BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 10, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2008

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

For the transition period from to .

Commission File Number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)

111 Barclay Boulevard

Lincolnshire, Illinois 60069

(Address of principal executive offices)

(847) 478-0500

(Registrant s telephone number including area code)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company) o Smaller reporting company o

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

As of November 10, 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

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

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Balance Sheets

September 30, 2008 and December 31, 2007 (Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,700,697	$ 15,648,948
Short-term investments	11,770,374	15,005,976
Accounts receivable	82,531	14,566
Prepaid expenses and other assets	998,210	337,420
	18,551,812	31,006,910
PROPERTY AND EQUIPMENT, NET	529,301	54,896
OTHER ASSETS		
Investment in MATC	140,000	140,000
Deposits	600,797	39,536
	$ 19,821,910	$ 31,241,342
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,420,066	$ 710,575
Due to licensor - Antares	4,663	1,063
Accrued compensation	878,555	717,409
Other accrued expenses	266,979	77,712
Deferred revenue		9,091
	4,570,263	1,515,850
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2008 - 391,286; 2007 - 391,286 Class C special stock	391	391
2008 - 27,042,764; 2007 - 26,794,607 Common stock	85,565,027	84,206,583
	85,565,418	84,206,974
Accumulated other comprehensive income	427,500	
Accumulated deficit	(70,741,271)	(54,481,482)
	15,251,647	29,725,492
	$ 19,821,910	$ 31,241,342

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three and nine months ended September 30, 2008 and 2007 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
REVENUE				
Licensing revenue	$	$ 9,091	$ 9,091	$ 50,000
Grant revenue	21,082	20,639	56,972	46,856
Royalty revenue	3,734	14,063	30,219	66,991
Other revenue	57,396		74,796	
	82,212	43,793	171,078	163,847
EXPENSES				
Research and development	5,322,472	1,145,764	11,934,536	3,539,081
General and administration	1,438,816	1,027,194	4,357,465	3,211,759
Depreciation and amortization	11,759	17,993	33,841	79,509
	6,773,047	2,190,951	16,325,842	6,830,349
OTHER - Impairment of short term investments			660,200	
OTHER - Interest income	105,751	379,114	555,175	756,131
NET LOSS BEFORE INCOME TAX EXPENSE	(6,585,084)	(1,768,044)	(16,259,789)	(5,910,371)
INCOME TAX EXPENSE		(75,000)		
NET LOSS	$ (6,585,084)	$ (1,693,044)	$ (16,259,789)	$ (5,910,371)
BASIC AND DILUTED NET LOSS PER SHARE (Note 3)	$ (0.24)	$ (0.06)	$ (0.60)	$ (0.24)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	27,380,217	27,137,431	27,265,906	24,928,682

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Nine months ended September 30, 2008 and 2007 (Unaudited)

	Nine Months Ended September 30, 2008	2007
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (16,259,789)	$ (5,910,371)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	33,841	79,509
Impairment of short term investments	660,200	
Employee & director stock-based compensation	865,074	511,044
Stock warrant expense - noncash	113,650	38,804
(Gain) Loss on disposal of equipment	(951)	21,748
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(1,222,051)	(160,657)
Accounts receivable	(67,965)	6,928,237
Accounts payable and accrued liabilities	2,805,464	(1,601,801)
Provision for contingencies		(412,941)
Due to licensor - Antares	3,600	
Deferred revenue	(9,091)	(50,000)
Net cash (used in) operating activities	(13,078,018)	(556,428)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES		
Redemption of short term investments	3,101,354	982
Purchase of short term investments	(98,452)	(157,637)
Purchase of capital assets	(252,855)	(8,000)
Net cash provided by (used in) investing activities	2,750,047	(164,655)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from sale or conversion of shares	379,720	18,469,795
Net cash provided by financing activities	379,720	18,469,795
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(9,948,251)	17,748,712
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	15,648,948	7,653,852
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,700,697	$ 25,402,564
SUPPLEMENTARY INFORMATION		
Other information:		
Unrealized gain on available-for-sale securities, non-cash	$ 427,500	$
Purchase of capital assets on account, non-cash investing activity	$ 254,440	$
Income tax paid	$	$ 75,000

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q

SEPTEMBER 30, 2008

NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of BioSante Pharmaceuticals, Inc. (the Company) as of September 30, 2008, the results of operations for the three and nine months ended September 30, 2008 and 2007, and the cash flows for the nine months ended September 30, 2008 and 2007, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and nine month periods ended September 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.

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

The Company has not commercially introduced any products and does not expect to do so in the foreseeable future. However, Nycomed US Inc. (Nycomed) (formerly Bradley Pharmaceuticals, Inc.), the Company s former marketing sublicensee for Elestrin, the Company s estradiol gel, commercially launched Elestrin in June 2007 (see Note 4). As a result, from June 2007 until the termination of the Company s agreement with Nycomed and reacquisition of the rights to Elestrin on August 6, 2008, the Company received royalties on net sales of Elestrin by Nycomed. However, such royalties were minimal. The Company recognized royalty and other revenues from sales of Elestrin of $61,130 and $105,015 during the three and nine month periods ended September 30, 2008, respectively.

The Company s business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. If and when the Company s proposed products for which it has not entered into marketing relationships receive U.S. Food and Drug Administration (FDA) approval, the Company may begin to incur other expenses, including sales and marketing related expenses if it chooses to market the products itself. The Company does not intend to incur material sales and marketing related expenses in the near future as a result of its re-acquisition of the marketing rights to Elestrin in the U.S. The Company currently does not have sufficient resources on a long-term basis to complete the FDA approval process or commercialization of any of its current or proposed products for which the Company has not entered into marketing relationships. As a result, the Company may seek to obtain additional financing prior to the occurrence of any such events. As an alternative to raising additional financing, the Company may choose to sublicense Elestrin, LibiGel or another product to a third party, sell certain assets or rights the Company has under its existing license agreements or enter into other business collaborations or combinations, including the possible sale of the company.

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2. COMPREHENSIVE LOSS

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

	Three Months Ended September 30, 2008		2007
Net loss	$	6,585,084	$ 1,693,044
Other Comprehensive Income:			
Unrealized Gain on Available for Sale Securities		427,500	
Comprehensive Loss	$	6,157,584	$ 1,693,044

	Nine Months Ended September 30, 2008		2007
Net loss	$	16,259,789	$ 5,910,371
Other Comprehensive Income:			
Unrealized Gain on Available for Sale Securities		427,500	
Comprehensive Loss	$	15,832,289	$ 5,910,371

3. BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company s outstanding options and warrants are antidilutive; accordingly, there is no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and nine months ended September 30, 2008 does not include options to purchase an aggregate of 2,088,191 and 2,070,691, respectively, shares of common stock with exercise prices ranging from $2.10 to $6.70 per share, and warrants to purchase an aggregate of 2,412,038 and 2,492,695, respectively, shares of common stock with exercise prices of $2.75 to $8.00 per share, because of their antidilutive effect on net loss per share. The computation of diluted net loss per share for the three and nine months ended September 30, 2007 does not include options to purchase an aggregate of 1,405,525 and 1,375,557, respectively, shares of common stock, with exercise prices ranging from $2.10 to $6.70 per share, and warrants to purchase an aggregate of 2,659,652 and 2,557,838, 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.

4. LICENSE AGREEMENTS AND OTHER COMMITMENTS

In November 2006, the Company entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. (Bradley) for the marketing of Elestrin in the United States. Effective February 21, 2008, Nycomed completed its acquisition of Bradley. As a result, all references to Bradley have been

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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 the Company s license agreement with Antares, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or its sub-licensees sell incorporating the licensed technology. Specifically, the Company 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.

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 the rights to Elestrin effective immediately. Pursuant to the Agreement, the Company assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has provided the Company all information, documents and know-how that Nycomed had that related 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 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 $1,500,000 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.

Nycomed commercially launched Elestrin in June 2007. The Company received royalty revenue from sales of Elestrin from Nycomed through August 6, 2008. Subsequent to August 6, 2008, the Company recognized other revenue resulting from sales of Elestrin less a reasonable fee paid to Nycomed in exchange for distributing, storing and processing continued Elestrin sales during a specified transition period. The Company recognized $61,130 and $105,015 in royalty and other revenue from sales of Elestrin during the three and nine months ended September 30, 2008, respectively. Such amounts represent the gross royalty revenue the Company received from Nycomed through August 5, 2008 other revenue from sales of Elestrin for the period from August 6, 2008 to September 30, 2008 and not the Company s corresponding obligation to pay Antares royalties. Under the Company s license agreement with Antares, the Company is required to pay Antares, among other payments, royalties based

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on net sales of any products the Company or its sub-licensees sell incorporating the licensed technology. The Company recognized $14,063 and $66,991 in royalty revenue for the three months and nine months ended September 30, 2007, respectively. The Company s corresponding obligation to pay Antares royalties as a result of sales of Elestrin, which obligation equaled $4,663 and $16,423 for the three and nine months ended September 30, 2008, is recorded within general and administrative expenses in the Company s condensed statements of operations.

The Company intends to pursue the best course of action to maximize the value of Elestrin. In the meantime, the Company is marketing and selling the product itself, although it does not intend to incur material sales and marketing expenses in doing so and thus does not expect material sales growth of Elestrin. If the Company chooses to perform the distribution or marketing of Elestrin itself for an extended period of time, the Company may incur material associated expenses. The Company currently does not have sufficient resources to establish its own sales and marketing functions. The manufacturer of Elestrin remains unchanged.

In June 2008, the Company announced that it engaged Deutsche Bank Securities Inc., an investment banking firm, as its strategic advisor in connection with the Company s 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. (See Part II; Item 1A Risk Factors)

5. STOCK-BASED COMPENSATION

The Company has two stockholder-approved 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). The 2008 Plan replaced the 1998 Plan, which was terminated with respect to future grants upon the effectiveness of the 2008 Plan. As of September 30, 2008, there were 2,000,000 shares of the Company s common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan. Of the 2,000,000 authorized shares, none had been issued and 53,000 shares were subject to outstanding stock options as of September 30, 2008. 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. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 and 2008 Plans was $305,188 and $865,074 for the three and nine months ended September 30, 2008, respectively, and $147,341 and $511,044 for the three and nine months ended September 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.

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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 nine months ended September 30, 2008 and 2007.

	Nine Months Ended September 30,	
	2008	**2007**
Expected life in years	6 years	10 years
Annualized volatility	67.63%	73.94%
Discount rate bond equivalent yield	3.45%	4.10%
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 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 Staff Accounting Bulletin (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 nine months ended September 30, 2008 is presented below:

Options	**Option Shares**	**Weighted Average Exercise Price**
Outstanding December 31, 2007	1,427,191	$ 3.50
Granted	682,250	3.74
Exercised		
Forfeited or expired	21,250	4.03
Outstanding September 30, 2008	2,088,191	3.57
(weighted average contractual term)	*7.65 years*	
Exercisable at September 30, 2008	1,024,692	$ 3.46
(weighted average contractual term)	*6.04 years*	

The aggregate intrinsic value of the Company s outstanding and exercisable options as of September 30, 2008 was $2,886,770 and $1,502,175, respectively. The aggregate intrinsic value of the Company s outstanding and exercisable options as of September 30, 2007 was $3,286,650 and $1,865,224, 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 nine months ended September 30, 2008 is presented below:

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Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2007	656,333	$ 3.65
Granted	682,250	3.74
Vested	(253,836)	3.65
Forfeited	(21,250)	4.03
Non-Vested at September 30, 2008	1,063,497	$ 3.68

As of September 30, 2008, there was $1,969,547 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the 1998 and 2008 Plans. The cost is expected to be recognized over a remaining weighted-average vesting period of 1.96 years.

There were no options exercised during the nine months ended September 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 September 30,	
	2008	2007
Stock-Based Compensation Expense:		
Research and development	$ 98,754	$ 59,260
General and administrative	206,434	88,081
Total stock-based compensation expense	$ 305,188	$ 147,341

	Nine Months Ended September 30,	
	2008	2007
Stock-Based Compensation Expense:		
Research and development	$ 274,395	$ 191,364
General and administrative	590,679	319,680
Total stock-based compensation expense	$ 865,074	$ 511,044

In July 2007, the Company issued a warrant to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrant is exercisable at an exercise price equal to $8.00 per share with 50 percent of the underlying warrant exercisable on July 19, 2008 and the remaining 50 percent becoming exercisable on July 19, 2009. The warrant is exercisable through and including July 18, 2010. The Company uses the Black-Sholes pricing model to value this warrant consideration and remeasures the award each quarter until the measurement date is established. During the nine months ended September 30, 2008, the Company recorded $60,107 in non-cash general and administrative expense pertaining to this warrant.

In May 2008, the Company issued warrants to purchase an aggregate of 80,000 shares of common stock to two individuals, the sole principal and a key executive officer, of an investor and public relations firm in return for various investor and public relations services. These warrants 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-Scholes pricing model to value this warrant consideration and remeasures the award each quarter until the

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measurement date is established. During the nine months ended September 30, 2008, the Company recorded $53,543 in non-cash general and administrative expense pertaining to these warrants.

6. RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, the Financial Accounting Standards Board (FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurement (SFAS 157). The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS 157 was effective for the Company on January 1, 2008. In October 2008, the FASB issued Staff Position (FSP) No. FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active which clarifies the application of SFAS 157 in an inactive market and illustrates how an entity would determine fair value when the market for a financial asset is not active. The Staff Position is effective immediately and applies to prior periods for which financial statements have not been issued, including interim or annual periods ending on or before September 30, 2008. See Note 8, Fair Value Measurements, for disclosure of the Company s adoption of SFAS 157.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 permits an entity to elect fair value as the initial and subsequent measurement attribute for many financial assets and liabilities. Entities electing the fair value option are required to recognize changes in fair value in earnings. SFAS 159 also requires additional disclosures to compensate for the lack of comparability that will arise from the use of the fair value option. SFAS 159 was effective for the Company beginning on 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 on 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.

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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 issued 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.

7. STOCKHOLDERS EQUITY

During the nine months ended September 30, 2008, options to purchase an aggregate of 682,250 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 nine months ended September 30, 2008, warrants to purchase an aggregate of 80,000 shares of common stock were granted. See Note 5 above. During the nine months ended September 30, 2008, warrants to purchase an aggregate of 176,614 shares of common stock were exercised for total cash proceeds of $379,720. 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. Warrants to purchase an aggregate of 500 shares of common stock expired without being exercised. All of the exercised warrants were granted in prior years.

8. FAIR VALUE MEASUREMENTS

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

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

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.

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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 September 30, 2008 are classified in the table below in one of the three categories described above:

Description	September 30, 2008 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Available for Sale Securities	$ 11,770,374	$ 3,074		$ 11,767,300
Total	$ 11,770,374	$ 3,074		$ 11,767,300

As of September 30, 2008, the Company s money market fund investment was classified as based on Level 1 inputs, as the fair value was based on the quoted security prices in active market. The Company s auction rate securities investments were 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 Company s auction rate securities were based on observable prices in active markets and as such would have been considered based on Level 1 inputs. At September 30, 2008, due to the failure of auctions during the first nine months of 2008, the auction rate securities were valued based on Level 3 inputs. As a result of these declines in fair value of the Company s auction rate securities, which the Company attributed 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 during the quarter ended June 30, 2008. During the quarter ended September 30, 2008, the Company recorded an unrealized gain of $427,500 to accumulated other comprehensive income for its auction rate securities investments, due to favorable developments in certain auction rate securities markets, which is described below. The table below presents a reconciliation of the auction rate securities balance at September 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)	
Included in net loss	(660,200)
Included in other comprehensive income	427,500
September 30, 2008	$ 11,767,300

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No realized gains or losses were included in the Company s condensed statement of operations for the nine months ended September 30, 2008.

The Company s auction rate securities were to continue to accrue interest at the contractual rate and are 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 several 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 nine months ended September 30, 2008.

9. SUBSEQUENT EVENT

On October 14, 2008, the Company received par value of $9,000,000 plus all accrued interest as a result of redemption of its auction rate securities investments held at Bank of America Securities LLC (BofA) pursuant to the terms of an offer letter from BofA pursuant to a settlement agreement between BofA and the Securities and Exchange Commission and other state regulatory agencies. In addition, on October 8, 2008, the Company accepted the terms of an offer letter from UBS Financial Services, Inc. (UBS) pursuant to a similar settlement agreement between UBS and the SEC and other state regulatory agencies for redemption of all remaining auction rate securities for par value of $3,000,000 plus accrued interest, to be paid beginning on January 2, 2009.

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

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

Business Overview

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. 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, three LibiGel Phase III trials are underway; two LibiGel Phase III safety and efficacy clinical trials and one 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

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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 likely will 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, The Pill-Plus and CaP 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 terminated by mutual agreement of the parties effective August 6, 2008. 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.

Pursuant to the August 2008 termination, release and settlement agreement with Nycomed, we reacquired Elestrin and have assumed all manufacturing, distribution and marketing responsibilities for Elestrin. Nycomed has provided us all information, documents and know-how that Nycomed had that related 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 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

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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 $1,500,000 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.

We license the transdermal estradiol gel formulation that is used in Elestrin from Antares Pharma, Inc. Under our license agreement with Antares, we are required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that we may receive. We received royalty revenue from sales of Elestrin from Nycomed through August 6, 2008. Subsequent to August 6, 2008, we recognized other revenue resulting from sales of Elestrin less a reasonable fee paid to Nycomed in exchange for distributing, storing and processing continued Elestrin sales during a specified transition period. We recognized $61,130 and $105,015 in royalty and other revenue from sales of Elestrin during the three and nine months ended September 30, 2008, respectively. These amounts represent the gross royalty revenue we received from Nycomed through August 5, 2008 and other revenue from sales of Elestrin for the period from August 6, 2008 to September 30, 2008 and not our corresponding obligation to pay Antares royalties. We recognized $14,063 and $66,991 in royalty revenue for the three months and nine months ended September 30, 2007, respectively. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $4,663 and $16,423 for the three and nine months ended September 30, 2008, is recorded within general and administrative expenses in our condensed statements of operations.

In the beginning of September 2008, we announced positive results of clinical work on our Pill-Plus triple hormone therapy oral contraceptive. The Pill-Plus adds a third hormone, an androgen, to the normal two hormone (estrogen and progestogen) oral contraceptive to prevent androgen deficiency which often leads to a decrease in sexual desire, sexual activity and mood changes. The Pill-Plus for oral use is licensed to Pantarhei Bioscience, a Netherlands-based pharmaceutical company for development and marketing in the United States. We retain rights to the Pill-Plus for transdermal development and marketing. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousabilty and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to improve the condition known as female sexual dysfunction in oral contraceptive users, among other potential benefits.

Our strategy with respect to our CaP technology is to continue development of our nanoparticle technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. In addition to continuing our own product development in the potential commercial applications of our CaP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CaP technology. For example, in November 2007, we signed a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial 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

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certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

One of our strategic goals for 2008 and 2009 is to continue to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor in connection with our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. No timetable has been set for completion of the exploration of strategic alternatives, and there can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. We do not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

Financial Overview

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

We have not introduced commercially 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. Subsequent to August 6, 2008, we recognized other revenue resulting from sales of Elestrin less a fee paid to Nycomed for distributing, storing and processing of Elestrin sales. We recognized $61,130 and $105,015 in royalty and other revenue from sales of Elestrin during the three and nine months ended September 30, 2008, respectively. These amounts represent the gross royalty revenue we received from Nycomed through August 5, 2008 and other revenue from sales of Elestrin for the period from August 6, 2008 to September 30, 2008 and not our corresponding obligation to pay Antares royalties. We recognized $14,063 and $66,991 in royalty revenue for the three months and nine months ended September 30, 2007, respectively. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $4,663 and $16,423 for the three and nine months ended September 30, 2008, is recorded within general and administrative expenses in our condensed statements 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 twelve months. (See Liquidity and Capital Resources section.) However, we may seek to obtain additional financing prior to that time. As an alternative to raising additional financing, we may choose to sublicense Elestrin, LibiGel or another product to a third party, sell certain assets or rights

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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 $1,800,000 per month on research and development activities during the three months ended September 30, 2008. Our research and development expenses increased $4,176,708, or 365 percent, to $5,322,472 for the three months ended September 30, 2008 from $1,145,764 for the three months ended September 30, 2007, primarily as a result of the conduct of the LibiGel Phase III clinical trials. We expect our monthly research and development expenses to be approximately $1,000,000 to $1,300,000 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, patient recruitment rate, 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 September 30, 2008 increased $411,622, or 40 percent, compared to the three months ended September 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 non-cash, stock option and warrant expense for the three months ended September 30, 2008 increased $355,225, or 191 percent, compared to the three months ended September 30, 2007. The primary reason for this increase was the grant of options to purchase an aggregate of 45,000 shares of our common stock to new employees in the third quarter 2008 and options and warrants to purchase an aggregate of 682,250 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 2008. Our general and administrative expenses may fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense, legal, public and investor relations, business development, accounting and corporate governance and other fees and expenses incurred.

We recognized a net loss for the three and nine months ended September 30, 2008 of approximately $6,600,000 and $16,300,000, respectively, compared to a net loss of approximately $1,700,000 and $5,900,000 for the three and nine months ended September 30, 2007. This increase was primarily due to the increased LibiGel clinical development expenses discussed above. During the nine months ended September 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. 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 our efforts, with the assistance of Deutsche Bank Securities, 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;

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- 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 September 30, 2008 Compared to Three Months Ended September 30, 2007

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

	Three Months Ended September 30,			
	2008	2007	$ Change	% Change
Revenue	$ 82,212	$ 43,793	$ 38,419	87.7%
Expenses				
Research and development	5,322,472	1,145,764	4,176,708	364.5%
General and administrative	1,438,816	1,027,194	411,622	40.1%
Interest income	105,751	379,114	(273,363)	(72.1)%
Net loss	$ (6,585,084)	$ (1,693,044)	$ 4,892,040	288.9%

Revenue increased $38,419 primarily as a result of an increase in royalty and other revenue from Elestrin sales during the three months ended September 30, 2008 compared to the same period in 2007.

Research and development expenses for the three months ended September 30, 2008 increased 365 percent compared to the three months ended September 30, 2007 primarily as a result of the conduct of the three LibiGel Phase III clinical trials.

General and administrative expenses for the three months ended September 30, 2008 increased 40 percent compared to the three months ended September 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 $355,225 during the three months ended September 30, 2008 from $186,145 for the three months ended September 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 September 30, 2008 compared to the same period in 2007. Our outstanding stock options

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and warrants have remaining lives of one to ten years and will be amortized over the respective remaining vesting periods. Certain of our outstanding stock options have performance condition-based vesting provisions, which will result in recognition of expense when such performance conditions have been satisfied.

Interest income for the three months ended September 30, 2008 decreased 72 percent compared to interest income for the three months ended September 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 September 30, 2008 compared to the same period in 2007.

Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

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

	Nine Months Ended September 30,			
	2008	**2007**	**$ Change**	**% Change**
Revenue	$ 171,078	$ 163,847	$ 7,231	4.4%
Expenses				
Research and development	11,934,536	3,539,081	8,395,455	237.2%
General and administrative	4,357,465	3,211,759	1,145,706	35.7%
Impairment of short-term investments	660,200		660,200	
Interest income	555,175	756,131	(200,956)	(26.6)%
Net loss	$ (16,259,789)	$ (5,910,371)	$ 10,349,418	175.1%

Revenue increased $7,231 primarily as a result of the increase in royalty and other revenue from Elestrin sales partially offset by a reduction in the recognition of deferred revenue as revenue related to a license associated with our CaP technology during the nine months ended September 30, 2008 compared to the same period in 2007.

Research and development expenses for the nine months ended September 30, 2008 increased 237 percent compared to the nine months ended September 30, 2007 primarily as a result of the conduct of the LibiGel Phase III clinical trials.

General and administrative expenses for the nine months ended September 30, 2008 increased 36 percent compared to the nine months ended September 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 $978,724 during the nine months ended September 30, 2008 from $549,848 for the nine months ended September 30, 2007 due to an increase in the number of stock options granted and the number of stock options and warrants outstanding during the nine months ended September 30, 2008 compared to the same period in 2007.

During the nine months ended September 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 nine months ended September 30, 2008 decreased 27 percent compared to interest income for the nine months ended September 30, 2007 as a result of lower average invested cash balances and lower average interest rates on invested cash balances during the nine months ended September 30, 2008 compared to the same period in 2007.

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Liquidity and Capital Resources

Working Capital

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. 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 by Nycomed. However, such royalties were minimal. Subsequent to August 6, 2008, we recognized other revenues resulting from sales of Elestrin less a fee paid to Nycomed for distributing, storing and processing of Elestrin sales. However, such other revenue also has been 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 intend to pursue the best course of action to maximize the value of Elestrin. If and when our other products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including material sales and marketing and other expenses if we choose to market the products ourselves. We currently do not have sufficient resources to establish our own sales and marketing function, obtain regulatory approval of our other proposed products or complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. We expect the ongoing Phase III clinical trial program of LibiGel to require significant resources.

To date, we have used primarily equity financings, licensing income and interest income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. As of September 30, 2008, we had approximately $5,700,000 of cash and cash equivalents and an additional $11,800,000 of short-term investments. Subsequent to September 30, 2008, $9,000,000 of our short-term investments was converted into cash and cash equivalents and we expect an additional $3,000,000 of our short-term investments to be converted into cash and cash equivalents in January 2009 as a result of the sale of our auction rate securities as described below. We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations. As of September 30, 2008, we did not have any outstanding debt or existing credit facilities under which we could borrow funds.

Our cash and cash equivalents are invested in highly-rated, investment grade financial instruments consisting primarily of commercial paper. As of September 30, 2008, our short-term investments consisted primarily of money market investments and investment-grade auction rate securities, the underlying assets of which were portfolios of student loans backed by the federal government. Although our auction rate securities historically had been very liquid, such liquidity had been reduced significantly beginning during the first quarter 2008 as a result of events in the credit markets, including the market for these auction rate securities.

As of September 30, 2008, $9,000,000 of our auction rate securities were held in an account with Bank of America Securities LLC (BofA). Subsequent to September 30, 2008, in the beginning of October 2008, BofA and its affiliates reached agreements with the Securities and Exchange Commission, the Secretary of the Commonwealth of Massachusetts and other regulators to restore liquidity to BofA clients who hold auction rate securities. Pursuant to these agreements, in October 2008, we received

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$9,000,000 plus accrued but unpaid interest from an affiliate of BofA in exchange for our auction rate securities held in our BofA account.

As of September 30, 2008, our auction rate securities with a $3,000,000 par value were held in an account with UBS Financial Services, Inc. (UBS). In August 2008, UBS and its affiliates reached agreements with the SEC, the New York Attorney General, the Massachusetts Securities Division, the Texas State Securities Board and other state regulatory agencies represented by the North American Securities Administrators Association to restore liquidity to UBS clients who hold auction rate securities. Pursuant to these agreements, in October 2008, we received rights from UBS entitling us to sell to UBS or its affiliates and requiring UBS or its affiliates to purchase our $3,000,000 in auction rate securities for their face (or par) value plus any accrued but unpaid interest at any time that we decide during a two-year period commencing on January 2, 2009. We intend to exercise our rights to require UBS to purchase our $3,000,000 of auction rate securities on January 2, 2009 or as soon as practicable thereafter.

We believe our cash, cash equivalents and short-term investments will be sufficient to meet our liquidity requirements through at least the next twelve months. However, we may seek to obtain additional financing prior to that time. 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:

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

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;

- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;

- the commercial success and net sales of Elestrin 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;

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- the commercial success of our proposed products;
- our general and administrative expenses;
- the timing and cost of obtaining third party reimbursement for our products; and
- the activities of our competitors.

Uses of Cash and Cash Flow

We used cash in operating activities of $13,078,018 for the nine months ended September 30, 2008 compared to cash used in operating activities of $556,428 for the nine months ended September 30, 2007. Cash used in operating activities for the nine months ended September 30, 2008 was primarily the result of the net loss for that period which was higher due to higher clinical trial related expenses, and to a lesser extent, an increase in prepaid expenses and other assets related to an increase in our prepaid clinical trial-related costs partially offset by an increase in accounts payable and accrued liabilities. Net cash used in operating activities of $556,428 for the nine months ended September 30, 2007 was due primarily due to the net loss and a decrease in accounts payable and other accrued liabilities, offset primarily by the receipt of a net payment of $7,000,000 from Nycomed under our now-terminated license agreement for Elestrin.

Net cash provided by investing activities was $2,750,047 for the nine months ended September 30, 2008 due to the redemption of approximately $3,000,000 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 $164,655 for the nine months ended September 30, 2007 and consisted primarily of purchases of short-term investments.

During the nine months ended September 30, 2008, net cash provided by financing activities was $379,720, which resulted from warrant exercises. Net cash provided by financing activities during the nine months ended September 30, 2007 was $18,469,795, which resulted primarily from the completion of a private placement resulting in net proceeds to us of approximately $17,300,000, after deduction of transaction expenses, and to a lesser extent, warrant and stock option exercises.

We recorded and paid $75,000 in income tax expense during the nine months ended September 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 September 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 September 30, 2008.

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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 6 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 news releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, might, possible, potential, project, will, intend, plan, predict, anticipate, estimate, approximate, contemplate or continue and other words and terms of similar meaning. The forward-looking statements may be contained in the notes to our condensed financial statements and elsewhere in this report, including under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations. Our forward-looking statements generally relate to:

- the timing of the commencement, enrollment and successful completion of our clinical trials and other regulatory status of our proposed products;

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- approval of our drugs by the U.S. Food and Drug Administration that are currently in clinical development;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;
- our engagement of Deutsche Bank Securities and our efforts, with the assistance of Deutsche Bank Securities, to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market and market acceptance of our products;
- our anticipated sales and marketing expenses for Elestrin;
- the effect of new accounting pronouncements;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

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

- our ability to implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;
- our ability to obtain additional capital when needed or on acceptable terms;
- the effects of the current global economic crisis and our ability to seek strategic alternatives or raise additional capital or otherwise conduct our business in light thereof;
- our ability to sell Elestrin ourselves or re-license the marketing rights to another third party on a timely basis or on attractive terms;
- the lack of market acceptance of Elestrin and our other products if and when they are commercialized;
- our dependence upon our licensees for the development, marketing and sale of certain of our products;
- 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;

- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- the failure of certain of our products to be commercially introduced for several years or at all;
- our failure to obtain and maintain required regulatory approvals on a timely basis or at all;
- our ability to compete in a competitive industry;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;

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- 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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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 September 30, 2008 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. **OTHER INFORMATION**

ITEM 1. **LEGAL PROCEEDINGS**

Not applicable.

ITEM 1A. RISK FACTORS

We are affected by risks specific to us as well as factors that affect all businesses operating in the pharmaceutical business and in a domestic and 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.

The current adverse domestic and worldwide economic conditions have affected our ongoing exploration of strategic alternatives process.

General domestic and worldwide economic conditions have experienced a significant downturn due to the effects of the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Our company is not immune to these adverse conditions. We believe the current domestic and worldwide economic crisis has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. One of our strategic goals has been, and continues to be, 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 engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor to assist us in our efforts to explore strategic alternatives. 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. While no timetable has been set for the completion of our exploration of strategic alternatives process, we believe that it is likely that the process will take significantly longer than we originally anticipated. We believe this is due, in significant part, to a currently very challenging capital markets environment and uncertain general domestic and worldwide economic conditions, both of which have reduced companies willingness to use their cash and/or stock to acquire other companies and products, especially development stage products that involve risk. We believe based on sales data for male sexual dysfunction products as well as published papers and independent market research that the estimated market for an FDA approved female sexual dysfunction product could reach more than $2.0 billion, and that if approved by the FDA, LibiGel could become the first FDA approved treatment specifically indicated for hypoactive sexual desire disorder in menopausal women. However, we expect the Phase III clinical trial program of LibiGel to require significant resources. We also understand the significant risks involved in conducting clinical trials, obtaining regulatory approvals and commercializing a product that could be the first product of its kind to reach the market. While we continue in our ongoing efforts to explore strategic alternatives, we are mindful of these risks and the general economic environment which currently exists, both of which we believe has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. Accordingly, we cannot provide any assurance as to when or if our exploration of strategic alternatives will result in any agreements or

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transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2008, warrants to purchase an aggregate of 160,814 shares of common stock held by five warrant holders were exercised for total cash proceeds of approximately $345,750. 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 September 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

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

Not applicable.

ITEM 5. **OTHER INFORMATION**

Not applicable.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between

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Exhibit No.	Description
	BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg
10.3	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, has been granted with respect to designated portions of this document.

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SIGNATURES

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

November 10, 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)

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BIOSANTE PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)
10.3	Termination, Release and Settlement Agreement dated as of August 6, 2008 between BioSante Pharmaceuticals, Inc. and Nycomed US Inc.*	Incorporated by reference to Exhibit 10.6 to BioSante s Quarterly Report on Form 10-Q as filed with the SEC on August 11, 2008 (File No. 001-31812)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

*Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.