BIOSANTE PHARMACEUTICALS INC
Form 10-Q
May 11, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

x	**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
	For the quarterly period ended March 31, 2009
o	**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	**58-2301143**
(State or other jurisdiction of	(IRS Employer Identification Number)

incorporation or organization)

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 x NO o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES o NO o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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.

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

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

As of May 11, 2009, 27,042,764 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

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As used 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-T-Gel , The Pill-Plus and BioLook . This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Balance Sheets

March 31, 2009 and December 31, 2008 (Unaudited)

	March 31, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 10,162,346	$ 11,760,920
Short-term investments		3,026,334
Accounts receivable	356,751	229,775
Prepaid expenses and other assets	1,133,012	1,070,051
	11,652,109	16,087,080
PROPERTY AND EQUIPMENT, NET	786,303	814,894
OTHER ASSETS		
Investment in MATC	140,000	140,000
Deposits	637,397	637,397
	$ 13,215,809	$ 17,679,371
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,429,446	$ 3,182,089
Due to licensor - Antares	4,887	5,393
Accrued compensation	241,488	290,583
Other accrued expenses	428,905	374,887
	3,104,726	3,852,952
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2009 - 391,286; 2008 - 391,286 Class C special stock	391	391
2009 - 27,042,764; 2008 - 27,042,764 Common stock	86,067,964	85,732,688
	86,068,355	85,733,079
Accumulated deficit	(75,957,272)	(71,906,660)
	10,111,083	13,826,419
	$ 13,215,809	$ 17,679,371

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three months ended March 31, 2009 and 2008 (Unaudited)

	Three Months Ended March 31,	
	2009	**2008**
REVENUE		
Licensing revenue	**$**	**$ 4,545**
Grant revenue	**62,943**	**25,648**
Royalty revenue	**5,485**	**15,404**
Other revenue		**17,400**
	68,428	**62,997**
EXPENSES		
Research and development	**3,072,240**	**2,677,946**
General and administration	**1,029,202**	**1,325,493**
Depreciation and amortization	**29,246**	**9,773**
	4,130,688	**4,013,212**
OTHER - Interest income	**11,648**	**323,577**
NET LOSS	**$ (4,050,612)**	**$ (3,626,638)**
BASIC AND DILUTED NET LOSS PER SHARE (Note 3)	**$ (0.15)**	**$ (0.13)**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**27,434,050**	**27,185,893**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Three months ended March 31, 2009 and 2008 (Unaudited)

	Three Months Ended March 31, 2009	2008
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (4,050,612)	$ (3,626,638)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	29,246	9,773
Employee & director stock-based compensation	336,119	258,775
Stock warrant expense - noncash	11,657	34,964
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(62,961)	(532,297)
Accounts receivable	(126,976)	(15,652)
Accounts payable and accrued liabilities	(595,701)	1,409,626
Due to licensor - Antares	(506)	5,869
Deferred revenue		(4,546)
Net cash (used in) operating activities	(4,459,734)	(2,460,126)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES		
Redemption of short term investments	3,037,982	
Purchase of short term investments	(11,648)	(68,074)
Purchase of capital assets	(152,674)	(14,625)
Net cash provided by (used in) investing activities	2,873,660	(82,699)
CASH FLOWS (USED IN) FINANCING ACTIVITIES		
Proceeds from sale or conversion of shares	(12,500)	
Net cash (used in) financing activities	(12,500)	
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,598,574)	(2,542,825)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	11,760,920	15,648,948
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 10,162,346	$ 13,106,123
SUPPLEMENTARY INFORMATION		
Other information:		
Unrealized loss on available-for-sale securities, noncash	$	$ 602,000

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

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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, 2009, the results of operations for the three months ended March 31, 2009 and 2008, and the cash flows for the three months ended March 31, 2009 and 2008, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009.

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, 2008.

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

The Company has not commercially introduced any products and does not expect to do so in the foreseeable future. However, Nycomed US Inc. (Nycomed) (formerly Bradley Pharmaceuticals, Inc.), the Company s former marketing sublicensee for Elestrin, the Company s estradiol gel, commercially launched Elestrin in June 2007. As a result, from June 2007 until the termination of the Company s agreement with Nycomed and reacquisition of the rights to Elestrin on August 6, 2008, the Company received royalties on net sales of Elestrin by Nycomed. However, such royalties were minimal. Pursuant to the termination, release and settlement agreement with Nycomed, the Company reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin. In December 2008, the Company entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited (Azur) for the marketing of Elestrin and the sale of certain assets related to Elestrin. Azur has agreed to promote Elestrin using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. The Company recognized royalty and other revenues from sales of Elestrin of $5,485 during the three month period ended March 31, 2009.

The Company s business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. The Company has not commercially introduced any products and does not expect to do so in the foreseeable future. If and when the Company s proposed products for which it has not entered into marketing relationships receive U.S. Food and Drug Administration (FDA) approval, the Company may begin to incur other expenses, including sales and marketing related expenses if it chooses to market the products itself. The Company currently does not have sufficient resources on a long-term basis to complete the FDA approval process or commercialization of any of its current or proposed products for which the Company has not entered into marketing relationships. As a result, the Company may seek to obtain

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additional financing prior to the occurrence of any such events. As an alternative to raising additional financing, the Company may choose to sublicense LibiGel or another product to a third party, sell certain assets or rights the Company has under its existing license agreements or enter into other business collaborations or combinations, including the possible sale of the company.

The Company believes that its cash, cash equivalents and short-term investments of $10.2 million at March 31, 2009 will be sufficient to meet its liquidity requirements through at least the next 12 months. However, if the Company does not raise additional financing or secure another funding source for its clinical trial program, the Company will need to temporarily slow or delay new enrollment in its Phase III clinical trial program of LibiGel. It is the Company s intention to continue the clinical program for those women already enrolled to the extent that it has sufficient funding to do so. The potential modification in clinical trial enrollment may slow or delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long the Company needs to continue this modification.

Due to the current economic recession and market conditions, as well as the status of product development programs, there is uncertainty regarding whether additional financing will be available to the Company on favorable terms, or at all. If adequate funds are not available or are not available on acceptable terms when needed, the Company may be required to delay, scale back or eliminate some or all of its programs designed to obtain regulatory approval of its proposed products, including most importantly, the Phase III clinical trial program for LibiGel. As an alternative to raising additional financing, the Company may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization, sell certain assets or rights under the Company s existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. The Company may be required to relinquish greater or all rights to its proposed products at an earlier stage of development or on less favorable terms than it otherwise would choose. Failure to obtain adequate financing also may adversely affect the Company s ability to operate as a going concern and cause the Company to significantly curtail or cease ongoing operations.

2. COMPREHENSIVE LOSS

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

	Three Months Ended March 31,	
	2009	2008
Net loss	$ 4,050,612	$ 3,626,638
Other Comprehensive Loss:		
Unrealized Loss on Available for Sale Securities		602,000
Comprehensive Loss	$ 4,050,612	$ 4,228,638

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,

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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, 2009 does not include options to purchase an aggregate of 2,770,025 shares of common stock with exercise prices ranging from $1.27 to $6.70 per share, and warrants to purchase an aggregate of 2,698,705 shares of common stock with exercise prices of $2.75 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, 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 ranging from $2.15 to $8.00 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 for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of $3.5 million. In addition, during 2007, Nycomed paid the Company $10.5 million triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter of 2006. Under the Company s license agreement with Antares, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or its sub-licensees sell incorporating the licensed technology. Specifically, the Company paid Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that the Company received, which the Company recognized as these payments were earned, based upon reported levels of Elestrin sales. The aggregate $14.0 million received from Nycomed 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.

On August 6, 2008, the Company and Nycomed entered into a termination, release and settlement agreement pursuant to which the exclusive sublicense agreement dated November 7, 2006 between the Company and Nycomed was terminated and the Company reacquired the rights to Elestrin effective immediately. As a result, the Company paid Nycomed $100,000 and an additional $150,000 as a result of the December 2008 Elestrin sublicense to Azur Pharma International II Limited (Azur) as described below. Nycomed has agreed on behalf of itself and its affiliates not to market or sell any low-dose topical estrogen gel products for the treatment of menopausal hot flashes for a period of 12 months. The agreement also provides for a mutual release between the parties and the survival of the confidentiality, indemnification and insurance provisions of the exclusive sublicense agreement for a period of five years.

In December 2008, the Company signed an exclusive agreement with Azur for the marketing of Elestrin in the United States. Upon execution of the agreement, the Company received $3.325 million comprised of a $500,000 product licensing fee and $2.825 million for transfer of the Elestrin trademark and inventories, among other items. The Company paid Antares $462,500 as a result of signing the Azur agreement. The Company also is entitled to receive additional payments of up to an aggregate of $144.5 million if certain sales-based milestones are achieved. In addition, Azur has agreed to pay to the Company royalties on sales of Elestrin ranging from 10 percent to 20 percent depending on the annual sales level. Azur has agreed to market Elestrin using its women s health and urology sales force of approximately 50 sales people that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement.

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In December 2008, the Company signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. PharmaSwiss will submit the Company s approved U.S. NDA (new drug application) to the Israeli authorities based on the Company s results and manufacturing information. Approval in Israel is expected to take approximately one year from the date of such submission.

5. STOCK-BASED COMPENSATION

As of March 31, 2009, the Company has two stockholder-approved equity-based compensation plans under which stock options have been granted and currently are outstanding the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan, which was terminated with respect to future grants upon the effectiveness of the 2008 Plan. As of March 31, 2009, there were 2,000,000 shares of the Company s common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan. Of the 2,000,000 authorized shares, none had been issued and 901,500 shares were subject to outstanding stock options as of March 31, 2009.

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 three years and have 10-year contractual terms. In certain instances, stock options have been granted which were exercisable immediately. Certain of the Company s employee stock options had performance condition-based vesting provisions which resulted in expense when such performance conditions were 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 and 2008 Plans was $336,119 and $258,775 for the three months ended March 31, 2009 and 2008, respectively. No income tax benefit was recognized in the Company s statements 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, 2009 and 2008.

	Three Months Ended March 31,	
	2009	2008
Expected life in years	6.0 years	6.01 years
Annualized volatility	76.81%	67.65%
Discount rate bond equivalent yield	2.76%	3.62%
Expected dividend yield	0.00%	0.00%

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. Since the Company has a limited history with option exercises, the Company estimates the expected life of its options in a manner consistent with Staff Accounting Bulletin (SAB) 107, and SAB 110, 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

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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.

The Company expects all outstanding unvested stock options to vest in accordance with their normal vesting schedule. A summary of activity under the 1998 and 2008 Plans during the three months ended March 31, 2009 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2008	2,038,191	$ 3.66
Granted	848,500	1.50
Exercised		
Forfeited or expired	116,666	
Outstanding March 31, 2009	2,770,025	$ 2.93
(weighted average contractual term)	*8.01 years*	
Exercisable at March 31, 2009	1,361,525	$ 3.48
(weighted average contractual term)	6.20 *years*	

The aggregate intrinsic values of the Company s outstanding and exercisable options as of March 31, 2009 and 2008 were $0 and $1,190,018, respectively.

A summary of the 1998 and 2008 Plans non-vested options at December 31, 2008 and activity under the Plan during the three months ended March 31, 2009 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2008	1,015,165	$ 3.74
Granted	848,500	1.51
Vested	(338,498)	3.51
Forfeited	(116,666)	4.42
Non-Vested at March 31, 2009	1,408,500	$ 2.50

As of March 31, 2009, there was $1,876,766 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the 1998 and 2008 Plans. The cost is expected to be recognized over a remaining weighted-average vesting period of 1.91 years.

There were no options exercised under the 1998 and 2008 Plans for the three months ended March 31, 2009.

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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 31,	
	2009	2008
Stock-Based Compensation Expense:		
Research and development	$ 100,546	$ 84,382
General and administrative	235,573	174,393
Total stock-based compensation expense	$ 336,119	$ 258,775

In July 2007, the Company issued a warrant to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrant is exercisable at an exercise price equal to $8.00 per share with 50 percent of the underlying warrant exercisable on July 19, 2008 and the remaining 50 percent becoming exercisable on July 19, 2009. The warrant is 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, 2009, the Company recorded $4,174 in non-cash general and administrative expense pertaining to this warrant.

