

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2008

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

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

Commission File Number 001-31812

**BIOSANTE PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**58-2301143**  
(IRS Employer Identification Number)

**111 Barclay Boulevard**  
**Lincolnshire, Illinois 60069**  
(Address of principal executive offices)

**(847) 478-0500**  
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES  NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Accelerated filer   
Smaller reporting company

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

As of August 11, 2008, 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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BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q  
JUNE 30, 2008

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

We own or have the rights to use various trademarks, trade names or service marks, including BioSante<sup>®</sup>, Elestrin<sup>™</sup>, LibiGel<sup>®</sup>, Bio-E-Gel<sup>®</sup>, Bio-E/P-Gel<sup>™</sup>, LibiGel-E/T<sup>™</sup>, Bio-T-Gel<sup>™</sup>, The Pill-Plus<sup>™</sup>, BioVant<sup>™</sup>, NanoVant<sup>™</sup>, BioLook<sup>™</sup>, CAP-Oral<sup>™</sup> and BioAir<sup>™</sup>. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

**BIOSANTE PHARMACEUTICALS, INC.**  
**Condensed Balance Sheets**  
**June 30, 2008 and December 31, 2007 (Unaudited)**

	June 30, 2008	December 31, 2007
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 10,325,577	\$ 15,648,948
Short-term investments	12,429,841	15,005,976
Accounts receivable	21,292	14,566
Prepaid expenses and other assets	677,330	337,420
	<u>23,454,040</u>	<u>31,006,910</u>
PROPERTY AND EQUIPMENT, NET	162,481	54,896
<b>OTHER ASSETS</b>		
Investment in MATC	140,000	140,000
Deposits	573,097	39,536
	<u>\$ 24,329,618</u>	<u>\$ 31,241,342</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 2,619,915	\$ 710,575
Due to licensor - Antares	4,972	1,063
Accrued compensation	712,626	717,409
Other accrued expenses	283,849	77,712
Deferred revenue	-	9,091
	<u>3,621,362</u>	<u>1,515,850</u>
<b>STOCKHOLDERS' EQUITY</b>		
Capital stock		
Issued and outstanding		
2008 - 391,286; 2007 - 391,286 Class C special stock	391	391
2008 - 26,881,950; 2007 - 26,794,607 Common stock	84,864,052	84,206,583
	<u>84,864,443</u>	<u>84,206,974</u>
Accumulated deficit	(64,156,187)	(54,481,482)
	<u>20,708,256</u>	<u>29,725,492</u>
	<u>\$ 24,329,618</u>	<u>\$ 31,241,342</u>

See accompanying notes to the condensed financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**  
**Condensed Statements of Operations**  
**Three and six months ended June 30, 2008 and 2007 (Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
<b>REVENUE</b>				
Licensing revenue	\$ 4,546	\$ 6,818	\$ 9,091	\$ 40,909
Grant revenue	10,242	9,700	35,890	26,217
Royalty revenue	11,081	52,928	26,485	52,928
Other revenue	-	-	17,400	-
	<u>25,869</u>	<u>69,446</u>	<u>88,866</u>	<u>120,054</u>
<b>EXPENSES</b>				
Research and development	3,934,118	1,405,847	6,612,064	2,393,317
General and administration	1,593,156	1,265,796	2,918,649	2,184,565
Depreciation and amortization	12,309	28,600	22,082	61,516
	<u>5,539,583</u>	<u>2,700,243</u>	<u>9,552,795</u>	<u>4,639,398</u>
OTHER - Impairment of short term investments	660,200	-	660,200	-
OTHER - Interest income	125,847	230,488	449,424	377,017
<b>NET LOSS BEFORE INCOME</b>				
TAX EXPENSE	(6,048,067)	(2,400,309)	(9,674,705)	(4,142,327)
<b>INCOME TAX EXPENSE</b>				
	-	-	-	75,000
<b>NET LOSS</b>	<u>\$ (6,048,067)</u>	<u>\$ (2,400,309)</u>	<u>\$ (9,674,705)</u>	<u>\$ (4,217,327)</u>
<b>BASIC AND DILUTED NET LOSS</b>				
PER SHARE (Note 3)	<u>\$ (0.22)</u>	<u>\$ (0.10)</u>	<u>\$ (0.36)</u>	<u>\$ (0.18)</u>
<b>WEIGHTED AVERAGE NUMBER</b>				
OF SHARES OUTSTANDING	<u>27,232,272</u>	<u>23,870,950</u>	<u>27,209,082</u>	<u>23,844,846</u>

See accompanying notes to the condensed financial statements.

**BIOSANTE PHARMACEUTICALS, INC.**  
**Condensed Statements of Cash Flows**  
Six months ended June 30, 2008 and 2007 (Unaudited)

	Six Months Ended June 30,	
	2008	2007
<b>CASH FLOWS (USED IN) PROVIDED BY OPERATING ACTIVITIES</b>		
Net loss	\$ (9,674,705)	\$ (4,217,327)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	22,082	61,516
Impairment of short term investments	660,200	-
Employee & director stock-based compensation	559,886	363,703
Stock warrant expense - noncash	63,613	-
(Gain) Loss on disposal of equipment	(951)	24,198
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(873,471)	39,737
Accounts receivable	(6,726)	6,933,190
Accounts payable and accrued liabilities	2,110,694	(1,372,858)
Provision for contingencies	-	(275,294)
Due to licensor - Antares	3,909	-
Deferred revenue	(9,091)	(40,909)
<b>Net cash (used in) provided by operating activities</b>	<b>(7,144,560)</b>	<b>1,515,956</b>
<b>CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>		
Redemption of short term investments	2,000,000	982
Purchase of short term investments	(84,065)	(108,533)
Purchase of capital assets	(128,716)	(7,194)
<b>Net cash provided by (used in) investing activities</b>	<b>1,787,219</b>	<b>(114,745)</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>		
Proceeds from sale or conversion of shares	33,970	18,327,105
<b>Net cash provided by financing activities</b>	<b>33,970</b>	<b>18,327,105</b>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(5,323,371)</b>	<b>19,728,316</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>15,648,948</b>	<b>7,653,852</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 10,325,577</b>	<b>\$ 27,382,168</b>
<b>SUPPLEMENTARY INFORMATION</b>		
<b>Other information:</b>		
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 June 30, 2008, the results of operations for the three and six months ended June 30, 2008 and 2007, and the cash flows for the six months ended June 30, 2008 and 2007, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 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 and six months ended June 30, 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 condensed statements of operations. In order to include such amounts in the relevant statement of operations captions to which the stock compensation expense related, prior period statements of operations reclassifications have been made as follows:

For the three months ended June 30, 2007:

<b>Account Description</b>	<b>As Previously Reported</b>	<b>Impact of Reclassification</b>	<b>As Corrected</b>
Research and development expense	\$ 1,347,361	\$ 58,486	\$ 1,405,847
General and administrative expense	1,181,377	84,419	1,265,796
Stock compensation expense	142,905	(142,905)	—

For the six months ended June 30, 2007:

<b>Account Description</b>	<b>As Previously Reported</b>	<b>Impact of Reclassification</b>	<b>As Corrected</b>
Research and development expense	\$ 2,261,213	\$ 132,104	\$ 2,393,317
General and administrative expense	1,952,966	231,599	2,184,565
Stock compensation expense	363,703	(363,703)	—

## 2. BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company's outstanding options and warrants are antidilutive; accordingly, there is no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and six months ended June 30, 2008 does not include options to purchase an aggregate of 2,053,191 and 1,977,316, respectively, shares of common stock with exercise prices ranging from \$2.10 to \$6.70 per share, and warrants to purchase an aggregate of 2,573,352 and 2,614,502, respectively, 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 and six months ended June 30, 2007 does not include options to purchase an aggregate of 1,349,357 and 1,360,573, respectively, shares of common stock, with exercise prices ranging from \$2.10 to \$6.70 per share, and warrants to purchase an aggregate of 2,479,652 and 2,506,931, respectively, 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.

## 3. 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 \$3,500,000. In addition, Nycomed paid the Company \$7,000,000 and \$3,500,000 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, which the Company recognizes as these payments are earned, based upon reported levels of Elestrin sales. The aggregate \$14,000,000 received from Nycomed (consisting of the following amounts paid by Nycomed to the Company: \$3,500,000 in the fourth quarter of 2006, \$7,000,000 in the first quarter of 2007 and \$3,500,000 in the fourth quarter of 2007) was recognized as revenue in 2006 since the entire \$14,000,000 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 had agreed to pay the Company additional payments of up to \$40,000,000 in the event certain sales-based milestones were achieved, plus royalties on sales of Elestrin.

Nycomed commercially launched Elestrin in June 2007. The Company recognized \$11,081 and \$26,485 in royalty revenue from sales of Elestrin during the three and six months ended June 30, 2008, respectively, which represent the gross royalty revenue received from Nycomed and not the Company's corresponding obligation to pay Antares a portion of the royalties received. The Company recognized \$52,928 in royalty revenue for the three months and six months ended June 30, 2007, as Elestrin was launched by Nycomed during the second quarter of 2007. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled \$4,972 and \$11,904 for the three and six month periods ended June 30, 2008, is recorded within general and administrative expenses.

On August 6, 2008, the Company and Nycomed entered into a termination, release and settlement agreement pursuant to which the exclusive sublicense agreement was terminated effective immediately and BioSante reacquired Elestrin. See Note 8 to our condensed financial statements.

In June 2008, the Company announced that it has engaged Deutsche Bank Securities Inc., an investment banking firm, as its strategic advisor in connection with its ongoing process to explore strategic alternatives in order to maximize value to the Company's stockholders. 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. The Company does not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

#### 4. STOCK-BASED COMPENSATION

The Company has two equity-based compensation plans under which stock options have been granted — the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the "1998 Plan") and the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the "2008 Plan"). On June 12, 2008, the Company's stockholders approved and adopted the 2008 Plan. The 2008 Plan replaced the 1998 Plan, which was terminated with respect to future grants upon the effectiveness of the 2008 Plan. There are 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. None of the shares of the Company's common stock remaining available for grant under the 1998 Plan at the time of its termination were 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 over a period of three years and have 10-year contractual terms. Certain of the Company's employee stock options have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. Beginning in March 2008, the Company began a program in which it annually will grant 10-year options to purchase 10,000 shares of common stock at an exercise price equal to the fair market value of the Company's common stock on the date of grant to the Company's non-employee directors and an additional 10-year option to purchase 5,000 shares of common stock at an exercise price equal to the fair market value of the Company's common stock on the date of grant to the Company's Chairman of the Board. These annual non-employee director stock options will be granted automatically on the last business day of each March and will vest on the one-year anniversary of the date of grant.



The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 and 2008 Plans was \$301,111 and \$559,886 for the three and six months ended June 30, 2008, respectively, and \$142,905 and \$363,703 for the three and six months ended June 30, 2007, 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 six months ended June 30, 2008 and 2007.

	Six Months Ended June 30,	
	2008	2007
Expected life in years	6 years	10 years
Annualized volatility	67.69%	71.00%
Discount rate – bond equivalent yield	3.47%	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 and 2008 Plans during the six months ended June 30, 2008 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2007	1,427,191	\$ 3.50
Granted	637,250	3.68
Exercised	-	-
Forfeited or expired	11,250	4.00
Outstanding June 30, 2008	2,053,191	\$ 3.56
(weighted average contractual term)	7.82 years	
Exercisable at June 30, 2008	980,528	\$ 3.37
(weighted average contractual term)	6.17 years	

The aggregate intrinsic value of the Company's outstanding and exercisable options as of June 30, 2008 was \$2,591,356 and \$1,361,234, respectively. The aggregate intrinsic value of the Company's outstanding and exercisable options as of June 30, 2007 was \$4,108,015 and \$2,354,192, respectively.

A summary of the 1998 Plan's non-vested options at December 31, 2007 and activity under the 1998 and 2008 Plans during the six months ended June 30, 2008 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2007	656,333	\$ 3.65
Granted	637,250	3.68
Vested	(209,670)	3.27
Forfeited	(11,250)	4.00
Non-Vested at June 30, 2008	<u>1,072,663</u>	<u>\$ 3.73</u>

As of June 30, 2008, there was \$2,149,208 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 2.12 years.

There were no options exercised under the 1998 Plan for the six months ended June 30, 2008.

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

	Three Months Ended June 30,	
	2008	2007
<b>Stock-Based Compensation Expense:</b>		
Research and development	\$ 91,259	\$ 58,486
General and administrative	209,852	84,419
Total stock-based compensation expense	<u>\$ 301,111</u>	<u>\$ 142,905</u>

	Six Months Ended June 30,	
	2008	2007
<b>Stock-Based Compensation Expense:</b>		
Research and development	\$ 175,641	\$ 132,104
General and administrative	384,245	231,599
Total stock-based compensation expense	<u>\$ 559,886</u>	<u>\$ 363,703</u>

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 six months ended June 30, 2008, the Company recorded \$42,049 in non-cash general and administrative expense pertaining to these warrants.

In May 2008, the Company issued warrants to purchase 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. The warrants are 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 continues to provide services to the Company. The warrants are exercisable through and including May 14, 2011. 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 six months ended June 30, 2008, the Company recorded \$21,564 in non-cash general and administrative expense pertaining to these warrants.

## 5. 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 7, Fair Value Measurements, for disclosure of the Company's adoption of SFAS 157.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 permits an entity to elect fair value as the initial and subsequent measurement attribute for many financial assets and liabilities. Entities electing the fair value option are required to recognize changes in fair value in earnings. SFAS 159 also requires additional disclosures to compensate for the lack of comparability that will arise from the use of the fair value option. SFAS 159 was effective for the Company beginning January 1, 2008. The Company did not elect the fair value option for any of its existing financial assets and liabilities, and therefore the adoption of SFAS 159 did not have an impact on the Company's current results of operations or financial condition. The future impact, if any on the Company's results of operations or financial condition of electing the fair value option for future financial assets and liabilities, is not known.

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

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

In May 2008, the FASB issued SFAS No. 162, "The Hierarchy of Generally Accepted Accounting Principles" ("SFAS 162") which provides a consistent framework for determining what accounting principles should be used when preparing financial statements under generally accepted accounting principles in the U.S. SFAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board (PCAOB) amendments to AU Section 411, "The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles." The adoption of SFAS 162 is not expected to have an impact on the Company's results of operations or financial condition.

In May 2008, the FASB issues SFAS No. 163, "Accounting for Financial Guarantee Insurance Contracts — an interpretation of FASB Statement No. 60" ("SFAS 163") which requires insurance enterprises that issue financial guarantee insurance contracts to initially recognize the premium received (or premiums expected to be received) for issuing the contract as unearned premium revenue and to recognize that premium revenue over the period in which the protection is provided and in proportion to it. SFAS 163 also requires recognition of a claim liability before an event of default if there is evidence that credit deterioration of the guaranteed obligation has occurred. SFAS 163 is effective for the Company on January 1, 2009. The adoption of SFAS 163 is not expected to have an impact on the Company's results of operations or financial condition.

## 6. STOCKHOLDERS' EQUITY

During the six months ended June 30, 2008, options to purchase an aggregate of 637,250 shares of common stock were granted to certain employees of the Company and the Company's non-employee directors. No stock options were exercised during such period.

During the six months ended June 30, 2008, warrants to purchase an aggregate of 80,000 shares of common stock were granted. See Note 4 above. During the six months ended June 30, 2008, warrants to purchase an aggregate of 15,800 shares of common stock were exercised for total cash proceeds of \$33,970. Warrants to purchase an aggregate of 71,543 shares of common stock were exercised on a cashless basis, for which 74,957 additional warrants were cancelled by the Company in payment of the exercise price for the exercised warrants. All of the exercised warrants were granted in prior years.

## 7. 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 June 30, 2008 are classified in the table below in one of the three categories described above:

Description	June 30, 2008 Balance	Quoted Prices in	Significant Other	Significant
		Active Markets for Identical Assets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Available for Sale Securities	\$ 12,429,841	\$ 1,090,041	—	\$ 11,339,800
Total	\$ 12,429,841	\$ 1,090,041	—	\$ 11,339,800

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

At January 1, 2008, the value of the auction rate securities were based on observable prices in active markets and as such would have been considered based on level 1 inputs. Due to the failure of auctions during the first half of 2008, the auction rate securities are valued based on level 3 inputs at June 30, 2008. As a result of the 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 other-than-temporary impairment loss of \$660,200 in the condensed statement of operations as of June 30, 2008. The table below presents a reconciliation of the auction rate securities balance at June 30, 2008.

	Fair Value Measurements Using Significant Unobservable Inputs	
	Auction Rate Securities	
January 1, 2008	\$	-
Transfers in and/or out of Level 3		14,000,000
Purchases, redemptions, issuances or settlements		(2,000,000)
Total gains or losses (realized/unrealized)		(660,200)
Included in net loss		(660,200)
Included in other comprehensive loss		-
June 30, 2008	\$	11,339,800

No realized gains or losses were included in the condensed statement of operations for the six months ended June 30, 2008.

The Company's auction rate securities will continue to accrue interest at the contractual rate and will be subject to attempted 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 are tendered or mature. The Company has observed instances of redemption and tendering of certain auction rate securities, including \$2,000,000 of securities which were successfully redeemed by the Company at par plus accrued and unpaid interest during the three months ended June 30, 2008. In addition, several auction rate securities dealers have recently announced settlement agreements with federal and state regulators under which they have agreed to purchase or provide liquidity for auction rate securities held by certain customers, and in some cases, provide such customers no cost loans prior to such repurchases or liquidity events. However, as of the filing of this report, the Company is unable to confirm the effect of any such settlement agreement on the Company's auction rate securities portfolio or otherwise predict how or when any additional redemptions or tenders may affect the remaining auction rate securities currently held in its portfolio or whether the Company may be able to hold its investments for a period of time sufficient for any anticipated recovery of market value. As a result, the Company recorded an other-than-temporary impairment charge of \$660,200 in the condensed statement of operations for the three months ended June 30, 2008, related to unrealized losses on its auction rate securities portfolio.

#### 8. SUBSEQUENT EVENT

On August 6, 2008, the Company and Nycomed entered into a termination, release and settlement agreement (the "Agreement") pursuant to which the exclusive sublicense agreement dated November 7, 2006 between the Company and Nycomed was terminated and BioSante reacquired Elestrin effective immediately. Pursuant to the Agreement, the Company has assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has agreed to provide the Company all information, documents and know-how that Nycomed has that relate to Elestrin, including the manufacture, use or sale of the product, and in exchange for reasonable compensation, to cooperate with the Company for a transition period of up to six months and to store the product in its warehouse facilities on behalf of the Company for up to 12 months in order to effect a smooth transition of the distribution of the product from Nycomed to the Company. The Company has agreed to pay Nycomed \$100,000 within five business days of the effective date of the Agreement and an additional \$150,000 within 15 days after the occurrence of certain events prior to January 1, 2010, including: (i) the grant by the Company to a third party of a sublicense or U.S. distribution rights to Elestrin; (ii) the transfer or assignment by the Company of all or substantially all of the rights to Elestrin in the U.S. to a third party; (iii) the acquisition of the Company through a merger, acquisition or combination with a third party; or (iv) the achievement of over \$1.5 million in net sales of Elestrin in the United States. 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.

We will pursue the best course of action to maximize the value of Elestrin. These considerations will become part of our formal strategic review being led by Deutsche Bank Securities Inc. who we recently engaged as our strategic advisor to assist us in our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. In the meantime, we intend to market and sell the product ourselves, although we do not intend to incur any material sales and marketing expenses in doing so and thus likely will not be successful in effecting a material amount of sales of Elestrin. If we choose to perform the manufacturing, distribution or marketing of Elestrin ourselves for an extended period of time, we may incur material associated expenses. We currently do not have sufficient resources to establish our own sales and marketing or manufacturing functions.

## 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 and six months ended June 30, 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 Phase III cardiovascular 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 safety and efficacy 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. These SPA trials use our validated instruments to measure the clinical endpoints. 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, two LibiGel Phase III safety and efficacy clinical trials are underway in addition to a 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. 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.

We have entered into several sublicense agreements covering our products, including a development and license agreement with Teva Pharmaceuticals USA, Inc. (Teva), pursuant to which Teva 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 our 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 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, which agreement, as described below, was recently terminated by mutual agreement of the parties effective August 6, 2008 and BioSante reacquired Elestrin. Upon execution of the sublicense agreement, we received an upfront payment of \$3,500,000. In addition, Nycomed paid us \$10,500,000 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 had agreed to pay us additional payments of up to \$40,000,000 in the event certain sales-based milestones were 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 \$11,081 and \$26,485 in royalty revenue from sales of Elestrin during the three and six months ended June 30, 2008, respectively, which represent the gross royalty revenue received from Nycomed and not our corresponding obligation to pay Antares a portion of the royalties received. Royalty revenue of \$52,928 was recorded for the three and six months ended June 30, 2007 as Elestrin was launched by Nycomed in the second quarter of 2007.



As previously announced, in light of the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, we approached Nycomed shortly after its acquisition of Bradley 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. Pursuant to an August 6, 2008 termination, release and settlement agreement with Nycomed, we reacquired Elestrin and have assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has agreed to provide us all information, documents and know-how that Nycomed has that relate to Elestrin, including the manufacture, use or sale of the product. In addition, Nycomed has agreed, in exchange for reasonable compensation, to cooperate with us for a transition period of up to six months and to store the product in its warehouse facilities on behalf of us for up to 12 months in order to effect a smooth transition of the distribution of the product from Nycomed to us. We have agreed to pay Nycomed \$100,000 within five business days of the effective date of the termination, release and settlement agreement and an additional \$150,000 within 15 days after the occurrence of certain events prior to January 1, 2010, including: (i) the grant by us to a third party of a sublicense or U.S. distribution rights to Elestrin; (ii) the transfer or assignment by us of all or substantially all of the rights to Elestrin in the U.S. to a third party; (iii) the acquisition of our company through a merger, acquisition or combination with a third party; or (iv) the achievement of over \$1.5 million in net sales of Elestrin in the United States. 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 termination, release and settlement 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.

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 (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.

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. 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 have 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. 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

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 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 on August 6, 2008, we received royalties on net sales of Elestrin. However, such royalties were minimal. We recognized royalty revenue from Nycomed's net sales of Elestrin of \$11,081 and \$26,485 during the three and six month periods ended June 30, 2008, respectively. 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 \$4,972 and \$11,904 for the three and six month periods ended June 30, 2008, respectively, is recorded within general and administrative expenses on our condensed statement of operations.

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 do not intend to incur material sales and marketing related expenses in the near future as a result of our re-acquisition of the marketing rights to Elestrin in the U.S. 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 our cash, cash equivalents and short-term investments will be sufficient to meet our liquidity requirements through at least the next 12 months. (See "—Liquidity and Capital Resources" section) However, we may seek to obtain additional financing prior to that time, especially if we are unable to restructure, redeem or liquidate our auction rate securities in the near future. If we are unable to restructure, redeem or liquidate our auction rate securities and are unable to obtain additional financing, we may be required to delay or scale back significantly our development activities. As an alternative to raising additional financing, we may choose to sublicense Elestrin, LibiGel 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 or enter into other business collaborations or combinations, including the possible sale of our company.

We incurred expenses of approximately \$1,100,000 per month on research and development activities during the six months ended June 30, 2008. Our research and development expenses increased \$2,528,271, or 180 percent, to \$3,934,118 for the three months ended June 30, 2008 from \$1,405,847 for the three months ended June 30, 2007, primarily as a result of the conduct of the LibiGel Phase III clinical studies. We expect our monthly research and development expenses to be approximately \$1,200,000 to \$1,400,000 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 three months ended June 30, 2008 increased \$327,360, or 26 percent, compared to the three months ended June 30, 2007. This increase was due primarily to an increase in investor and public relations expenses and business development 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 option and warrant expense for the three months ended June 30, 2008 increased \$186,855, or 131 percent, compared to the three months ended June 30, 2007. The primary reason for this increase was the grant of options and warrants to purchase an aggregate of 163,000 and 80,000 shares of our common stock, respectively, to new and certain existing employees and an investor and public relations firm in the second quarter of 2008.

We recognized a net loss for the three and six months ended June 30, 2008 of approximately \$6,000,000 and \$9,700,000, respectively, compared to a net loss of approximately \$2,400,000 and \$4,200,000 for the three and six months ended June 30, 2007. This increase was primarily due to the increased LibiGel clinical development expenses discussed above. During the three and six months ended June 30, 2008, our net loss included impairment charges related to the other-than-temporary impairment of auction rate securities totaling \$660,200. 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 success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including Deutsche Bank Securities' efforts to assist us as we 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 and our ability to sell it ourselves or re-license it to another third party;
- 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.

## Results of Operations

### Three Months Ended June 30, 2008 Compared to Three Months Ended June 30, 2007

The following table sets forth our results of operations for the three months ended June 30, 2008 and 2007.

	<u>Three Months Ended June 30,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2008</u>	<u>2007</u>		
Revenue	\$ 25,869	\$ 69,446	\$ (43,577)	(62.7)%
Expenses				
Research and development	3,934,118	1,405,847	2,528,271	179.8%
General and administrative	1,593,156	1,265,796	327,360	25.9%
Impairment of short-term investments	660,200	-	660,200	-
Interest income	125,847	230,488	(104,641)	(45.4)%
Net loss	\$ (6,048,067)	\$ (2,400,309)	\$ 3,647,758	152.0%

Revenue decreased \$43,577 primarily as a result of the decrease in royalty revenue from Nycomed on Elestrin sales during the three months ended June 30, 2008 compared to the same period in 2007.

Research and development expenses for the three months ended June 30, 2008 increased 180 percent compared to the three months ended June 30, 2007 primarily as a result of the conduct of the two LibiGel Phase III clinical studies.

General and administrative expenses for the three months ended June 30, 2008 increased 26 percent compared to the three months ended June 30, 2007 primarily as a result of an increase in investor and public relations expenses and business development and other personnel-related costs.

Non-cash, stock option and warrant expense increased to \$329,760 during the three months ended June 30, 2008 from \$142,905 for the three months ended June 30, 2007 due to an increase in the number of stock options granted and the number of stock options and warrants outstanding during the three months ended June 30, 2008 compared to the same period in 2007. Our outstanding stock options and warrants have remaining lives of less than one to ten years and will be amortized over the respective remaining vesting periods. Certain of our outstanding stock options have performance condition-based vesting provisions, which will result in recognition of expense when such performance conditions have been satisfied.

During the three months ended June 30, 2008, net loss included impairment charges related to the other-than-temporary impairment of auction rate securities totaling \$660,200.

Interest income for the three months ended June 30, 2008 decreased 45 percent compared to interest income for the three months ended June 30, 2007 as a result of lower average invested cash balances and lower average interest rates on invested cash balances during the three months ended June 30, 2008 compared to the same period in 2007.

**Six Months Ended June 30, 2008 Compared to Six Months Ended June 30, 2007**

The following table sets forth our results of operations for the six months ended June 30, 2008 and 2007.

	Six Months Ended June 30,		\$ Change	% Change
	2008	2007		
Revenue	\$ 88,866	\$ 120,054	\$ (31,188)	(26.0)%
Expenses				
Research and development	6,612,064	2,393,317	4,218,747	176.3%
General and administrative	2,918,649	2,184,565	734,084	33.6%
Impairment of short-term investments	660,200	-	660,200	-
Interest income	449,424	377,017	72,407	19.2%
Net loss	\$ (9,674,705)	\$ (4,217,327)	\$ 5,457,378	131.7%

Revenue decreased \$31,188 primarily as a result of the decrease in royalty revenue from Nycomed on Elestrin sales combined with a reduction in deferred revenue related to a license associated with our CaP technology during the six months ended June 30, 2008 compared to the same period in 2007.

Research and development expenses for the six months ended June 30, 2008 increased 176 percent compared to the six months ended June 30, 2007 primarily as a result of the conduct of the LibiGel Phase III clinical studies.

General and administrative expenses for the six months ended June 30, 2008 increased 34 percent compared to the six months ended June 30, 2007 primarily as a result of an increase in investor and public relations expenses and business development and other personnel-related costs.

Non-cash, stock option and warrant expense increased to \$623,499 during the six months ended June 30, 2008 from to \$363,703 for the six months ended June 30, 2007 due to an increase in the number of stock options granted and the number of stock options and warrants outstanding during the six months ended June 30, 2008 compared to the same period in 2007.

During the six months ended June 30, 2008, net loss included impairment charges related to the other-than-temporary impairment of auction rate securities totaling \$660,200.

Interest income for the six months ended June 30, 2008 increased 19 percent compared to interest income for the six months ended June 30, 2007 as a result of higher average invested cash balances during the six months ended June 30, 2008 compared to the same period in 2007.

**Liquidity and Capital Resources**

**Working Capital**

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our 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 on August 6, 2008, we received royalties on net sales of Elestrin. However, such royalties were minimal.

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. Simultaneous with the reacquisition of Elestrin, we have assumed all manufacturing, distribution and marketing responsibilities for Elestrin. We will pursue the best course of action to maximize the value of Elestrin. These considerations will become part of our formal strategic review being led by Deutsche Bank Securities Inc. who we recently engaged as our strategic advisor to assist us in our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. 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 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 June 30, 2008, we had approximately \$10,300,000 of cash and cash equivalents and an additional \$12,400,000 of short-term investments. We expect our cash balance to decrease as we continue to use cash to fund our operations. We do not have any outstanding debt.

Our cash and cash equivalents are invested in highly-rated, investment grade financial instruments consisting primarily of commercial paper. Our short-term investments consist primarily of money market investments and investment-grade auction rate securities, the underlying assets of which are portfolios of student loans backed by the federal government. Although such securities typically have been very liquid, such liquidity has been reduced significantly as a result of events in the credit markets, including the market for these auction rate securities. Although we believe these securities may be restructured, redeemed or repurchased in the future without any significant loss, we are not able to assess whether or not we will be able to hold the investments for a period of time sufficient for these events to occur for our specific investments. Currently, there is no liquid market for these securities.

Our investments continue to accrue interest at contractual rates and will be subject to attempted auctions every 7 or 28 days, depending upon the securities, until the auction process succeeds, the issuers redeem the securities, a successful tender offer occurs, or the underlying debt instruments mature. Although we have observed instances of redemption and tendering of similar auction rate securities, including certain securities that had been in our portfolio as of March 31, 2008 (as discussed below), we are not able to predict how or when additional redemptions or tenders may affect our remaining auction rate securities. During the three months ended June 30, 2008, we reviewed many factors in determining whether to recognize an impairment charge related to unrealized losses on our auction rate securities portfolio, including the magnitude of the unrealized loss compared to the cost of the investments, the length of time the investment has been in a loss position, methods of expected recovery of the investments and our intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery of market value. As a result of this review, as of June 30, 2008, we determined that the unrealized losses associated with our auction rate securities are other-than-temporary, and recorded impairment charges of \$660,200 which are included in the accompanying condensed statement of operations for the three and six months ended June 30, 2008. We continue to monitor the market for auction rate securities and to consider its impact (if any) on the fair market value of our investments.

On April 22, 2008, JPMorgan Chase Bank, National Association commenced a tender offer to purchase any and all of the outstanding student loan asset-backed auction rate notes of each of the following securitization trusts: Collegiate Funding Services Education Loan Trust 2003-A, Collegiate Funding Services Education Loan Trust 2003-B and Collegiate Funding Services Education Loan Trust 2004-A. We owned \$2,000,000 in principal amount of such notes and tendered all of such notes to JPMorgan and received the entire \$2,000,000 principal plus accrued and unpaid interest on May 21, 2008.

In August 2008, several auction rate securities dealers announced settlement agreements with federal and state regulators under which they have agreed to purchase or provide liquidity for auction rate securities held by certain customers, and in some cases, provide such customers no cost loans prior to such repurchases or liquidity events. However, as of the filing of this report, the Company is unable to confirm the effect of any such settlement agreement on the Company's auction rate securities portfolio.

We believe our cash, cash equivalents and short-term investments will be sufficient to meet our liquidity requirements through at least the next 12 months. However, we may seek to obtain additional financing prior to that time, especially if we are unable to restructure, redeem or liquidate our auction rate securities in the near future. If we are unable to restructure, redeem or liquidate our auction rate securities, we may be required to delay or scale back significantly our development activities. As an alternative to raising additional financing, we may choose to sublicense Elestrin, LibiGel 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 or enter into other business collaborations or combinations, including the possible sale of our company. If we raise additional funds through the issuance of equity securities, our stockholders may experience dilution, which could be significant. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. If financing is not available when required or is not available on acceptable terms, or additional sublicense agreements are not signed, we may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the development of our proposed products and commercial introduction of our products.

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

- our ability and the timing of our ability to liquidate our auction rate securities;
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including Deutsche Bank Securities' efforts to assist us as we 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 and our ability to sell it ourselves or re-license it to another third party;
- 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;

- our 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.

#### ***Uses of Cash and Cash Flow***

We used cash in operating activities of \$7,144,560 for the six months ended June 30, 2008 versus receiving cash from operating activities of \$1,515,956 for the six months ended June 30, 2007. Cash used in operating activities for the six months ended June 30, 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 related to an increase in our prepaid clinical trial-related costs, offset primarily by an increase in accounts payable and accrued liabilities. Net cash provided by operations in the six months ended June 30, 2007 was due primarily to the receipt of a net payment of \$5,250,000 from Nycomed under our former license agreement for Elestrin, offset primarily by the net loss and a decrease in accounts payable and other accrued liabilities.

Net cash provided by investing activities was \$1,787,219 for the six months ended June 30, 2008 due to the redemption of \$2,000,000 in short-term investments, partially offset by purchases of short-term investments and capital assets associated with added office space, furniture and equipment due to the conduct of our LibiGel clinical trial program. Net cash used in investing activities was \$114,745 for the six months ended June 30, 2007 and consisted primarily of purchases of short-term investments. During the six months ended June 30, 2008, net cash provided by financing activities was \$33,970, which resulted from a warrant exercise. Net cash provided by financing activities during the six months ended June 30, 2007 was \$18,327,105, which resulted from the completion of a private placement resulting in net proceeds to us of approximately \$17,300,000, after deduction of transaction expenses, and warrant and stock option exercises.

We recorded and paid \$75,000 in income tax expense during the six months ended June 30, 2007 as we were subject to the corporate alternative minimum tax provision. Pursuant to further review and tax advice, we recorded and filed for a tax refund for that same amount. The \$75,000 tax refund was received in October 2007.

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

We did not have any material commitments for capital expenditures as of June 30, 2008. We have, however, several potential financial commitments, including product development milestone payments to the licensors of certain of our products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments.

We refer you to the description of our contractual obligations and commitments as of March 31, 2008 as set forth in our quarterly report on Form 10-Q for the quarter ended March 31, 2008. There were no material changes to such information since that date through June 30, 2008.

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

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.



## Critical Accounting Policies

The discussion and analysis of our condensed financial statements and results of operations are based upon our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified certain of our accounting policies as critical accounting policies. Our critical accounting policies are described in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2007.

## Recent Accounting Pronouncements

We refer you to the information contained in Note 5 to our condensed financial statements for the effect of recent accounting pronouncements on our results of operations and financial condition.

## Forward-Looking Statements

This quarterly report on Form 10-Q contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "could," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained in the notes to our condensed financial statements and elsewhere in this report, including under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our forward-looking statements generally relate to:

- the timing of the commencement, enrollment and completion of our clinical trials and other regulatory status of our proposed products;
- the future market and market acceptance of our products;
- our anticipated sales and marketing expenses for Elestrin;
- the effect of new accounting pronouncements;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;

- our engagement of Deutsche Bank Securities and their efforts to assist us as we continue to evaluate various strategic alternatives with respect to our products and our company;
- collaborating, merging or acquiring entities that have businesses or technologies complementary to our business;
- whether and how long our existing cash will be sufficient to fund our operations;
- valuation, expected returns and ability to liquidate investments in our investment portfolios based on risks affecting underlying securities or the markets in which they are bought and sold;
- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

Forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors that affect all businesses operating in a global market as well as matters specific to us. These uncertainties and factors are difficult to predict and many of them are beyond our control. The following are some of the uncertainties and factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements:

- lack of market acceptance of Elestrin and our other products if and when they are commercialized;
- our ability to sell Elestrin ourselves or re-license the marketing rights to another third party on a timely basis or on substantially the same terms;
- our failure to obtain liquidity for our auction rate securities on a timely basis or obtain additional capital when needed or on acceptable terms;
- our failure to recover the carrying value of our investment in auction rate securities, which may be limited or non-existent in the near term;
- our ability to realize the par value and accrued interest of our investment in auction rate securities;
- the failure of our products to be commercially introduced for several years or at all;
- our failure to obtain and maintain required regulatory approvals on a timely basis or at all;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- our dependence upon our sublicensees for the development, marketing and sale of certain of our products;
- our dependence upon the maintenance of our licenses with Antares Pharma IPL AG, Wake Forest University Health Sciences and Cedars-Sinai Medical Center and the University of California – Los Angeles;
- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;
- the scope, timing and results of our clinical trials and other uncertainties associated with clinical trials;
- our ability to compete in a competitive industry;
- our ability to implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;

- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;
- adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
- changes in generally accepted accounting principles; or
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 under the heading "Part I – Item 1A. Risk Factors" on pages 23 through 34 of such report and 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 to the uncertainties and factors described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 under the heading "Part I – Item 1A. Risk Factors" and included 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, 2007 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**

We are exposed to interest rate risk on the investments of our excess cash and short-term investments, although due to the nature of our short-term investments, we have concluded that such risk is not material. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we typically have invested in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically have invested in short-term securities with maturities of less than one year.

At June 30, 2008, we held investments in approximately \$11,300,000 of high quality, investment-grade auction rate securities, the underlying assets of which are student loans backed by the federal government. As a result of the temporary declines in fair value of our auction rate securities, which we attribute to liquidity issues affecting the credit markets associated with these securities rather than counterparty credit issues, we have recorded an unrealized loss of \$660,200 to Accumulated other comprehensive loss. Although such securities historically were very liquid, such liquidity has been affected as a result of recent events in the credit markets, including the markets for these securities, and currently there is no liquid market for these securities. Although we believe we will be able to recover our investments in our auction rate securities in the near term without any loss, the timing of such an outcome is uncertain. Therefore, we are exposed to market risk related to our investments in auction rate securities. For further details, see "Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to reasonably ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated can provide only reasonable assurance of achieving the desired control objectives and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this quarterly report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that material information relating to our company is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

##### **Changes in Internal Control Over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during our quarter ended June 30, 2008 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

Not applicable.

**ITEM 1A. RISK FACTORS**

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2007 under the heading "Part I – Item 1A. Risk Factors" and our subsequent quarterly reports on Form 10-Q under the heading "Part II – Item 1A. Risk Factors," including this report, which could materially adversely affect our business, financial condition or operating results. Other than as set forth below, there have been no material changes to such disclosures.

*Our ongoing process to explore strategic alternatives may not result in a strategic transaction that is perceived by our stockholders as being a positive development, which may cause our stock price to decline.*

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. In June 2008, we announced that we have 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. Strategic alternatives we may pursue could include, but are not limited to, licenses, partnering or other collaboration agreements, a sale of some or all of our assets, a merger or sale of the entire company, continued execution of our operating plan, or other strategic transaction. 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.

*As a result of the reacquisition of Elestrin and the termination of our exclusive sublicense agreement with Nycomed, we have assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Although we intend to pursue the best course of action to maximize the value of Elestrin, no assurance can be provided that we will be successful in completing a strategic alternative with respect to Elestrin or otherwise. In addition, it is unlikely that we will effect a material amount of sales of Elestrin in the meantime.*

On August 6, 2008, we entered into a termination, release and settlement agreement with Nycomed US Inc. pursuant to which the exclusive sublicense agreement dated November 7, 2006 between BioSante and Bradley Pharmaceuticals, Inc. (Bradley was purchased by Nycomed in February 2008) was terminated and we reacquired Elestrin effective immediately. As previously announced, in light of the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, we approached Nycomed shortly after its acquisition of Bradley 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. Pursuant to the termination, release and settlement agreement, we assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has agreed to provide us all information, documents and know-how that Nycomed has that relate to Elestrin, including the manufacture, use or sale of the product, and in exchange for reasonable compensation, to cooperate with us for a transition period of up to six months and to store the product in its warehouse facilities on our behalf for up to 12 months in order to effect a smooth transition of the distribution of the product from Nycomed to us.

We will pursue the best course of action to maximize the value of Elestrin. These considerations will become part of our formal strategic review being led by Deutsche Bank Securities Inc. who we recently engaged as our strategic advisor to assist us in our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. In the meantime, we intend to market and sell the product ourselves, although we do not intend to incur any material sales and marketing expenses in doing so and thus likely will not be successful in effecting a material amount of sales of Elestrin. If we choose to perform the manufacturing, distribution or marketing of Elestrin ourselves for an extended period of time, we may incur material associated expenses. We currently do not have sufficient resources to establish our own sales and marketing or manufacturing functions.

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

### **Recent Sales of Unregistered Equity Securities**

In May 2008, we issued warrants to purchase 80,000 shares of our 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. The warrants are 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 continues to provide services to us. The warrants are exercisable through and including May 14, 2011. The issuance of these warrants was made in reliance on either Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. Certain inquiries were made by us to establish that such issuances qualified for such exemption from the registration requirements. In particular, we confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act each warrant holder gave assurance of investment intent and the certificates for the shares will bear a legend accordingly and the issuances of the warrants were made to a limited number of persons.

During the three months ended June 30, 2008, warrants to purchase an aggregate of 15,800 shares of common stock held by five warrant holders were exercised for total cash proceeds of \$33,970. The exercise price of the exercised warrants was \$2.15 per share. The issuance of the shares of our common stock upon exercise of these warrants was made in reliance on either Section 4(2) of the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. Certain inquiries were made by us to establish that such issuances qualified for such exemption from the registration requirements. In particular, we confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act each warrant holder gave assurance of investment intent and the certificates for the shares bear a legend accordingly and the issuances of the shares were made to a limited number of persons.

Except as described above, during the three months ended June 30, 2008, we did not issue or sell any shares of our common stock or other equity securities of ours that were not registered under the Securities Act of 1933, as amended.

**Issuer Purchases of Equity Securities**

Other than the withholding of 74,957 shares of our common stock in connection with the net exercise of warrants, we did not purchase any shares of our common stock or other equity securities of ours during the three months ended June 30, 2008. Our Board of Directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

(a) The Annual Meeting of Stockholders of BioSante was held on June 12, 2008.

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

	<u>For</u>	<u>Against/ Withheld</u>	<u>Abstain</u>	<u>Broker Non-Vote</u>
<b>1. Election of Directors</b>				
Fred Holubow	16,321,655	89,153	0	0
Peter Kjaer	16,186,999	223,809	0	0
Ross Mangano	16,317,173	93,635	0	0
Edward C. Rosenow, M.D.	16,315,438	95,370	0	0
Stephen M. Simes	16,196,916	213,892	0	0
Louis W. Sullivan, M.D.	16,315,238	95,570	0	0
<b>2. Approval of 2008 Stock Incentive Plan</b>	6,524,354	2,852,514	51,557	6,982,383
<b>3. Ratification of Selection of Independent Registered Public Accounting Firm</b>	16,297,892	34,545	78,371	0

**ITEM 5. OTHER INFORMATION**

On August 6, 2008, BioSante and Nycomed US Inc. entered into a termination, release and settlement agreement pursuant to which the exclusive sublicense agreement dated November 7, 2006 between BioSante and Bradley Pharmaceuticals, Inc. (Bradley was purchased by Nycomed in February 2008) was terminated and we reacquired Elestrin effective immediately. As previously announced, in light of the poor sales performance of Elestrin in the U.S. estrogen market and Nycomed's focus in dermatology, BioSante approached Nycomed shortly after its acquisition of Bradley regarding Nycomed's promotion of Elestrin and BioSante's alternatives going forward, including the possibility that BioSante may reacquire the U.S. marketing rights to the product.

Pursuant to the termination, release and settlement agreement, BioSante reacquired Elestrin and has assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has agreed to provide BioSante all information, documents and know-how that Nycomed has that relate to Elestrin, including the manufacture, use or sale of the product. In addition, Nycomed has agreed, in exchange for reasonable compensation, to cooperate with BioSante for a transition period of up to six months and to store the product in its warehouse facilities on behalf of BioSante for up to 12 months in order to effect a smooth transition of the distribution of the product from Nycomed to BioSante. BioSante has agreed to pay Nycomed \$100,000 within five business days of the effective date of the termination, release and settlement agreement and an additional \$150,000 within 15 days after the occurrence of certain events prior to January 1, 2010, including: (i) the grant by BioSante to a third party of a sublicense or U.S. distribution rights to Elestrin; (ii) the transfer or assignment by BioSante of all or substantially all of the rights to Elestrin in the U.S. to a third party; (iii) the acquisition of BioSante through a merger, acquisition or combination with a third party; or (iv) the achievement of over \$1.5 million in net sales of Elestrin in the United States. 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 termination, release and settlement 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.

BioSante disclosed the material terms of the exclusive license agreement in its current report on Form 8-K filed with the Securities and Exchange Commission on November 7, 2006 and filed a copy of the exclusive license agreement as an exhibit to its annual report on Form 10-K for the fiscal year ended December 31, 2006, both the description and agreement of which are incorporated herein by reference.

The foregoing description of the termination, release and settlement agreement is qualified in its entirety by reference to the actual terms of the agreement, a copy of which has been filed as Exhibit 10.6 to this report and is incorporated herein by reference.

#### ITEM 6. EXHIBITS

The following exhibits are being filed or furnished with this quarterly report on Form 10-Q:

Exhibit No.	Description
10.1	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago
10.2	BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan
10.3	Form of Incentive Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under 2008 Stock Incentive Plan
10.4	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under 2008 Stock Incentive Plan
10.5	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under 2008 Stock Incentive Plan
10.6	Termination, Release and Settlement Agreement dated as of August 6, 2008 between BioSante Pharmaceuticals, Inc. and Nycomed US Inc.*
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, is being requested with respect to designated portions of this document.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

August 11, 2008

**BIOSANTE PHARMACEUTICALS, INC.**

By: /s/ Stephen M. Simes  
Stephen M. Simes  
Vice Chairman, President and Chief Executive  
Officer  
(principal executive officer)

By: /s/ Phillip B. Donenberg  
Phillip B. Donenberg  
Chief Financial Officer, Treasurer and Secretary  
(principal financial and accounting officer)

**BIOSANTE PHARMACEUTICALS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**EXHIBIT INDEX**

Exhibit No.	Description	Method of Filing
10.1	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the SEC on April 21, 2008 (File No. 001-31812)
10.2	BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.3	Form of Incentive Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.4	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.5	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.4 to BioSante's Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.6	Termination, Release and Settlement Agreement dated as of August 6, 2008 between BioSante Pharmaceuticals, Inc. and Nycomed US Inc.*	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

\* Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, is being requested with respect to designated portions of this document.

## TERMINATION, RELEASE AND SETTLEMENT AGREEMENT

This termination, release and settlement agreement (the “**Agreement**”) is made and entered into as of this 6th day of August, 2008 (the “**Effective Date**”), between BioSante Pharmaceuticals, Inc., a Delaware corporation with offices at 111 Barclay Boulevard, Lincolnshire, Illinois 60069, on its own behalf and on behalf of its predecessors, successors, assigns, parents, subsidiaries, affiliates and/or affiliated companies (“**BioSante**”) and Nycomed US Inc., a New York corporation with offices at 60 Baylis Road, P.O. Box 2006, Melville, NY 11747, on its own behalf and on behalf of its predecessors, successors, assigns, parents, subsidiaries, affiliates and/or affiliated companies (“**Nycomed**”). BioSante and Nycomed may hereinafter be individually referred to as “Party” and collectively referred to as the “Parties”.

### RECITALS

WHEREAS, BioSante and Bradley Pharmaceuticals, Inc. (“**Bradley**”) have entered into an exclusive sublicense agreement, dated November 7, 2006 (the “**Sublicense Agreement**”), pursuant to which BioSante has sublicensed certain rights for Elestrin (f/k/a Bio-E-Gel) to Bradley, as more fully set forth in the Sublicense Agreement;

WHEREAS, Nycomed acquired Bradley on or about February 21, 2008 and succeeded to the rights and obligations of Bradley under the Sublicense Agreement;

WHEREAS, Nycomed no longer wishes to sell Elestrin and the Parties desire that all rights and licenses concerning the product be returned and transferred by Nycomed to BioSante on the terms and conditions set forth in this Agreement; and

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and subject to and on the terms and conditions herein set forth, the Parties hereto hereby agree as follows:

### ARTICLE 1

### DEFINITIONS

1.1 Capitalized terms used herein and not otherwise defined herein shall have the meanings set forth for such terms in the Sublicense Agreement.

### ARTICLE 2

### RETURN OF PRODUCT AND TERMINATION OF SUBLICENSE

#### 2.1 Transfer of NDA.

(a) Nycomed hereby assigns all right, title and interest in and to the NDA for the Product to BioSante, shall promptly transfer all documentation related to such NDA in Nycomed’s possession to BioSante, and agrees to take all further commercially reasonable action and promptly execute such further documents as may be reasonably necessary to give full effect to such assignment, including without limitation, submitting a letter to the FDA requesting transfer of the NDA to BioSante together with any related documents necessary to effect such transfer. For the avoidance of doubt, the foregoing activities by Nycomed shall be rendered without additional charge to BioSante and are included in the payment being made pursuant to Section 3.1.

(b) BioSante shall cooperate with Nycomed, and take all further commercially reasonable action, promptly comply with all reasonable requests by Nycomed and promptly execute any documents as may be reasonably necessary, to give full effect to the foregoing assignment. In any event, from and after the Effective Date, BioSante shall be responsible for the payment of all fees and expenses in connection with the maintenance of the NDA, and in connection with the foregoing transfer. Once the NDA for the Product is transferred to BioSante, BioSante shall be responsible for all obligations, responsibilities and liabilities with respect to the NDA, and Nycomed’s obligations with respect to the NDA shall cease, except as specifically provided in this Agreement.

2.2 Transfer of Other Information. Nycomed hereby assigns and shall immediately provide to BioSante any and all material information, documents, and know-how Nycomed has in its possession that relate to the Product (including the manufacture, use or sale of the Product), and any other information and documents in Nycomed’s possession that BioSante may reasonably request, and further including all reasonably accessible copies in whatever form or media; provided, however, that Nycomed may retain one copy of the foregoing for purposes of complying with its obligations under this Agreement and the Sublicense Agreement. Nycomed represents and warrants that Nycomed (including through its predecessor, Bradley) has not made any modifications or improvements to the patents and know-how provided by BioSante relating to the Product. For the avoidance of doubt, the foregoing activities by Nycomed shall be rendered without additional charge to BioSante and are included in the payment being made pursuant to Section 3.1.

#### 2.3 Regulatory Transition Services by Nycomed.

(a) Nycomed shall cooperate with BioSante for a reasonable transition period, not to exceed six (6) months after the Effective Date but no longer than as provided in Section 4.5, so that BioSante may exercise its rights under this Agreement and effect a smooth transition of the Product from Nycomed to BioSante. Such cooperation shall include the following activities: (i) post FDA Approval regulatory obligations for the Product, including without limitation, the preparation of annual reports and reports of adverse events for submission to the FDA by BioSante, and cooperating with governmental regulatory agencies regarding the current FDA Approval; and (ii) investigating all complaints and adverse drug experiences related to the Product. For the avoidance of doubt, the services to be provided by Nycomed pursuant to this Section 2.3(a) shall not include the review of promotional materials.

(b) BioSante may request services described in Section 2.3(a) from time to time during the transition period set forth therein. At the time of such request, BioSante may also request that Nycomed provide a non-binding good faith estimate of the time required to complete the requested services. In the event that BioSante is not satisfied with the estimate, BioSante may elect to withdraw its request for such services from Nycomed.

(c) BioSante shall reimburse Nycomed for all of its out-of-pockets costs and expenses (including costs paid to third parties for certain of the foregoing activities) incurred in connection with Nycomed’s performance of the foregoing activities in this Section 2.3. In addition, BioSante shall pay Nycomed at the rate of \$220 per hour for Nycomed’s time spent on the foregoing activities. Following the end of each calendar month, Nycomed shall issue an invoice to BioSante setting forth the time spent by Nycomed personnel on such matters, and the expenses incurred in connection with such activities. BioSante shall pay such invoices within thirty (30) days after receipt of such invoices.

2.4 Termination of Sublicense Agreement. As of the Effective Date, and subject to the terms of this Agreement, the Sublicense Agreement is hereby terminated by the mutual agreement of BioSante and Nycomed and is of no further force and effect, and BioSante and Nycomed shall have no further rights and/or obligations under the Sublicense Agreement, including without limitation the effect of termination provisions set forth in Sections 16(f) through (j) of the Sublicense Agreement, except as specifically provided for herein. The Parties agree that the effect of the termination of the Sublicense Agreement shall be as provided in this Agreement. The performance of all obligations of Nycomed under this Agreement shall be for and on behalf of BioSante, unless otherwise specifically provided. Notwithstanding the foregoing, solely to the extent necessary for Nycomed to perform its obligations under this Agreement, BioSante grants Nycomed a limited, non-exclusive, non-sublicensable, non-transferable license to the patents and know-how relating to the Product previously licensed to Nycomed pursuant to the Sublicense Agreement.

2.5 Communications with FDA. After the Effective Date, Nycomed shall provide BioSante with copies of all correspondence and documents to and from the FDA with respect to the Product in its possession, and all notices received from the FDA related thereto, within three (3) business days following transmission or receipt from the FDA. However, after the Effective Date, Nycomed shall not communicate with the FDA with respect to the Product. BioSante shall be responsible for all communications with the FDA with respect to the Product after the Effective Date.

#### 2.6 Marketing Materials.

(a) Nycomed shall, within fifteen (15) days of the Effective Date, provide BioSante with copies of all materials concerning the marketing, sale and distribution of the Product in its possession, including but not limited to, market research performed by or for Nycomed or Bradley and all customer lists, sales data, and marketing plans for the Product in order to assist BioSante with a smooth transition of the Product from Nycomed. BioSante may use, including transfer, such materials and information, provided however that BioSante must remove Nycomed’s name from any such materials and information prior to such use. Nycomed shall have no further obligations with respect to such materials.

(b) All of the materials being provided pursuant to Section 2.6(a) are being provided “AS IS, WHERE IS” and Nycomed expressly disclaims any representations or warranties of any kind, express or implied, as to such materials. BioSante shall be solely responsible for the accuracy of the information contained in the materials and compliance with all laws, rules and regulations.

#### 2.7 Third Party Agreements.

(a) All managed care contracts, commercial insurance contracts, government contracts, contracts providing chargebacks, distribution agreements and manufacturing arrangements concerning the manufacture, marketing, sale and distribution of the Product to which Nycomed is a party are identified on Schedule 2.7.

(b) With respect to all manufacturing arrangements described on Schedule 2.7, promptly following the Effective Date, Nycomed shall notify the other party to such agreements that Nycomed no longer has rights to the Product and advising that the Product is to be removed from the list of products covered by such arrangements. Nycomed shall notify all manufacturers that BioSante will, from and after the Effective Date, be responsible for the Product. Nycomed will transfer all manufacturing agreements, protocols, documentation and samples relating to the manufacture of the Product in its possession to BioSante, and will notify all manufacturers that they may share with BioSante all manufacturing history for the Product, including but not limited to Product (and samples) manufacturing records and files, out of spec reports, and stability studies. As of the Effective Date, BioSante shall be responsible for entering into any manufacturing agreements, as BioSante deems necessary or appropriate, for the Product. All on-going work (e.g., stability studies) will be continued by BioSante at its sole option and expense from the Effective Date; Nycomed will not cause any stability studies or any other ongoing activities essential to the manufacture or ongoing stability studies of the Product to be cancelled or delayed. BioSante acknowledges that activities relating to several development activities, including but not limited to samples, bottles and containers for the Product have been suspended by Nycomed. In the event that BioSante elects to re-commence any of the foregoing activities, BioSante shall be responsible for such activities, including without limitation all costs associated with such activities, following the Effective Date. Nycomed shall be responsible for the costs associated with ongoing stability studies for Product and Product samples through the Effective Date, and BioSante shall be responsible for such costs following the Effective Date.

(c) With respect to all managed care contracts, commercial insurance contracts, contracts providing chargebacks, government contracts and distribution agreements described on Schedule 2.7, at the appropriate time following the Effective Date, which shall be promptly after BioSante obtains its own NDC code for the Product pursuant to Section 2.11 and has Product manufactured with BioSante’s NDC code pursuant to Section 4.2 available for sale, XXXXXXXXXXXXXXXXXXXXXXXXXX, Nycomed shall notify the other party to such contracts, agreements and arrangements that Nycomed no longer has rights to the Product and advising that the Product is to be removed from the list of products covered by such contracts, agreements and arrangements and that from that date BioSante will supply Product. Following BioSante obtaining its own NDC code for the Product pursuant to Section 2.11, BioSante shall be responsible for entering into any managed care contracts, commercial insurance contracts, contracts providing chargebacks, government contracts, and distribution agreements, as BioSante deems necessary or appropriate, for the



prepare the communication to customers regarding such price change, and Nycomed shall be responsible for sending such communication to such customers on behalf of BioSante. All services provided pursuant to this Section 4.3 shall be provided by Nycomed in a manner consistent with Nycomed's normal practice and course of business with which Nycomed provides such services for its other products.

(c) Payments for Product received by Bradley or Nycomed pursuant to Nycomed's activities under this section shall be held in trust for BioSante and paid over to BioSante monthly, less: (i) any portion of such payments for other charges for third party costs such as shipping, insurance, taxes, customs, duties and similar charges that Nycomed actually incurs, whether or not reflected on the invoice to customers, and (ii) any cost of Product to be reimbursed to Nycomed pursuant to Section 4.1(b) for Product shipped in the prior month. For providing the services specified in this section, BioSante shall pay Nycomed an administrative handling fee of XXXXXXXXXX (X%) of the net selling price shown on the invoices for sales of Product during the preceding month that Nycomed ships on behalf of BioSante pursuant to this section, which Nycomed may deduct from its payments to BioSante under this section. **[Portions of this Section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]**

(d) For the avoidance of doubt: (i) Nycomed shall not be responsible for any services whatsoever with respect to Product samples; and (ii) Nycomed shall not provide any warehousing services under this Section 4.3 for any Product that BioSante has manufactured pursuant to Section 4.2.

4.4 **Insurance.** Nycomed shall maintain, for a period of one (1) year after the Effective Date, comprehensive products liability insurance with reputable and financially secure insurance carriers (but in no event less than rated A by AM Best) to cover its activities related to the Product under this Agreement, for minimum limits of \$XXXXXXXXXX combined single limit for bodily injury and property damage per occurrence and in the aggregate. Such insurance shall include BioSante as an additional named insured. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or within three (3) years after the Effective Date. **[Portions of this Section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]**

4.5 **Early Termination of Services.** In the event that BioSante (i) grants to a third party a sublicense or distribution rights for the Product in the Territory, or (ii) transfers or assigns all or substantially all of the rights to the Product in the Territory to a third party, or (iii) is acquired through merger, acquisition or combination by a third party; BioSante shall notify Nycomed within two business days of the execution of any agreement with respect to the foregoing, and Nycomed's obligations under Sections 2.3 and 4.3 shall terminate sixty (60) days after the effective date or closing date of such agreement, as applicable, (unless such obligations sooner terminate as provided in such agreement or pursuant to Section 4.3).

4.6 **BioSante Ongoing Obligations.** From and after the Effective Date, BioSante shall be responsible for all obligations, responsibilities and liabilities in connection with all matters pertaining to the Product, except as explicitly set forth in this Agreement, including without limitation all obligations for any on-going development and manufacturing activities.

## ARTICLE 5

### RELEASE OF CLAIMS

5.1 Except as specifically provided for in this Agreement, the Parties hereby unconditionally, absolutely and irrevocably waive, release and forever discharge the other from any and all, past, present or future causes of action, suits, dues, sums of money, accounts, covenants, controversies, guarantees, promises, damages, judgments, executions, rights, obligations, liabilities, defenses, rights of set-off, claims for damages or specific performance, or claims or counterclaims or demands of any nature whatsoever, at law or in equity, known or unknown, fixed or contingent, which they may have or hereafter may acquire against the other by reason of, arising out of, or related to any act or omission under the Sublicense Agreement. For clarification, the Parties do not release any obligations they may have to each other under provisions that survive the termination of the Sublicense Agreement, including but not limited to the confidentiality and indemnification provisions of the Sublicense Agreement.

## ARTICLE 6

### MISCELLANEOUS

6.1 **Reports and Payments.** Any payments due to BioSante under this Agreement shall be made in accordance with Section 4 of the Sublicense Agreement and the provisions of Section 4 of the Sublicense Agreement, including, but not limited to the inspection and audit provisions.

6.2 **Notices.** Any notice required or permitted to be given under this Agreement shall be sufficient if sent by certified mail (return receipt requested) or express courier, postage pre-paid, to the attention of the Chief Executive Officer of the respective company at the address set forth above or to such other address as a Party may specify by notice hereunder.

6.3 **Assignment.** This Agreement and any of its respective rights and obligations shall be freely assignable by BioSante, but shall only be assignable by Nycomed in connection with a merger or acquisition of Nycomed US Inc.. This Agreement shall be enforceable against and inure to the benefit of the permissible successors and assigns of BioSante, and shall be enforceable against and inure to the benefit of the permissible successors and assigns of Nycomed.

6.4 **Non-Waiver and Entirety.** Any failure of either Party to enforce any obligations under this Agreement shall not be deemed a waiver of such obligations. This Agreement constitutes the entire agreement and understanding of the Parties and supersedes all previous communication between the Parties.

6.5 **Governing Law.** This Agreement is governed by and construed in all respects in accordance with the laws of the State of Illinois, USA and the United States of America (without regard to conflicts of laws principles), excluding the United Nations Convention on Contracts for the International Sale of Goods.

#### 6.6 Dispute Resolution.

6.6.1 **Conciliation.** The parties wish first to seek an amicable settlement of all disputes, controversies or claims arising out of or relating to this Agreement by conciliation in accordance with the UNCITRAL Conciliation Rules now in force. If assistance is needed in connection with the appointment of a conciliator or other administrative matters, JAMS Endispute, Inc., shall be the institution to render such assistance. The language to be used in the conciliation proceedings shall be English.

6.6.2 **Arbitration.** Subject to possible court proceedings under section 6.6.4 of this Agreement, if any conciliation proceedings under section 6.6.1 of this Agreement are terminated in accordance with Article 15 of the UNCITRAL Conciliation Rules or rejected in accordance with Article 2 of those Rules, without resolution of the disputes, controversies or claims, then all said disputes, controversies or claims shall be determined by arbitration in accordance with the UNCITRAL Arbitration Rules now in force, as supplemented by the IBA Rules on the Taking of Evidence in International Commercial Arbitration, as adopted June 1, 1999, insofar as said IBA Rules are not inconsistent with the express provisions of this Agreement. The language to be used in the arbitral proceedings shall be English. There shall be three (3) arbitrators, and the appointing authority shall be JAMS Endispute, Inc. In rendering the award, the arbitrator shall follow and apply the substantive laws of the State of Illinois (without regard to conflict or choice of laws principles). The arbitrator shall have the authority to award compensatory damages only, subject to the limitations described in this Agreement. Each Party shall pay the fees of its own attorneys, expenses of witnesses and all other expenses and costs in connection with the presentation of such party's case (collectively, "Attorneys' Fees"). The remaining cost of the arbitration, including without limitation, fees of the arbitrator, costs of records or transcripts and administrative fees (collectively, "Arbitration Costs") shall be borne equally by the Parties. Notwithstanding the foregoing, the arbitrator in the award may apportion said Attorneys' Fees and Arbitration Costs pursuant to Articles 38 through 40 of the UNCITRAL Arbitration Rules. The award rendered by the arbitrator shall be final, and judgment may be entered in accordance with the applicable law by any court having jurisdiction thereof.

6.6.3 **Confidentiality.** The existence and resolution of any conciliation and/or arbitration shall be kept confidential, and the Parties, the conciliator and the arbitrator shall not disclose to any person any information about such arbitration.

6.6.4 **Court Proceedings.** Section 6.6.2 of this Agreement shall not be construed to prevent either Party from seeking injunctive relief against the other Party from any judicial or administrative authority of competent jurisdiction to enjoin that party from breaching this Agreement or interim relief pending the resolution of a dispute by arbitration, pursuant to said section 6.6.2. Any action to confirm an arbitration award or any other legal action related to this Agreement between the Parties may be instituted in any court of competent jurisdiction. BioSante and Nycomed each waive their right to a trial by jury in any such court proceedings.

6.6.5 **Location.** The conciliation and arbitration shall be conducted in New York, New York, unless the dispute also involves a dispute with respect to the Product between BioSante and Antares pursuant to an agreement between BioSante and Antares, in which case they shall be conducted in Chicago, Illinois.

6.7 **Severability.** Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties agree that it is their intent that the remainder of the Agreement shall continue in effect, and shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions.

6.8 **Headings.** Section headings contained in this Agreement are for convenience of reference only and shall not in any way affect the interpretation of this Agreement.

6.9 **Further Assurances.** Each Party agrees to take or cause to be taken such further actions, and to execute, deliver and file or cause to be executed, delivered and filed such further documents and instruments, and to obtain such consents, as may be reasonably required or requested in order to effectuate fully the purposes, terms and conditions of this Agreement.

6.10 **Execution.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

\* \* \* \* \*

IN WITNESS THEREOF, BioSante and Nycomed have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes  
Stephen M. Simes  
Chief Executive Officer and President

NYCOMED US INC.

By: Paul B. McGarty  
Paul B. McGarty  
Chief Executive Officer

**Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002  
and SEC Rule 13a-14(a)**

I, Stephen M. Simes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2008

/s/ Stephen M. Simes  
Stephen M. Simes  
Vice Chairman, President and Chief Executive Officer

**Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**  
**and SEC Rule 13a-14(a)**

I, Phillip B. Donenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2008

/s/ Phillip B. Donenberg  
Phillip B. Donenberg  
Chief Financial Officer, Treasurer and Secretary  
(principal financial officer)



**Certification of CEO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen M. Simes, Vice Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen M. Simes  
Stephen M. Simes  
Vice Chairman, President and Chief Executive Officer  
August 11, 2008

**Certification of CFO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip B. Donenberg, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Phillip B. Donenberg  
Phillip B. Donenberg  
Chief Financial Officer, Treasurer and Secretary  
August 11, 2008