BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 13, 2007

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, 2007

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

For the transition period from _____ to _____.

Commission File Number 001-31812

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer: o Accelerated filer: o Non-accelerated filer: x

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 12, 2007, 26,790,607 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

BIOSANTE PHARMACEUTICALS, INC.

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

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

BIOSANTE PHARMACEUTICALS, INC.
Balance Sheets
September 30, 2007 and December 31, 2006 (Unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 25,402,564**	**$ 7,653,852**
Short-term investments	**3,952,633**	**3,795,977**
Accounts receivable	**3,599,764**	**10,528,001**
Prepaid expenses and other sundry assets	**391,301**	**230,644**
	33,346,262	**22,208,474**
PROPERTY AND EQUIPMENT, NET	**43,783**	**137,040**
OTHER ASSETS		
Security deposits	**25,326**	**25,326**
	$ 33,415,371	**$ 22,370,840**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 559,380**	**$ 621,818**
Due to licensor - Antares	**881,328**	**2,625,000**
Accrual for contingencies	**137,647**	**550,588**
Accrued compensation	**569,831**	**368,522**
Other accrued expenses	**68,500**	**65,500**
Deferred revenue	**18,182**	**68,182**
TOTAL CURRENT LIABILITIES	**2,234,868**	**4,299,610**
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
2007 - 391,286; 2006 - 391,286 Class C special stock	**391**	**391**
2007 - 26,787,273; 2006 - 22,975,040 Common stock	**83,987,530**	**64,967,887**
	83,987,921	**64,968,278**
Accumulated deficit	**(52,807,418)**	**(46,897,047)**
	31,180,503	**18,071,231**
	$ 33,415,371	**$ 22,370,840**

See accompanying notes to the financial statements.
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BIOSANTE PHARMACEUTICALS, INC.
Statements of Operations
Three and nine months ended September 30, 2007 and 2006 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
REVENUE				
Licensing revenue	$ 9,091	$ 34,091	$ 50,000	$ 102,273
Grant revenue	20,639	106,233	46,856	242,981
Royalty revenue	14,063	-	66,991	-
Other revenue	-	-	-	55,000
	43,793	140,324	163,847	400,254
EXPENSES				
Research and development	1,145,764	766,592	3,539,081	2,900,057
General and administration	1,027,194	210,552	3,211,759	3,902,183
Depreciation and amortization	17,993	30,725	79,509	85,291
	2,190,951	1,007,869	6,830,349	6,887,531
OTHER - Interest income	379,114	122,484	756,131	288,821
NET LOSS BEFORE INCOME TAX EXPENSE	$ (1,768,044)	$ (745,061)	$ (5,910,371)	$ (6,198,456)
INCOME TAX EXPENSE	(75,000)	-	-	-
NET LOSS	$ (1,693,044)	$ (745,061)	$ (5,910,371)	$ (6,198,456)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.06)	$ (0.03)	$ (0.24)	$ (0.30)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	27,137,431	22,412,189	24,928,682	20,472,383

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
Statements of Cash Flows
Nine months ended September 30, 2007 and 2006 (Unaudited)

	Nine Months Ended September 30, 2007	2006
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	**$ (5,910,371)**	**$ (6,198,456)**
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	**79,509**	**85,291**
Employee & director compensation - noncash	**511,044**	**1,024,425**
Consultant compensation - noncash	**38,804**	**-**
Loss on disposal of equipment	**21,748**	**-**
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other sundry assets	**(160,657)**	**(20,689)**
Accounts receivable	**6,928,237**	**(17,472)**
Accounts payable and accrued liabilities	**(1,601,801)**	**(885,697)**
Accrual for contingencies	**(412,941)**	**(61,765)**
Deferred revenue	**(50,000)**	**(102,272)**
Net cash (used in) operating activities	**(556,428)**	**(6,176,635)**
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Redemption of short term investments	**982**	**6,909,815**
Purchase of short term investments	**(157,637)**	**(8,022,684)**
Purchases of capital assets	**(8,000)**	**(39,254)**
Net cash (used in) investing activities	**(164,655)**	**(1,152,123)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from sale of shares and exercise of options and warrants	**18,469,795**	**7,384,289**
Net cash provided by financing activities	**18,469,795**	**7,384,289**
NET INCREASE IN CASH AND CASH EQUIVALENTS	**17,748,712**	**55,531**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**7,653,852**	**310,643**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 25,402,564**	**$ 366,174**
SUPPLEMENTARY INFORMATION		
Other information:		
Income tax paid	**$ 75,000**	**$ -**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
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SEPTEMBER 30, 2007

NOTES TO THE FINANCIAL STATEMENTS (UNAUDITED)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited 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, 2007, the results of operations for the three and nine months ended September 30, 2007 and 2006, and the cash flows for the nine months ended September 30, 2007 and 2006, 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, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

These unaudited interim 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, 2006.

2. BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company's outstanding options and warrants are antidilutive; accordingly, there is no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and nine months ended September 30, 2007 does not include options to purchase an aggregate of 1,405,525 and 1,375,557 shares of common stock, for the three and nine month periods, respectively, 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 shares of common stock, with exercise prices of $2.15 to $8.00 per share, for the three and nine month periods respectively, because of their antidilutive effect on net loss per share. The computation of diluted net loss per share for each of the three and nine months ended September 30, 2006 does not include options to purchase an aggregate of 1,037,979 shares of common stock, with exercise prices ranging from $2.10 to $7.60 per share, and warrants to purchase an aggregate of 2,586,710 shares of common stock, with exercise prices ranging from $2.15 to $7.00 per share, because of their antidilutive effect on net loss per share.

3. LICENSE AGREEMENTS

In November 2006, the Company entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin, the Company's estradiol gel, in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of $3.5 million. In addition, Bradley paid the Company $7 million in the first quarter of 2007 triggered by the FDA approval of Elestrin in the U.S. and an additional $3.5 million is due on the one-year anniversary of such approval during the fourth quarter of 2007. Upon receipt of these payments from Bradley, the Company paid or will pay Antares Pharma IPL AG ("Antares"), the Company's licensor of the transdermal estradiol gel formulation in Elestrin, 25 percent of the payments and upon receipt of the additional $3.5 million payment, the Company will be obligated to pay Antares 25 percent of the additional payment. Bradley also has agreed to pay the Company additional sales-based milestone payments of up to $40 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. The Company will pay 25% of any sales-based milestone payments and a portion of royalties to Antares. Bradley commercially launched Elestrin in

mid-June 2007.

4. CONTINGENCIES

In May 2006, the Company, certain officers, one of its directors and a former officer entered into a settlement agreement related to a personnel matter, under which the Company agreed to pay the former officer post-termination payments in the aggregate amount of $780,000 in equal installments in accordance with the Company's regular payroll cycle through December 31, 2007, plus $110,000 of legal fees incurred by the former officer. As required by the agreement, the payments are secured by an irrevocable letter of credit, which is supported by the Company's short-term investment account. The outstanding balance under the letter of credit and corresponding accrued liability was $137,647 as of September 30, 2007 and will continue to decrease as payments are made through December 2007. In August 2006, the Company's employment practices liability carrier paid the Company $500,000 in settlement of the Company's claim against the carrier for coverage in this matter. The costs of the settlement agreement recognized in the first half of 2006 and corresponding insurance payment receipt recognized in the third quarter 2006 were included in general and administrative expenses in the Company's statements of operations in 2006.

On March 28, 2007, the Company received notice that the staff of the Securities and Exchange Commission's Division of Enforcement (the "Staff") was conducting an inquiry arising out of allegations contained in a complaint made in February 2006 by the former officer with whom the Company entered into the above-described settlement agreement to the U.S. Department of Labor, Occupational Safety & Health Administration ("OSHA") under the "whistleblower" provision of the Sarbanes-Oxley Act of 2002 ("SOX"). Immediately upon notice of the former officer's intent to file the SOX complaint in January 2006, the Board of Directors of the Company directed that an independent investigation be made into the allegations of securities and other law violations contained in the former officer's SOX complaint. The results of the investigation led to the conclusion by the Company and the Company's outside legal counsel that the allegations in the SOX complaint were without merit. OSHA closed its investigation into the SOX complaint in August 2006. On October 22, 2007, the Company received notice that the Staff had completed its investigation and intended to recommend no enforcement action by the Commission with respect to the matter, thereby closing the inquiry.

5. STOCK-BASED COMPENSATION

The Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), *Share-Based Payment* ("SFAS No. 123(R)") under the modified prospective method on January 1, 2006. Under the "modified prospective" method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS No. 123(R) for all share-based payments granted after that date, and based on the requirements of Statement of Financial Accounting Standards No.123, *Accounting for Stock Based Compensation* ("SFAS No. 123") for all unvested awards granted prior to the effective date of SFAS No. 123(R). SFAS No. 123(R) eliminates the intrinsic value measurement method of accounting in Accounting Principles Board Opinion 25 and generally requires measuring the cost of the employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of the grant. The standard requires grant date fair value to be estimated using either an option-pricing model which is consistent with the terms of the award or a market observed price, if such a price exists. Such costs must be recognized over the period during which an employee is required to provide service in exchange for the award. The standard also requires estimating the number of instruments that will ultimately be issued, rather than accounting for forfeitures as they occur.

As of September 30, 2007, the Company maintained one stock-based compensation plan, the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan, which is described below. The non-cash, stock-based compensation cost that has been incurred by the Company in connection with this plan was $511,044 and $1,024,425 for the nine months ended September 30, 2007 and 2006, respectively. No income tax benefit has been recognized in the Company's statement of operations for stock-based compensation arrangements due to the Company's net loss position.

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The BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the "Plan") permits the grant of stock options and stock awards to its employees, directors and consultants. As of September 30, 2007, 3,000,000 shares of the Company's common stock were reserved for issuance under the Plan, and 1,234,336 shares remained available for issuance, in each case, subject to adjustment as provided in the Plan. The Company believes that equity-based incentives, such as stock options and stock awards, align the interest of its employees, directors and consultants with those of its stockholders. Options are granted with an exercise price equal to the market price of the Company's common stock on the date of the grant; outstanding employee stock options generally vest ratably over a period of time and have 10-year contractual terms. In certain instances, stock options have been granted which were exercisable immediately. In these instances, stock-based compensation expense was recognized on the grant date in an amount equal to the fair value of the related options. No stock awards have been granted under the Plan. The Compensation Committee of the Board of Directors of the Company may at its sole discretion modify or accelerate the vesting of any stock option or stock award at any time but may not reprice any outstanding options without obtaining stockholder approval.

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, 2007 and 2006.

	Nine Months Ended September 30,	
	2007	**2006**
Expected life in years	10	10
Annualized volatility	69.61%	73.94%
Discount rate – bond equivalent yield	4.71%	4.10%
Expected dividend yield	0.0%	0.0%

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 American Stock Exchange. Since the Company has a limited history with option exercises, the expected life was set to the entire life of the option grant. 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 Plan during the nine months ended September 30, 2007 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2006	1,011,479	$ 3.61
Granted	565,000	3.53
Exercised	(49,747)	3.88
Forfeited or expired	(121,207)	4.88
Outstanding September 30, 2007	1,405,525	$ 3.47
(weighted average contractual term)	*8.5 years*	
Exercisable at September 30, 2007	771,414	$ 3.40
(weighted average contractual term)	*6.35 years*	

The aggregate intrinsic values of the Company's outstanding and exercisable options as of September 30, 2007 were $3,286,650 and $1,865,224, respectively.

A summary of the Plan's non-vested options at December 31, 2006 and activity under the Plan during the nine months ended September 30, 2007 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2006	207,833	$ 3.65
Granted	565,000	3.53
Vested	(97,146)	3.98
Forfeited	(32,999)	4.49
Non-Vested at September 30, 2007	642,688	$ 3.56

As of September 30, 2007, there was $1,455,971 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan. The cost is expected to be recognized over a remaining weighted-average vesting period of 2.27 years.

Cash received from option exercises under the Plan for the nine months ended September 30, 2007 was $176,235. The intrinsic value of options exercised during the nine months ended September 30, 2007 was $118,876. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position.

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

	Nine Months Ended September 30,	
	2007	**2006**
Stock-Based Compensation Expense:		
Research and development	$ 191,364	$ 41,051
General and administrative	319,680	983,374
Total stock-based compensation expense	$ 511,044	$ 1,024,425

6. ADOPTION OF FIN 48

The Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. FIN 48 requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. The adoption of FIN 48 did not have an impact on the Company's results of operations or financial condition. The Company is not aware of any uncertain tax positions existing as of September 30, 2007.

7. STOCKHOLDERS' EQUITY

During the nine months ended September 30, 2007, warrants to purchase 367,500 shares of common stock were exercised for total cash proceeds of $1,010,625. Warrants to purchase an aggregate of 339,987 shares of common also were exercised on a cashless basis, for which 163,321 of the underlying shares were withheld by the Company in payment of the exercise price for the exercised warrants, thus reducing the number of shares outstanding on a fully diluted basis.

During the nine months ended September 30, 2007, options to purchase an aggregate of 45,867 shares of common stock were exercised for total cash proceeds of $176,235. In addition, options to purchase an aggregate of 3,880 shares of common were exercised on a cashless basis, for which 7,453 of the underlying shares were withheld and cancelled by the Company in payment of the exercise price for the exercised options, thus reducing the number of shares outstanding on a fully diluted basis.

On June 13, 2007, the Company closed a private placement of 3,054,999 shares of its common stock and associated warrants to purchase 763,750 shares of its common stock at a purchase price of $6.00 per share to certain institutional and other accredited investors for gross proceeds of approximately $18.3 million. The private placement resulted in net proceeds to the Company of approximately $17.3 million, after deduction of transaction expenses. The warrants are exercisable for a period of three years, beginning December 14, 2007, at an exercise price of $8.00 per share. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities.

In July 2007, the Company issued warrants to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrants are exercisable at an exercise price equal to $8.00 per share with 50% of the warrants becoming exercisable on July 19, 2008 and the remainder becoming exercisable on July 19, 2009. The warrants are exercisable through and including July 18, 2010. The Company uses the Black-Sholes pricing model to value these warrants and remeasures the award each quarter until the measurement date is established. In the nine months ended September 30, 2007, the Company recorded $38,804 in non-cash general and administrative expense pertaining to these consultant warrants.

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 biopharmaceutical company that licenses and develops hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for vaccine adjuvants or immune system boosters, drug delivery systems and aesthetic medicine.

Our hormone therapy products are gel formulations of testosterone, estradiol and various combinations of estrogens, progestogens and androgens. Our hormone therapy products include Elestrin, LibiGel, Bio-T-Gel, triple hormone contraceptives (e.g. The Pill-plus), Bio-E/P-Gel and LibiGel-E/T,. We license the technology underlying our hormone therapy products, except Bio-T-Gel and triple hormone contraceptives, from Antares Pharma IPL AG. Bio-T-Gel was developed and is fully-owned by us. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the licensed technology and required us to pay an up-front license fee. We license the technology underlying our proposed triple hormone contraceptives from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include an upfront license fee, regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and is subsequently marketed.

We have entered into several sublicense agreements covering our hormone therapy products, including a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA agreed to develop our proposed Bio-T-Gel product for the U.S. market, an agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product and an agreement with Paladin Labs Inc. covering Canadian rights to certain of our hormone therapy products. The financial terms of these agreements generally include an upfront license fee, milestone payments and royalty payments to us if a product incorporating the licensed technology gets approved and is subsequently marketed.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of $3.5 million. In addition, in March 2007, Bradley paid us $7 million which was triggered by U.S. Food and Drug Administration, or FDA, approval of Elestrin in the U.S. and has agreed to pay us an additional $3.5 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. We are required to pay Antares 25% of these payments as a result of our license agreement with Antares. Bradley also has agreed to pay us additional sales-based milestone payments of up to $40 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. Bradley commercially launched Elestrin in the U.S. in mid-June 2007. 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.

Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety study are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel. Following NDA submission and potential approval, we will continue to follow the subjects in the safety trial for an additional four years. The Phase III cardiovascular safety study will be 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. The LibiGel safety study will track a list of cardiovascular events including cardiovascular death, myocardial infarction and stroke in women 50 years of age or older and suffering from at least one cardiovascular risk factor including hypertension or diabetes. We plan to initiate this Phase III safety study by year-end 2007 or in early 2008. The objective of the safety study is to show the relative safety of testosterone compared to placebo in the number of cardiovascular events. The incidence of breast cancer also will be tracked over the course of the study.

The Phase III efficacy trials of LibiGel in the treatment of female sexual dysfunction, one of which has been initiated, are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The efficacy trial already initiated is being conducted under a Phase III protocol reviewed by and on file with the FDA and in which written FDA comments have been received and incorporated. We hope to initiate the second Phase III efficacy trial in early 2008.

In April 2007, we announced that a new patent had issued covering the formulations used in Elestrin and LibiGel. The patent, which was issued on April 3, 2007 covering both Elestrin and LibiGel, will expire on June 25, 2022.

In May 2007, we announced that we licensed U.S. rights to a new oral contraceptive to Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market the product. We may receive certain development and regulatory milestones for the first product developed under the license. In addition, we will receive royalty payments on any sales of the product in the U.S., if and when approved and marketed. If the product is sublicensed by Pantarhei to another company, we will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. We have retained all rights under our licensed patents to the transdermal delivery of triple hormone contraceptives. In June 2007, we announced that Pantarhei initiated a Phase II human clinical trial of the new oral contraceptive. The Phase II trial, being conducted in the Netherlands, will enroll approximately 72 women in a double-blind, placebo controlled, randomized, comparative 2-way crossover study to determine the effect of a new patented oral contraceptive on sexual arousability and the vascular component of the sexual arousal response in women. Results should be available by mid-2008.

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, under a subcontract with DynPort Vaccine Company LLC, we provided BioVant, our vaccine adjuvant, and DynPort provided recombinant antigens to be used in potential vaccines against anthrax. The objective was to assess the immunogenic potential of BioVant when used in anthrax vaccines versus the immunogenic response of anthrax vaccines that use alum as the vaccine adjuvant. We have completed this subcontract and recorded approximately $300,000 in revenue over the life of the subcontract with $1,806 and $82,985 recognized in 2007 and 2006, respectively. Currently, we are seeking additional funding from government sources or potential partners for our anthrax program.

While our main overall business strategy is to continue to pursue the development of our hormone therapy products, especially LibiGel, we simultaneously are continuing to monitor opportunities to enter into business collaborations, mergers, acquisitions or joint ventures with entities that have businesses or technologies complementary to our business. In addition, we will consider opportunities to in-license or otherwise acquire other products in the late-stage development phase that will add value to our current product portfolio, and as a matter of course, we from time to time engage in discussions with third parties regarding the licensing or acquisition of products.

Financial Overview

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future, although Bradley, our marketing sublicensee for Elestrin, launched Elestrin in mid-June 2007, and as such, we are entitled to receive royalties on net sales of Elestrin and additional milestone payments of up to $40 million in the event certain sales-based milestones are achieved.

To date, we have used primarily equity financing and licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. In 2006, we recognized $14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in December 2006. Upon execution of the Bradley agreement, we received an upfront payment of $3.5 million. In addition, in March 2007, Bradley paid us $7 million and has agreed to pay us an additional $3.5 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. We are required to pay Antares 25% of these payments as a result of our license agreement with Antares.

In June 2007, we completed a private placement of 3,054,999 shares of our common stock and associated warrants to purchase 763,750 shares of our common stock at a purchase price of $6.00 per share. The private placement resulted in net proceeds of approximately $17.3 million, after deduction of transaction expenses. Our cash, cash equivalents and short-term investments were $29,355,197 as of September 30, 2007.

Our business operations to date have consisted mostly of licensing and research and development activities and we expect this to continue for the immediate future. If and when our proposed products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves**.** We currently do not have sufficient resources on a long-term basis to complete the commercialization of any of our proposed products for which we have not entered into marketing relationships. Based on our current cash resources, including the additional sublicensing payments we expect to receive from Bradley, and our current commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next 18 months, although no assurance can be made that we will not need or seek additional cash prior to such time. As an alternative to raising additional financing, we may license LibiGel or another product, to a third party who may finance a portion or all of the continued development and if approved, commercialization of LibiGel or the other product, or we may elect to sell certain assets or rights we have under our existing license agreements.
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Bradley commercially launched Elestrin in mid-June 2007. As such, we recognized royalty revenue of $14,063 and $66,991 from the sale of Elestrin for the three month and nine month periods ended September 30, 2007, respectively. This royalty is based on a percentage of Bradley's net sales of Elestrin. The royalty revenue presented in our financial statements represents the gross royalty revenue to be received from Bradley and does not reflect our corresponding obligation to pay Antares a portion of the royalties received. While we believe that royalty revenues from Bradley may be significant in the long term, we have not received any meaningful royalty revenue to date, and we do not know when, if ever, Bradley's Elestrin sales will result in significant royalty revenue to us.

We spent an average of approximately $350,000 to $400,000 per month on research and development activities during the nine months ended September 30, 2007. Our research and development expenses increased $379,172 or 50 percent, to $1,145,764 for the three months ended September 30, 2007 from $766,592 for the three months ended September 30, 2006, primarily as a result of increased clinical expenses associated with the LibiGel clinical program. We expect our research and development expenses to be higher for the remainder of 2007 and thereafter compared to the first nine months of 2007 as a result of the commencement of our Phase III clinical development program for LibiGel. Specifically, we expect our research and development expenses to increase to approximately $400,000 to $600,000 per month beginning in the fourth quarter of 2007. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) resources available; (2) our development schedule, including the timing of our clinical trials and subject recruitment and enrollment; (3) results of 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, 2007 increased $816,642 or 388 percent, compared to the three months ended September 30, 2006. This increase was due to an increase in non-cash stock-based compensation expense during the three months ended September 30, 2007 combined with recognizing and receiving $500,000 in settlement of our claim against our insurance carrier for coverage in a personnel-related matter during the three months ended September 30, 2006. Our general and administrative expenses may fluctuate from year-to-year depending upon the amount of legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

Although we recognized net income of $2,791,273 for the year ended December 31, 2006 primarily due to recognizing $14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in 2006 and although we expect to receive royalty income and possibly sales-based milestone payments from Bradley, 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 preclinical and clinical trials commence or continue, including in particular the Phase III clinical trial program for LibiGel which commenced in December 2006 and other trials and studies associated with LibiGel. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the commercial success and net sales of Elestrin, on which we will receive royalties and potential sales-based milestone payments; and
- the costs of licensure or acquisition of new products.

Results of Operations

Three Months Ended September 30, 2007 Compared to Three Months Ended September 30, 2006

The following table sets forth our results of operations for the three months ended September 30, 2007 and 2006.