In May 2008, the Company issued warrants to purchase an aggregate of 80,000 shares of common stock to two individuals, the sole principal and a key executive officer, of an investor and public relations firm in return for various investor and public relations services. These warrants were originally exercisable at an exercise price equal to $4.78 per share with 1/12 of the warrants becoming exercisable on June 15, 2008 and the remainder becoming exercisable on a monthly basis thereafter through May 15, 2009 so long as the investor and public relations firm continued to provide services to the Company. The Company terminated its relationship with the firm effective March 31, 2009, at which time 66,667 of the warrants were then exercisable. The warrants that were exercisable as of March 31, 2009 will remain exercisable through and including May 14, 2011. The Company uses the Black-Scholes 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, 2009, the Company recorded $7,483 in non-cash general and administrative expense pertaining to these warrants.

6. STOCKHOLDERS EQUITY

During the three months ended March 31, 2009, options to purchase an aggregate of 848,500 shares were granted to certain employees of the Company and the Company s non-employee directors.

7. FAIR VALUE MEASUREMENTS

The Company has 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.

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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.

The table below presents a reconciliation of the level 3 fair value measurements, which are based on significant unobservable inputs, at March 31, 2009.

	Fair Value Measurements Using Significant Unobservable Inputs Auction Rate Securities	Fair Value Measurements Using Significant Unobservable Inputs Put Asset Related to Auction Rate Securities
December 31, 2008	$ 2,534,820	$ 465,180
Transfers into Level 3		
Purchases, redemptions, issuances or settlements	(2,534,820)	(465,180)
Total gains or losses (realized/unrealized) included in net loss		
March 31, 2009	$	$

In January 2009, all $3.0 million of our then short-term investments were converted into cash and cash equivalents as a result of the sale of $3.0 million of our auction rate securities to UBS Financial Services, Inc. and its affiliates for full par value plus accrued but unpaid interest.

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

This Management s Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the caption Forward-Looking Statements below. The following discussion of the results of operations and financial condition of BioSante should be read in conjunction with our condensed financial statements and the related notes thereto.

Business Overview

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

Our primary products are gel formulations of testosterone and estradiol. Our key products include:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment for the treatment of female sexual dysfunction (FSD).

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.

- Bio-T-Gel once daily transdermal testosterone 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.

With respect to LibiGel, we believe based on 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 Phase III cardiovascular and breast cancer 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) in menopausal women. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD, specifically, HSDD in naturally menopausal women.

Currently, three LibiGel Phase III trials are underway; two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer 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 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

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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.

With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006 with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive sublicense agreement with Bradley (which was subsequently purchased by Nycomed) for the marketing of Elestrin in the United States, which agreement was subsequently terminated by the parties effective August 6, 2008. Upon execution of the sublicense agreement with Nycomed, 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 and royalties on sales of Elestrin commencing in June 2007, when Nycomed commercially launched Elestrin. We did not receive any meaningful royalties from Nycomed on sales of Elestrin.

In August 2008, we entered into a termination, release and settlement agreement with Nycomed, pursuant to which we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin in exchange for, among other things, a $100,000 payment to Nycomed. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur for the marketing of Elestrin and the sale of certain assets related to Elestrin pursuant to which we received approximately $3.3 million, comprised of a $500,000 product sublicensing fee and approximately $2.8 million for transfer of the Elestrin trademark and inventories, among other items. Under the sublicense agreement, we are entitled to receive additional payments of up to an aggregate of $144.5 million if certain sales-based milestones are achieved. In addition, under the sublicense agreement, Azur has agreed to pay us royalties on sales of Elestrin ranging primarily from 10 percent to 20 percent depending primarily upon the annual sales levels. Azur has agreed to promote Elestrin using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. As a result of our sublicense agreement with Azur, we were required to pay Nycomed an additional $150,000. In December 2008, we signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. PharmaSwiss intends to submit our approved U.S. NDA (new drug application) to the Israeli authorities based on our results and manufacturing information. Approval of Elestrin in Israel is expected approximately one year after such submission.

We license the technology underlying certain of our products, other than Bio-T-Gel, The Pill-Plus and the CaP technology, from Antares Pharma, Inc. 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. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. 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 regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and is subsequently marketed.

In September 2008, we announced positive results of clinical work on our Pill-Plus triple hormone therapy oral contraceptive. The Pill-Plus adds a third hormone, an androgen, to the normal two hormone (estrogen and progestogen) oral contraceptive to prevent androgen deficiency which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to

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the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to improve FSD in oral contraceptive users, among other potential benefits.

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 line filler in aesthetic medicine (BioLook). 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. As another example, in November 2008, we announced that we had been awarded a $150,000 Small Business Innovation Research grant from the NIH to support our development of formulations for the pulmonary delivery of interferon alpha (IFN-α) using our CaP technology. The grant will be used to fund product development for IFN-α formulated with CaP particles for administration via inhalation. We have conducted extensive studies using our CaP vaccine adjuvant, BioVant, to increase the immune response of potential vaccines. We have focused on flu vaccines and based on recent reports of swine flu in the U.S. and around the world we plan to study BioVant in a potential swine flu vaccine.

One of our strategic goals 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. 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. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor in connection with our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. The world s economic and market conditions have limited the number of available strategic alternatives from which to choose. Taking into account current conditions, we have expanded our review beyond Deutsche Bank to include our own efforts and those of other investment banks including Oppenheimer & Co. Healthcare Investment Banking. No timetable has been set for completion of the exploration of strategic alternatives, and there can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. We do not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

Financial Overview

Substantially 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.

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We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our former marketing sublicensee for Elestrin, commercially launched Elestrin in June 2007. As a result, from June 2007 until the termination of our agreement with Nycomed and reacquisition of Elestrin in August 2008, we received royalties on net sales of Elestrin. Subsequent to August 2008, we recognized other revenue resulting from sales of Elestrin less a fee paid to Nycomed for distributing, storing and processing of Elestrin sales. We recognized $142,656 in other revenue and $34,200 in royalty revenue from sales of Elestrin during the year ended December 31, 2008. This royalty revenue amount represents the gross royalty revenue we received from Nycomed through December 31, 2008 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $21,830 for the year ended December 31, 2008, is recorded within general and administrative expenses in our condensed statements of operations. We recognized $5,485 in royalty revenue from sales of Elestrin during the quarter ended March 31, 2009. Our corresponding obligation to pay Antares a portion of the royalties received equaled $4,887 for the quarter ended March 31, 2009, 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 current or proposed products for which we have not entered into marketing relationships. We believe that our cash, cash equivalents and short-term investments of $10.2 million at March 31, 2009 will be sufficient to meet our liquidity requirements through at least the next 12 months. However, if we do not raise additional financing or secure another funding source for our clinical trial program, we will need to temporarily slow or delay new enrollment in our Phase III clinical trial program of LibiGel. It is our intention to continue the clinical program for those women already enrolled to the extent that we have sufficient funding to do so. The potential modification in clinical trial enrollment may slow or delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this modification.

As an alternative to raising additional financing, we may choose to sublicense LibiGel or another product to a third party, 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 incurred expenses of approximately $1.0 million per month on research and development activities during the first quarter of 2009. Our research and development expenses increased 15 percent to $3.1 million for the first quarter of 2009 compared to $2.7 million for the first quarter of 2008, primarily as a result of the conduct of the LibiGel Phase III clinical trials. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash and cash equivalents, 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 products; and (5) competitive developments.

Our general and administrative expenses for the first quarter of 2009 decreased $296,291, or 22 percent, compared to the first quarter 2008. This decrease was due primarily to a decrease in business development and other personnel-related costs.

Our non-cash, stock option and warrant expense for the first quarter of 2009 increased $54,037, or 18 percent, compared to the first quarter of 2008. The primary reason for this increase was the grant of options to purchase an aggregate of 848,500 shares of our common stock to new and existing

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employees and our non-employee directors in the first quarter of 2009. 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.

We recognized a net loss for the first quarter of 2009 of $4.1 million compared to a net loss of approximately $3.6 million for the first quarter of 2008. This increase primarily was due to the increased LibiGel clinical development expenses discussed above and lower interest income as a result of lower average invested cash balances and lower average interest rates on invested cash balances. 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 continue, including in particular the Phase III clinical trial program for LibiGel. The actual amount of these losses, however, may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts to evaluate various strategic alternatives available with respect to our products and our company;

- 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 commercial success and net sales of Elestrin;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our proposed products;

- the rate of technological advances;

- ongoing determinations of the potential markets for and commercial success of our proposed products;

- the timing and cost of various cash and non-cash general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products;

- the activities of our competitors; and

- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

In December 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of our common stock through the end of December 2010. We may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average

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market price of our common stock during the applicable pricing period. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase 300,000 shares of common stock at an exercise price of $4.00. The warrant will become exercisable on June 15, 2009, the six-month anniversary of the date of the purchase agreement (December 15, 2008), and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys fees and other direct costs related to the registration of these shares, we did not make any other payments to secure the CEFF. The CEFF does not impose any material restrictions on our operating or financial activities. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, including a minimum price for our common stock of $1.15 per share. As of March 31, 2009, we had not sold any shares to Kingsbridge under the CEFF.

Results of Operations

Three Months Ended March 31, 2009 Compared to Three Months Ended March 31, 2008

The following table sets forth our results of operations for the three months ended March 31, 2009 and 2008.

	Three Months Ended March 31,			
	2009	**2008**	**$ Change**	**% Change**
Revenue	$ 68,428	$ 62,997	$ 5,431	8.6%
Expenses				
Research and development	3,072,240	2,677,946	394,294	14.7%
General and administrative	1,029,202	1,325,493	(296,291)	(22.4)%
Interest income	11,648	323,577	(311,929)	(96.4)%
Net loss	$ (4,050,612)	$ (3,626,638)	$ 423,974	11.7%

Revenue increased $5,431 primarily as a result of the recognition of grant revenue from a $150,000 Small Business Innovation Research grant from the NIH to support our development of formulations for the pulmonary delivery of interferon alpha (IFN-α) using our CaP technology.

Research and development expenses for the three months ended March 31, 2009 increased 15 percent compared to the three months ended March 31, 2008 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, 2009 decreased 22 percent compared to the three months ended March 31, 2008 primarily as a result of a decrease in business development and other personnel-related costs.

Non-cash, stock-based compensation expense increased $54,037 as a result of the recognition of $347,776 in non-cash stock-based compensation and consideration expense during the three months ended March 31, 2009 compared to $293,739 for the three months ended March 31, 2008 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, 2009 compared to the same period in 2008. 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 employee stock options have performance condition-based vesting provisions, which will result in recognition of expense when such performance conditions have been satisfied.

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Interest income for the three months ended March 31, 2009 decreased 96 percent compared to interest income for the three months ended March 31, 2008 as a result of lower average invested cash balances and lower average interest rates on invested cash balances during the three months ended March 31, 2009 compared to the same period in 2008.

Liquidity and Capital Resources

Working Capital

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. 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 other products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including material sales and marketing and other 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 ongoing Phase III clinical trial program of LibiGel to require significant resources.

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, 2009, we had approximately $10.2 million of cash and cash equivalents. In January 2009, all $3.0 million of our then short-term investments were converted into cash and cash equivalents as a result of the sale of $3.0 million of our auction rate securities to UBS Financial Services, Inc. and its affiliates for full par value plus accrued but unpaid interest. We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations. As of March 31, 2009, we did not have any outstanding debt or existing credit facilities under which we could borrow funds, other than the Committed Equity Financing Facility described below.

In December 2008, we entered into a Committed Equity Financing Facility with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of our common stock through the end of December 2010. Under the terms of the CEFF, we are not obligated to utilize any of the $25.0 million available under the CEFF and there are no minimum commitments or minimum use penalties. We have access, at our discretion, to the funds through the sale of newly-issued shares of our common stock. The funds that can be raised under the CEFF over the two-year term will depend on the then-current price for our common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. We may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase 300,000 shares of common stock at an exercise price of $4.00. The warrant will become exercisable on June 15, 2009, the six-month anniversary of the date of the purchase agreement (December 15, 2008), and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys fees and other direct costs related to the registration of these shares, we did not make any other payments to secure the CEFF. The CEFF does not impose any material restrictions on our operating or financial activities. During the term of the CEFF, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to our common stock. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, including a minimum price for our common stock of $1.15 per share. As of March 31, 2009, we had not sold any shares to Kingsbridge under the CEFF.

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As of March 31, 2009, our cash and cash equivalents resided in a 100% FDIC insured, non-interest bearing checking account.

Our future capital requirements will depend upon numerous factors, including:

- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts to continue to evaluate various strategic alternatives available with respect to our products and our company;

- 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 commercial success and net sales of Elestrin;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our proposed products;

- the rate of technological advances;

- the commercial success of our proposed products;

- our general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products; and

- the activities of our competitors.

We believe that our cash and cash equivalents of $10.2 million at March 31, 2009 will be sufficient to meet our liquidity requirements through at least the next 12 months. However, if we do not raise additional financing or secure another funding source for our clinical trial program, we will need to temporarily slow or delay new enrollment in our Phase III clinical trial program of LibiGel. It is our intention to continue the clinical program for those women already enrolled to the extent that we have sufficient funding to do so. The potential modification in clinical trial enrollment may slow or delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this modification.

Due to the current economic recession and market conditions, as well as the status of our product development programs, we cannot assure you that additional financing will be available on terms favorable to us, or at all. If adequate funds are not available or are not available on acceptable terms when we need them, we may be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, including most importantly, as mentioned above, our Phase III clinical trial program for LibiGel. As an alternative to raising additional financing, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization, sell certain assets or rights we have under our existing license agreements

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or enter into other business collaborations or combinations, including the possible sale of our company. We may be required to relinquish greater or all rights to our proposed products at an earlier stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern and cause us to significantly curtail or cease ongoing operations.

If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we incur debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities.

Uses of Cash and Cash Flow

Net cash used in operating activities was $4.5 million for the three months ended March 31, 2009 compared to net cash used in operating activities of $2.5 million for the three months ended March 31, 2008. Net cash used in operating activities for the three months ended March 31, 2009 was primarily the result of the net loss for that period which was higher compared to the prior year period due to higher clinical trial related expenses, and to a lesser extent, a decrease in accounts payable and accrued liabilities. Net cash used in operating activities of $2.5 million 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 investing activities was $2.9 million for the three months ended March 31, 2009 compared to net cash used in investing activities of $82,699 for the three months ended March 31, 2008. Net cash provided by investing activities for the three months ended March 31, 2009 was due to the redemption of approximately $3.0 million in short-term investments, partially offset by purchases of capital assets. Net cash used in investing activities for the three months ended March 31, 2008 consisted primarily of purchases and sales, respectively, of short-term investments.

Net cash used in financing activities was $12,500 for the three months ended March 31, 2009 compared to $0 for the three months ended March 31, 2008.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of March 31, 2009. 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.

We refer you to the description of our contractual obligations and commitments as of December 31, 2008 as set forth in our annual report on Form 10-K for the year ended December 31, 2008. There were no material changes to such information since that date through March 31, 2009.

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.

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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, 2008. 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, 2008.

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 news 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, intend, plan, predict, anticipate, estimate, approximate, contemplate or continue and other words and terms of similar meaning. The 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 successful completion of our clinical trials and other regulatory status of our proposed products;
- approval of our drugs by the U.S. Food and Drug Administration that are currently in clinical development;
- 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;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market and market acceptance of our products;
- the effect of new accounting pronouncements;

- whether and how long our existing cash will be sufficient to fund our operations;

- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and

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- 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:

- 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 obtain additional capital when needed or on acceptable terms;
- the effects of the current global economic crisis and our ability to seek strategic alternatives or raise additional capital or otherwise conduct our business in light thereof;
- the level of market acceptance of Elestrin and our other products if and when they are commercialized;
- our dependence upon our licensees for the development, marketing and sale of certain of our products, including in particular Azur to sell Elestrin;
- 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;
- subject recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- the failure of certain 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;
- our ability to compete in a competitive industry;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;

- 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, 2008 under the heading Part I Item 1A. Risk Factors on pages 23 through 34 of such report and our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due

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to the uncertainties and factors described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008 under the heading Part I Item 1A. Risk Factors and included in our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report 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, 2008 under the heading Part I Item 1A. Risk Factors and included in our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report. 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

The primary objective of our investment activities is to preserve principal. To achieve this objective, we typically in the past have sought to invest in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically seek to invest our excess funding in cash and cash equivalents and high-quality, short-term securities with maturities of less than one year. Currently, all of our cash and cash equivalents reside in our 100% FDIC-insured non-interest bearing checking account.

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.

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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, 2009 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

There has been no material change in the risk factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2008 under the heading Part I Item 1A. Risk Factors, any one or more of which could materially adversely affect our business, financial condition or operating results.

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

Recent Sales of Unregistered Equity Securities

During the three months ended March 31, 2009, 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, 2009. 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
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)

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Exhibit No.	Description
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

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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 11, 2009

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)

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BIOSANTE PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
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