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

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 incorporation or organization)	(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 x NO o

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

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In this report, references to "BioSante," "the company," "we," "our" or "us," unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, 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.

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

	March 31, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS		
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
PROPERTY AND EQUIPMENT, NET	59,748	54,896
OTHER ASSETS		
Investment in MATC	140,000	140,000
Deposits	573,097	39,536
	$ 28,717,392	$ 31,241,342
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
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
STOCKHOLDERS' EQUITY		
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
REVENUE		
Licensing revenue	$ 4,545	$ 34,091
Grant revenue	25,648	16,517
Royalty revenue	15,404	-
Other revenue	17,400	-
	62,997	50,608
EXPENSES		
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
NET LOSS BEFORE INCOME TAX EXPENSE	(3,626,638)	(1,742,018)
INCOME TAX EXPENSE	-	75,000
NET LOSS	$ (3,626,638)	$ (1,817,018)
BASIC AND DILUTED NET LOSS PER SHARE (Note 3)	$ (0.13)	$ (0.08)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	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
CASH FLOWS (USED IN) PROVIDED BY OPERATING ACTIVITIES		
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
CASH FLOWS USED IN INVESTING ACTIVITIES		
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)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from sale or conversion of shares	-	142,662
Net cash provided by financing activities	-	142,662
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,542,825)	3,636,890
CASH AND CASH EQUIVALENTS		
AT BEGINNING OF PERIOD	15,648,948	7,653,852
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 13,106,123	$ 11,290,742
SUPPLEMENTARY INFORMATION		
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.
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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, 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 31,	
	2008	2007

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%

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 31,	
	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.

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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.

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 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.

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;

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- 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,	
	2008	2007