	Three Months Ended September 30,			
	2007	**2006**	**$ Change**	**% Change**
Revenue	$ 43,793	$ 140,324	$ (96,531)	(68.8)%
Expenses				
Research and development	1,145,764	766,592	379,172	49.5%
General and administrative	1,027,194	210,552	816,642	387.9%
Interest income	379,114	122,484	256,630	209.5%
Net loss	$ (1,693,044)	$ (745,061)	$ 947,983	127.2%

Revenue decreased $96,531 primarily as a result of the completion of our activities under the Dynport subcontract and a reduction in funding from our University of Nebraska subcontract.

Research and development expenses for the three months ended September 30, 2007 increased approximately 50 percent compared to the three months ended September 30, 2006 primarily as a result of the commencement of our Phase III clinical development program for LibiGel in December 2006.

General and administrative expenses for the three months ended September 30, 2007 increased 388 percent compared to the three months ended September 30, 2006 primarily as a result of an increase in non-cash, stock-based compensation expense in the third quarter of 2007 combined with recognizing and receiving $500,000 in settlement of our claim against our insurance carrier for coverage in a personnel-related matter during the third quarter of 2006.

Non-cash, stock-based compensation expense increased as a result of the recognition of $186,145 in non-cash stock-based compensation expense during the three months ended September 30, 2007 compared to $49,203 for the three months ended September 30, 2006 due to an increase in the number of options granted and outstanding during the nine month period ended September 30, 2007 versus the same period in 2006. Our stock option and warrant grants have remaining lives of one to ten years and will be amortized over the remaining vesting period. Certain of our stock option grants also have performance condition-based vesting provisions, which will result in recognition of expense when such performance conditions are reached.

Interest income for the three months ended September 30, 2007 increased 210 percent compared to interest income for the three months ended September 30, 2006 as a result of higher average invested cash balances and higher average interest rates on invested cash balances during the three month period ended September 30, 2007 compared to the same period in 2006.

Nine Months Ended September 30, 2007 Compared to Nine Months Ended September 30, 2006

The following table sets forth our results of operations for the nine months ended September 30, 2007 and 2006.

	Nine Months Ended September 30,			
	2007	2006	$ Change	% Change
Revenue	$ 163,847	$ 400,254	$ (236,407)	(59.1)%
Expenses				
Research and development	3,539,081	2,900,057	639,024	22.0%
General and administrative	3,211,759	3,902,183	(690,424)	(17.7)%
Interest income	756,131	288,821	467,310	161.8%
Net loss	$ (5,910,371)	$ (6,198,456)	$ (288,085)	(4.6)%

Revenue decreased $236,407 primarily as a result of the completion of our activities under the Dynport subcontract and a reduction in funding from our University of Nebraska subcontract offset partially by royalty revenue of $66,991 as a result of Bradley's commercial launch of Elestrin in mid-June 2007.

Research and development expenses for the nine months ended September 30, 2007 increased 22 percent compared to research and development expenses for the nine months ended September 30, 2006 primarily as a result of the commencement of our Phase III clinical development program for LibiGel in December 2006.

General and administrative expenses for the nine months ended September 30, 2007 decreased 18 percent compared to general and administrative expenses for the nine months ended September 30, 2006, primarily as result of lower legal costs incurred during the nine months ended September 30, 2007 combined with a decrease in non-cash, stock-based compensation expense and recognizing and receiving $500,000 in settlement of our claim against our insurance carrier for coverage in a personnel-related matter during the nine months ended September 30, 2006.

Non-cash stock-based compensation expense decreased 46% primarily as a result of a $746,616 charge related to a March 2006 grant of stock options with immediate vesting to the non-employee members of our Board of Directors, which were fully expensed on the grant date due to the terms of those awards. Our other stock option and warrant grants have remaining service lives of one to ten years and are being amortized over the remaining vesting period. Certain of our stock option grants also have performance condition-based vesting provisions, which would result in recognition of expense when such performance conditions are reached.

Interest income for the nine months ended September 30, 2007 increased 162 percent compared to interest income during the nine months ended September 30, 2006, as a result of higher average invested cash balances and higher average interest rates on invested cash balances in 2007.

The overall decrease in net loss for the nine months ended September 30, 2007 compared to the nine months ended September 30, 2006 was primarily due to the impact of decreases in general and administrative expenses and non-cash, stock-based compensation expense and an increase in interest income, partially offset by increases in research and development expense, as described above.

Liquidity and Capital Resources

Working Capital

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sub-licensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future, although our marketing sublicensee for our Elestrin product, Bradley Pharmaceuticals, Inc., commercially launched Elestrin in mid-June 2007, as a result of which we have received and will be entitled to receive royalties on any net sales of Elestrin and milestone payments of up to $40 million in the event certain sales-based milestones are achieved. Our cash, cash equivalents and short-term investments available to fund current operations were $29,355,197 and $11,449,829 at September 30, 2007 and December 31, 2006, respectively. The increase in our cash and short-term investment balances was primarily due to our receipt during the first quarter of 2007 of a net payment of $5.25 million as a result of our sublicense agreement with Bradley and the completion in June 2007 of a private placement of 3,054,999 shares of our common stock and associated warrants to purchase 763,750 shares of our common stock resulting in net proceeds to us of approximately $17.3 million, after deduction of transaction expenses, partially offset by our use of cash to fund operations. We do not have any outstanding debt.

Our business operations to date have consisted mostly of licensing and research and development activities, and we expect this to continue for the immediate future. If and when our proposed products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves. We currently do not have sufficient resources to obtain regulatory approval of our other proposed products or to complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we may need to raise substantial additional capital to fund our operations or alternatively, we may choose to sublicense LibiGel or another product for development and commercialization, enter into other business collaborations or combinations or sell certain assets or rights we have under our existing license agreements.

To date, we have used primarily equity financing and licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice, if a similar financing is necessary, for the foreseeable future. During the nine months ended September 30, 2007, we also received $1,186,860 in cash proceeds from stock option and warrant exercises.

We believe that our cash and short-term investments as of September 30, 2007, together with payments we expect to receive from Bradley under our sublicense agreement with Bradley, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 18 months. However, we may seek to obtain additional financing prior to that time. Our future capital requirements will depend upon numerous factors, including:

- the progress and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the commercial success and net sales of Elestrin, on which we receive royalties and may receive potential sales-based milestone payments;
- the rate of technological advances;
- the potential commercial success of our proposed products;
- our general and administrative expenses;

- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

If we raise additional funds through the issuance of equity securities, our stockholders may experience dilution, which could be significant. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. If financing is not available when required or is not available on acceptable terms, or additional sublicense agreements are not signed, we may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the development of our proposed products, commercial introduction of our products or restrict us from acquiring new products that we believe may be beneficial to our business.

Uses of Cash and Cash Flow

We used cash in operating activities of $556,428 for the nine months ended September 30, 2007 versus cash used in operating activities of $6,176,635 for the nine months ended September 30, 2006. Cash used in operating activities for the nine months ended September 30, 2007 and 2006 was primarily the result of the net loss for that period partially offset by the receipt of $7.0 million Bradley receivable, 25% of which was due to our licensor. Net cash used in investing activities was $164,655 for the nine months ended September 30, 2007 versus cash used in investing activities of $1,152,123 for the nine months ended September 30, 2006. Redemption of short-term investments provided $6,909,815 in cash during the first nine months of 2006. 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 in June 2007 of 3,054,999 shares of our common stock and associated warrants to purchase 763,750 shares of our common stock resulting in net proceeds to us of approximately $17.3 million, after deduction of transaction expenses, and warrant and stock option exercises. Net cash provided by financing activities during the nine months ended September 30, 2006 was $7,384,289 primarily as a result of the completion of a June 2006 private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock.

We recorded and paid $75,000 in income tax expense during the nine month period 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 during the period ended September 30, 2007. 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, 2007. We have, however, several potential financial commitments, including product development milestone payments to the licensors of certain of our hormone therapy products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of September 30, 2007:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating Leases	$ 110,386	$ 110,386	—	—	—
Obligation for Settlement Agreement	137,647	137,647	—	—	—
Obligation under License Agreement with Antares	881,328	881,328	—	—	—
Commitments Under License Agreement with Wake Forest	710,000	30,000	160,000	160,000	360,000
Total Contractual Cash Obligations	$ 1,839,361	$ 1,159,361	$ 160,000	$ 160,000	$ 360,000

We expect to continue to spend capital on:

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- general administrative expenses, involving investor relations, legal and accounting fees and expenses; and
- the licensure or acquisition of new products, general business development including out-licensing of our products in our territories.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our pre-clinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;
- time and cost necessary to seek marketing partners to market our products for us;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

In addition, our license agreement with the licensor of certain of our hormone therapy products requires us to make certain payments as development milestones are achieved. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

- enter into additional leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

Under the terms of the license agreements with the University of California and Wake Forest University Health Sciences and Cedars-Sinai Medical Center, we have the right to terminate the license agreements for any reason, with our only obligation being the payment of monies owed at the date of termination.

Recent Accounting Pronouncements

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. FIN 48 requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. The adoption of FIN 48 did not have an impact on our results of operations or financial condition.

In September 2006, the FASB issued 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 would be separately disclosed by level within the fair value hierarchy. The statement will be effective for us January 1, 2008 though early adoption is permitted. We have not yet determined the impact, if any, that the implementation of SFAS 157 will have on our results of operations or financial condition.

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 is effective for fiscal years beginning after November 15, 2007. The adjustment to reflect the difference between the fair value and the carrying amount would be accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. We have not yet determined the impact, if any, that the adoption of SFAS 159 will have on our results of operations or financial condition.

Forward-Looking Statements

This quarterly report on Form 10-Q contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "could," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "approximate," "contemplate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained in the notes to our 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 and completion of our clinical trials and other regulatory status of our proposed products;
- the future market and market acceptance of our products;
- the amount of royalty revenue we expect to receive from Bradley Pharmaceuticals, Inc. on net sales of Elestrin;
- the effect of new accounting pronouncements;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of marketing capabilities and licensure or acquisition of new products;
- collaborating, merging or acquiring entities that have businesses or technologies complementary to our business;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

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

- lack of market acceptance of Elestrin and our other hormone therapy products if and when they are commercialized
- failure to obtain additional capital when needed or on acceptable terms;
- failure of products to be commercially introduced for several years or at all;
- failure to obtain and maintain required regulatory approvals on a timely basis or at all;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- our dependence upon Bradley Pharmaceuticals, Inc, for the marketing and sale of our Elestrin product and our dependence upon other sublicensees for the development, marketing and sale of certain of our other hormone therapy 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;
- the scope, timing and results of our clinical trials and other uncertainties associated with clinical trials;
- our ability to compete in a competitive industry;
- our ability to collaborate, merge or acquire entities that have businesses or technologies complementary to our business;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;
- adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
- changes in generally accepted accounting principles; or
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 under the heading "Part I – Item 1A. Risk Factors" on pages 22 through 32 of such report and "Part II — Item 1A. Risk Factors" included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 and elsewhere in 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, 2006 under the heading "Part I – Item 1A. Risk Factors" and under the heading "Part II — Item 1A. Risk Factors" included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 and included elsewhere in 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, 2006 under the heading "Part I – Item 1A. Risk Factors" and under the heading "Part II — Item 1A. Risk Factors" included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 and included elsewhere in 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 DISCLOSURE ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to reasonably ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, 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 and our consolidated subsidiaries 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, 2007 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We refer you to the description under the heading "Contingencies" in note 4 of our financial statements included within this report, which is incorporated herein by reference.

ITEM 1A. DEFAULTS UPON SENIOR SECURITIES

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2006 under the heading "Part I – Item 1A. Risk Factors" and under the heading "Part II — Item 1A. Risk Factors" included in our quarterly report on Form 10-Q for the quarter ended March 31, 2007 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.

On October 22, 2007, we received notice that the staff of the Securities and Exchange Commission's Division of Enforcement completed its investigation and intended to recommend no enforcement action by the Commission with respect to an informal inquiry the Staff commenced in March 2007 arising out of allegations contained in a complaint made in February 2006 by a former officer of our company to the U.S. Department of Labor, Occupational Safety & Health Administration under the "whistleblower" provision of the Sarbanes-Oxley Act of 2002.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2007, we did not issue any shares of our common stock or other equity securities of ours that were not registered under the Securities Act of 1933, as amended, other than in July 2007, we issued warrants to purchase 180,000 shares of common stock to a certain investor relations firm in return for various investor relations services. The warrants are exercisable at an exercise price equal to $8.00 per share with 50% of the warrants becoming exercisable on July 19, 2008 and the remainder becoming exercisable on July 19, 2009. The warrants are exercisable through and including July 18**,** 2010. The sale of the warrants to the investor relations firm was made in reliance on either Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering or Regulation D of the Securities Act. Certain inquiries of the investor relations firm were made by BioSante to establish that the offer and sale qualified for such exemption from the registration requirements. In particular, BioSante confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) the offer and sale of the warrant was made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) the investor relations firm made representations that it was sophisticated in relation to its investment (and BioSante has no reason to believe that such representations were incorrect), (iii) the investor relations firm gave assurance of investment intent and the warrant, as well as the certificate representing the shares of our common stock issuable upon exercise of the warrant, will bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

Issuer Purchases of Equity Securities

Other than the withholding of 742 shares of our common stock in connection with the cashless net exercise of stock options to pay the exercise price of such options, we did not purchase any shares of our common stock or other equity securities during the three months ended September 30, 2007, and 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.

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

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

November 13, 2007

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 andSecretary
(principal financial and accounting officer)

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

Exhibit No.	Description	Method of Filing
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith