. If our agreement with Nycomed is terminated and we reacquire the U.S. marketing rights to the product and subsequently are unable to sublicense the product to another party on substantially the same or better terms or continue the future commercialization of the product ourselves, our royalty revenue will continue to be minimal.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Equity Securities

During the three months ended March 31, 2008, we did not issue or sell any shares of our common stock or other equity securities of ours 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 of ours during the three months ended March 31, 2008. 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, other than in connection with the cashless exercise of outstanding warrants and stock options.

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:

Exhibit

No.	Description
10.1	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's directors and executive officers
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 9, 2008

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

Exhibit No.	Description	Method of Filing
10.1	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's directors and executive officers	Incorporated by reference to Exhibit 10.30 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith