BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 14, 2006

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

FORM 10-Q

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

For the quarterly period ended September 30, 2006

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 14, 2006, 22,975,040 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-Q
SEPTEMBER 30, 2006

TABLE OF CONTENTS

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®, BioVant™,

NanoVant™, CAP-Oral™, BioAir™, Bio-E-Gel®, E/P-Gel™, LibiGel®, LibiGel-E/T™ and Bio-T-Gel™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
September 30, 2006 and December 31, 2005 (Unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 366,174	$ 310,643
Short-term investments	9,903,757	8,790,888
Prepaid expenses and other sundry assets	270,293	245,465
	10,540,224	9,346,996
PROPERTY AND EQUIPMENT, NET	169,529	215,566
OTHER ASSETS		
Security deposits	25,325	11,992
	$ 10,735,078	$ 9,574,554
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 318,254	$ 1,139,566
Accrual for contingencies	688,234	750,000
Accrued compensation	361,570	492,980
Other accrued expenses	192,651	147,125
Deferred revenue	102,273	136,363
TOTAL CURRENT LIABILITIES	1,662,982	2,666,034
LONG TERM LIABILITIES		
Leasehold retirement liability	43,000	21,500
Deferred revenue	-	68,182
TOTAL LONG TERM LIABILITIES	43,000	89,682
TOTAL LIABILITIES	$ 1,705,982	$ 2,755,716
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding		
2006 - 391,286; 2005 - 391,286 Class C special stock	398	398
2006 - 22,975,040; 2005 - 19,007,800 Common stock	64,915,474	56,653,219
	64,915,872	56,653,617

Deferred unearned compensation	**-**	**(146,459)**
Deficit accumulated during the development stage	**(55,886,776)**	**(49,688,320)**
	9,029,096	**6,818,838**
	$ 10,735,078	**$ 9,574,554**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and nine months ended September 30, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2006 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative period from August 29, 1996 (date of incorporation) to September 30,
	2006	2005	2006	2005	2006
REVENUE					
Licensing income	$ 34,091	$ 11,364	$ 102,273	$ 11,364	$ 4,740,671
Grant income	106,233	43,742	242,981	118,016	491,763
Other Income	-	32,000	55,000	32,000	87,000
	140,324	87,106	400,254	161,380	5,319,434
EXPENSES					
Research and development	766,592	1,314,283	2,900,057	5,393,852	33,376,130
General and administration	210,552	704,966	3,902,183	2,200,635	22,984,484
Depreciation and amortization	30,725	25,464	85,291	76,449	947,592
Loss on disposal of capital assets	-	-	-	-	157,545
Costs of Acquisition of Structured Biologicals Inc.	-	-	-	-	375,219
Purchassed in-process research and development	-	-	-	-	5,377,000
	1,007,869	2,044,713	6,887,531	7,670,936	63,217,970
OTHER - Interest income	122,484	104,390	288,821	304,263	2,011,760
NET LOSS	$ (745,061)	$ (1,853,217)	$ (6,198,456)	$ (7,205,293)	$ (55,886,776)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.03)	$ (0.10)	$ (0.30)	$ (0.37)	

WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**22,412,189**	**19,399,086**	**20,472,383**	**19,389,960**

See accompanying notes to the financial statements.

4

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
nine months ended September 30, 2006 and 2005 and the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2006 (Unaudited)

	Nine Months ended September 30, 2006	2005	Cumulative period from August 29, 1996 (date of incorporation) to September 30, 2006
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	**$ (6,198,456)**	**$ (7,205,293)**	**$ (55,886,776)**
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	**85,291**	**76,449**	**947,592**
Amortization of deferred unearned compensation	**-**	**-**	**42,290**
Repurchase of licensing rights	**-**	**-**	**125,000**
Employee & director compensation - noncash	**1,024,425**	**263,625**	**2,292,466**
Purchased in-process research and development	**-**	**-**	**5,377,000**
Loss on disposal of equipment	**-**	**-**	**157,545**
Changes in other assets and liabilities affecting cash flows from operations			
Prepaid expenses, deposits and other sundry assets	**(38,161)**	**43,793**	**(292,650)**
Accounts payable and accrued liabilities	**(885,697)**	**(538,253)**	**220,833**
Accrual for contingencies	**(61,765)**	**-**	**688,235**
Deferred revenue	**(102,272)**	**238,636**	**102,273**
Due from SBI	**-**	**-**	**(128,328)**
Net cash used in operating activities	**(6,176,635)**	**(7,121,043)**	**(46,354,520)**
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES			
Redemption of short term investments	**6,909,815**	**6,350,149**	**14,609,965**
Purchase of short term investments	**(8,022,684)**	**(296,841)**	**(24,513,722)**

Purchase of capital assets	**(39,254)**	**(45,916)**	**(1,240,556)**
Net cash (used in) provided by investing activities	**(1,152,123)**	**6,007,392**	**(11,144,313)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	**-**	**-**	**500,000**
Proceeds from sale or conversion of shares	**7,384,289**	**197,768**	**57,368,057**
Fractional share payout	**-**	**-**	**(3,050)**
Net cash provided by financing activities	**7,384,289**	**197,768**	**57,865,007**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**55,531**	**(915,883)**	**366,174**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**310,643**	**1,170,025**	**-**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 366,174**	**$ 254,142**	**$ 366,174**
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	**$ -**	**$ -**	**$ 5,377,000**
Other net liabilities assumed	**-**	**-**	**(831,437)**
	-	**-**	**4,545,563**
Less: subordinate voting shares issued therefor	**-**	**-**	**4,545,563**
	$ -	**$ -**	**$ -**
Income tax paid	**$ -**	**$ -**	**$ -**
Interest paid	**$ -**	**$ -**	**$ 3,421**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
FORM 10-Q
SEPTEMBER 30, 2006

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, 2006, the results of operations for the three and nine months ended September 30, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 2006, and the cash flows for the nine months ended September 30, 2006 and 2005 and for the cumulative period from August 29, 1996 (date of incorporation) to September 30, 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, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006.

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, 2005.

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, 2006 does not include options to purchase an aggregate of 1,037,979 and 1,037,979 shares of common stock, respectively, 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 of $2.15 and $7.00 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, 2005 does not include options to purchase an aggregate of 1,499,530 and 1,238,086 shares of common stock, respectively, with exercise prices ranging from $2.10 to $7.60 per share, and warrants to purchase an aggregate of 1,644,355 shares of common stock, with exercise prices ranging from $2.15 to $8.75 per share, because of their antidilutive effect on net loss per share.

3. LICENSE AGREEMENTS

In February 2006, the Company signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation ("MATC") for the use of the Company's calcium phosphate nanotechnology ("CaP") in the field of aesthetic medicine. Under the terms of the option and license agreement, MATC will use the Company's CaP technology to develop products for commercialization in the field of aesthetic medicine, specifically, the improvement and/or maintenance of the external appearance of the head, face, neck and body. Within the first 12 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to the Company of a license fee. The Company has the right to receive additional milestone payments upon approval by the U.S. Food and Drug Administration or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

4. COMMITMENTS AND CONTINGENCIES

Commitments

The Company is a party to various licensing agreements, including agreements with the Regents of the University of California, Antares Pharma, Inc. and Wake Forest University. Certain of these agreements require the Company to indemnify the licensor for claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of the license agreement, including but not limited to, any product liability claim. The Company has no knowledge of events having occurred which would require indemnification by the Company, and has not recorded any liability in connection with these obligations as of September 30, 2006 or December 31, 2005.

In August 2006, the Company entered into a Fourth Amendment to Exclusive License Agreement for patents related to the Company's CaP technology with The Regents of the University of California. Under the terms of the amendment, the Company amended certain terms of the agreement, including the elimination of future specified minimum annual royalties which equal in excess of $3 million owed to the University of California in exchange for an immediate payment of $100,000. Under the terms of the original agreement, $75,000 would have been due on February 28, 2007 for which the Company had accrued $37,500 at the time of the amendment.

Contingencies

In May 2006, the Company, certain officers, one of its directors, and a former officer entered into a Confidential Settlement Agreement under which, the parties thereto agreed to voluntarily withdraw and dismiss any and all charges, claims and pending litigation with prejudice and execute mutual releases and covenants not to sue. The Company agreed to pay the former officer post-termination installment payments in the aggregate amount of $780,000 in equal installments in accordance with the Company's regular payroll cycle through December 31, 2007 and to secure such payments with an irrevocable letter of credit. The Company also paid the legal fees incurred by the former officer in the amount of $110,000 in August 2006.

To secure payments under the Settlement Agreement described above, on May 26, 2006, the Company entered into an irrevocable letter of credit with UBS AG in the amount of $780,000 supported by the Company's short term investment account with UBS AG. The outstanding balance under the letter of credit and corresponding accrued liability as of September 30, 2006 is $688,234 and will continue to decrease as payments are made through December 2007.

In July 2006, the Company reached an agreement with its employment practices liability insurance carrier pursuant to which in August 2006, the carrier paid the Company $500,000 in settlement of the Company's claim against the carrier for coverage in this matter. This amount has been included in general and administrative expenses for the three- and nine-month periods ended September 30, 2006.

5. STOCK-BASED COMPENSATION

The Company adopted Statement of Financial Accounting Standards 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 APB 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, 2006, 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 $1,024,425 and $263,625 for the nine months ended September 30, 2006 and 2005, 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.

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, 2006, 3,000,000 shares of the Company's common stock were reserved for issuance under the Plan, 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 and directors with those of its stockholders. Options are generally 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 to directors 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 using the assumptions in the table below:

	Nine Months Ended September 30,	
	2006	**2005**
Expected life in years	10	10
Annualized volatility	73.94%	76.58%
Discount rate - bond equivalent yield	4.10%	3.96%

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 as published in *The Wall Street Journal* as of the grant date. 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, 2006 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2005	1,425,530	$ 3.41
Granted	362,500	3.87
Exercised	(152,894)	2.51
Forfeited or expired	(597,157)	3.65
Outstanding September 30, 2006	1,037,979	$ 3.61
(weighted average contractual term)	*7.7 years*	
Exercisable at September 30, 2006	798,478	$ 3.50
(weighted average contractual term)	*7.2 years*	

The aggregate intrinsic values of the Company's outstanding and exercisable options as of September 30, 2006 were $0 and $0, respectively.

A summary of the Plan's non-vested options at December 31, 2005 and activity under the Plan during the nine months ended September 30, 2006 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2005	398,000	$ 3.61
Granted	362,500	3.87
Vested	(341,944)	3.56
Forfeited	(179,055)	3.49
Non-Vested at September 30, 2006	239,501	$ 3.58

As of September 30, 2006, there was $466,129 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 weighted-average period of 2.17 years.

As a result of a March 2006 issuance of stock options with immediate vesting to the non-employee members of our Board of Directors, $746,616 of non-cash, stock based compensation expense was recorded in the nine months ended September 30, 2006.

Cash received from option exercises under the Plan for the nine months ended September 30, 2006 was $243,675. The intrinsic value of options exercised during the nine months ended September 30, 2006 was $218,613. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position.

	Three Months Ended September 30, 2006	Three Months Ended September 30, 2005
Net loss		
As reported	**$ (745,061)**	$ (1,853,217)
Stock-based compensation included in net loss as reported	**49,203**	87,875
Total stock-based employee compensation determined under fair value based method for all awards	**(49,203)**	(226,083)
Net loss, pro forma	**$ (745,061)**	$ (1,991,425)
Basic and diluted net loss per share		
As reported	**$ (0.03)**	$ (0.10)
Pro forma	**$ (0.03)**	$ (0.10)

	Nine Months Ended September 30, 2006	Nine Months Ended September 30, 2005
Net loss		
As reported	**$ (6,198,456)**	$ (7,205,293)
Stock-based compensation included in net loss as reported	**1,024,425**	263,625
Total stock-based employee compensation determined under fair value based method for all awards	**(1,024,425)**	(595,090)
Net loss, pro forma	**$ (6,198,456)**	$ (7,536,758)
Basic and diluted net loss per share		
As reported	**$ (0.30)**	$ (0.37)
Pro forma	**$ (0.30)**	$ (0.39)

6. STOCKHOLDERS' EQUITY

On July 21, 2006, the Company closed a private placement of 3,812,978 shares of its common stock and associated warrants to purchase 1,334,542 shares of its common stock at a purchase price of $2.00 per unit to certain institutional and other accredited investors for gross proceeds of approximately $7.6 million. The private placement resulted in net proceeds to the Company of approximately $7.2 million, after deduction of transaction expenses. The warrants are exercisable for a period of four years and nine months, beginning January 22, 2007, at an exercise price of $2.75 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.

During the nine months ended September 30, 2006, options to purchase an aggregate of 91,849 shares of common stock were exercised for total cash proceeds of $243,675. In addition, options to purchase an aggregate of 61,045 shares of common were exercised on a cashless basis, for which 91,768 options were withheld 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.

7. SUBSEQUENT EVENTS

In November 2006, the Company signed an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel® (transdermal estradiol gel) in the United States. Upon execution of the agreement, the Company received an upfront payment of $2.625 million. In addition, if and when Bio-E-Gel is approved by the U.S. Food and Drug Administration (FDA), Bradley has agreed to pay the Company $10 to $10.5 million, $7 million of which would be due upon the earlier of 14 weeks after obtaining such approval or the first commercial sale of Bio-E-Gel by Bradley in the U.S. and up to an additional $3.5 million which would be due on the one-year anniversary of such approval,. Upon receipt of these payments, BioSante will be obligated to pay Antares Pharma IPL AG, BioSante's licensor of the transdermal estradiol gel formulation in Bio-E-Gel, 25 percent of such payments resulting in BioSante receiving an aggregate of $7.5 million to $7.875 million from Bradley. Bradley also has agreed to pay BioSante additional sales based milestone payments, as well as royalties on sales of Bio-E-Gel.

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 development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat both 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 and drug delivery systems.

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., are gel formulations for transdermal administration that deliver bioidentical estradiol, testosterone, a combination of estradiol and testosterone and a combination of estradiol and progestogen. Our hormone therapy products include Bio-E-Gel, LibiGel, Bio-E/P-Gel, Bio-E/T-Gel and Bio-T-Gel. We have conducted human clinical trials on several of our hormone therapy products, which are required to obtain U.S. Food and Drug Administration, or FDA approval to market the products. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted our New Drug Application, or NDA with the FDA in February 2006. We expect Bradley Pharmaceuticals, Inc., our Bio-E-Gel licensee, to commercially launch our Bio-E-Gel product after obtaining FDA approval, which we hope to receive in late 2006 or early 2007. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials which we hope to begin by year-end 2006 or early 2007. We have not received FDA or any other government approval for any of our products and thus have not commercialized any of them in the United States or elsewhere.

We also are developing our CaP technology, several of whose issued patents we license on an exclusive basis from the University of California, for novel vaccines, including avian flu and biodefense vaccines for toxins such as anthrax and ricin, and drug delivery systems. Our strategy with respect to CaP is to continue development of our CaP technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. We have entered into an agreement with the U.S. Army's Medical Research Institute of Infectious Disease for the development of non-injected biodefense vaccines, including anthrax, staph and ricin, and an agreement with DynPort Vaccine Company LLC for the development of anthrax vaccines for delivery via alternative routes of administration, including nasal, oral and needle-free transcutaneous routes. We have also entered into a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products, a subcontract with the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration, and an exclusive option and license agreement with Medical Aesthetics Technology Corporation, or MATC, for the use of our CaP technology in the field of aesthetic medicine.

Financial Overview

All of our revenue to date has been derived from upfront and milestone 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 until 2007 at the earliest depending upon the timing of the potential approval by the FDA on our NDA for our Bio-E-Gel product, which we submitted in February 2006.

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. For the nine months ended September 30, 2006, we received approximately $244,000 from option exercises. Our cash, cash equivalents and short-term investments were $10,269,931 as of September 30, 2006. On July 21, 2006, we completed a private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock at a purchase price of $2.00 per unit. The private placement resulted in net proceeds of approximately $7.2 million, after deduction of transaction expenses.

In November 2006, BioSante signed an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel® (transdermal estradiol gel) in the United States. Upon execution of the agreement, BioSante received an upfront payment of $2.625 million. In addition, if and when Bio-E-Gel is approved by the U.S. Food and Drug Administration (FDA), Bradley has agreed to pay BioSante $10 to $10.5 million, $7 million of which would be due upon the earlier of 14 weeks after obtaining such approval or the first commercial sale of Bio-E-Gel by Bradley in the U.S. and up to an additional $3.5 million which would be due on the one-year anniversary of such approval;. Upon receipt of these payments, BioSante will be obligated to pay Antares Pharma IPL AG, BioSante's licensor of the transdermal estradiol gel formulation in Bio-E-Gel, 25 percent of such payments resulting in BioSante receiving an aggregate of $7.5 million to $7.875 million from Bradley. Bradley also has agreed to pay BioSante additional sales based milestone payments, as well as royalties on sales of Bio-E-Gel.

Our business operations to date have consisted mostly of 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 net proceeds we received from our July 2006 private placement and the upfront payment we recently received 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 twelve months, although no assurance can be made that we will not need additional cash prior to such time.

We spent an average of approximately $325,000 per month on research and development activities during the nine months ended September 30, 2006. Our research and development expenses decreased $547,691 or 42 percent, to $766,592 for the three months ended September 30, 2006 from $1,314,283 for the same period ended September 30, 2005, and decreased $2,493,795 or 46 percent to $2,900,057 in the nine months ended September 30, 2006 from $5,393,852 for the same period in 2005. This reduction is primarily as a result of the completion of the Phase III clinical trial of Bio-E-Gel in March 2005, partially offset by the costs associated with the preparation of the Bio-E-Gel NDA. We expect our research and development expenses to remain at approximately the same level as the first nine months of 2006 until the commencement of our LibiGel Phase III clinical program, which we expect to commence by year-end 2006 or early 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; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our proposed products; and (5) competitive developments.

Our general and administrative expenses decreased $494,414 or 70 percent, to $210,552 for the three months ended September 30, 2006 from $704,966 for the same period ended September 30, 2005, and increased $1,701,548 or 77 percent to $3,902,183 in the nine months ended September 30, 2006 from $2,200,635 in the same period in 2005. This increase was primarily as a result of recognition of $1,024,425 in non-cash, stock-based compensation expense during the nine months ended September 30, 2006 compared to $263,625 for the nine months ended September 30, 2005 as a result of our adoption of SFAS No. 123(R) “Share-Based Payment” (“SFAS 123”) and increased legal expenses and settlement costs incurred due to a personnel-related matter partially offset by insurance proceeds related to the matter. $746,616 of the non-cash, stock-based compensation expense recorded in the nine months ended September 30, 2006 related to a March 2006 issuance 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 general and administrative expenses may fluctuate from quarter-to-quarter and year-to-year depending upon the amount of legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

In August 2006, we entered into a Fourth Amendment to Exclusive License Agreement for patents related to the Company’s CaP technology with The Regents of the University of California. Under the terms of the amendment, we amended certain terms of the agreement, including the elimination of future specified minimum annual royalties which equal in excess of $3 million owed to the University of California in exchange for an immediate payment of $100,000. Under the terms of the original agreement, $75,000 would have been payable on February 28, 2007. The amendment also eliminated provisions that required us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve specific research and development milestones within specified time periods.

Since our inception, we have experienced significant operating losses. We incurred a net loss of $745,061 and $6,198,456 for the three and nine months ended September 30, 2006, respectively, resulting in an accumulated deficit of $55,886,776 as of September 30, 2006. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs expand and various preclinical and clinical trials commence and continue. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the costs of licensure or acquisition of new products or sublicensing of our products;
- the timing and cost of making necessary regulatory filings and obtaining approvals;
- the timing and cost of obtaining third party reimbursement; and
- the cost of sales and marketing activities.

Results of Operations

Three Months Ended September 30, 2006 Compared to Three Months Ended September 30, 2005

The following table sets forth our results of operations for the three months ended September 30, 2006 and 2005.

	Three Months Ended September 30,			
	2006	**2005**	**$ Change**	**% Change**
Revenue	$ 140,324	$ 87,106	$ 53,218	61.1%
Expenses				
Research and development	766,592	1,314,283	(547,691)	(41.7)%
General and administrative	210,552	704,966	(494,414)	(70.1)%
Interest income	122,484	104,390	18,094	17.3%
Net loss	$ (745,061)	$ (1,853,217)	$ 1,108,156	59.8%

We earned $34,091 in licensing income during the three months ended September 30, 2006 due to the CaP option and material transfer agreement we entered into in September 2005 compared to $11,364 in licensing income during the same period in 2005. We earned $106,233 and $43,472 in grant revenue during the three months ended September 30, 2006 and 2005, respectively. This increase is due to a subcontract we entered into with the University of Nebraska in December 2005, for the development of alternative routes of delivery of Factor IX formulations for Hemophilia B therapy.

Research and development expenses for the three months ended September 30, 2006 decreased 42 percent compared to research and development expenses for the three months ended September 30, 2005 primarily as a result of completion of the Phase III clinical trial of Bio-E-Gel in March 2005 and submission of our NDA for Bio-E-Gel in February 2006.

General and administrative expenses for the three months ended September 30, 2006 decreased 70 percent compared to general and administrative expenses for the three months ended September 30, 2005 as a result of recognizing and receiving $500,000 in settlement of our claim against our insurance carrier for coverage in a personnel-related matter.

Interest income for the three months ended September 30, 2006 increased 17 percent compared to interest income during the three months ended September 30, 2005, as a result of higher invested cash balances and higher interest rates on invested cash balances in 2006.

Nine Months Ended September 30, 2006 Compared to Nine Months Ended September 30, 2005

The following table sets forth our results of operations for the nine months ended September 30, 2006 and 2005.

	Nine Months Ended September 30,			
	2006	**2005**	**$ Change**	**% Change**
Revenue	$ 400,254	$ 161,380	$ 238,874	148.0%
Expenses				
Research and development	2,900,057	5,393,852	(2,493,795)	(46.2)%
General and administrative	3,902,183	2,200,635	1,701,548	77.3%
Interest income	288,821	304,263	(15,442)	(5.1)%
Net loss	$ (6,198,456)	$ (7,205,293)	$ 1,006,837	14.0%

15

We earned $102,273 in licensing income during the nine months ended September 30, 2006 due to the CaP option and material transfer agreement we entered into in September 2005 compared to $11,364 in licensing income during the same period in 2005. We earned $242,981 and $118,061 in grant revenue during the nine months ended September 30, 2006 and 2005, respectively. This increase is due to a subcontract we entered into with the University of Nebraska in December 2005.

Research and development expenses for the nine months ended September 30, 2006 decreased 46 percent compared to research and development expenses for the nine months ended September 30, 2005 primarily as a result of completion of the Phase III clinical trial of Bio-E-Gel in March 2005 and submission of our NDA for Bio-E-Gel in February 2006.

General and administrative expenses for the nine months ended September 30, 2006 increased 77 percent compared to general and administrative expenses for the nine months ended September 30, 2005, primarily as result of the recognition of $1,024,425 in non-cash, stock-based compensation expense during the nine months ended September 30, 2006 compared to $263,625 for the nine months ended September 30, 2005 as a result of our adoption of SFAS No. 123(R) “Share-Based Payment” (“SFAS 123”) and additional legal costs incurred due to a personnel-related matter partially offset by insurance proceeds related to the matter. Of the non-cash, stock-based compensation expense recorded in the nine months ended September 30, 2006, $746,616 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 grants have remaining service lives of one to ten years and will be amortized over that period. Certain of our employee stock option grants also have milestone provisions, which will result in recognition of expense upon such milestones being reached.

Interest income for the nine months ended September 30, 2006 decreased 5 percent compared to interest income during the nine months ended September 30, 2005, as a result of lower invested cash balances, partially offset by higher interest rates on invested cash balances in 2006.

Liquidity and Capital Resources

Working Capital

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and most recently, from a subcontract. To date, we have used primarily equity financing and received licensing 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, 2006, we have raised net proceeds totaling approximately $57.3 million from equity financings, class A and class C stock conversions, warrant and option exercises and the issuance of a $500,000 convertible debenture, and have received $4.7 million, net of sublicensing costs, as a result of licensing upfront payments and milestones. Our cash, cash equivalents and short-term investments available to fund current operations were $10,269,931 and $9,101,531 at September 30, 2006 and December 31, 2005, respectively. We do not have any outstanding borrowings.

On July 21, 2006, we completed a private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock at a purchase price of $2.00 per unit. The private placement resulted in net proceeds of approximately $7.2 million, after deduction of transaction expenses.

In July 2006, we reached an agreement with our employment practices liability insurance carrier pursuant to which in August 2006, the carrier paid us $500,000 in settlement of our claim against the carrier for coverage in the personnel-related matter described in more detail in note 4 to our financial statements.

In November 2006, BioSante signed an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel® (transdermal estradiol gel) in the United States. Upon execution of the agreement, BioSante received an upfront payment of $2.625 million. In addition, if and when Bio-E-Gel is approved by the U.S. Food and Drug Administration (FDA), Bradley has agreed to pay BioSante $10 to $10.5 million, $7 million of which would be due upon the earlier of 14 weeks after obtaining such approval or the first commercial sale of Bio-E-Gel by Bradley in the U.S. and up to an additional $3.5 million which would be due on the one-year anniversary of such approval;. Upon receipt of these payments, BioSante will be obligated to pay Antares Pharma IPL AG, BioSante's licensor of the transdermal estradiol gel formulation in Bio-E-Gel, 25 percent of such payments resulting in BioSante receiving an aggregate of $7.5 million to $7.875 million from Bradley. Bradley also has agreed to pay BioSante additional sales based milestone payments, as well as royalties on sales of Bio-E-Gel.

Our business operations to date have consisted mostly of 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 net proceeds we received from our July 2006 private placement and the upfront payment we recently received 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 twelve months, although no assurance can be made that we will not need additional cash prior to such 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 clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the commercial success of our proposed products;
- our general and administrative expenses, including if we receive FDA approval of any of our proposed products and the amount of resources we devote to sales and marketing capabilities;
- our ability to sublicense our products;
- 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, 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 $6,176,635 for the nine months ended September 30, 2006 versus cash used in operating activities of $7,121,043 for the nine months ended September 30, 2005. The decrease in cash used in operating activities primarily reflects a decrease in our net loss over the same nine month period. During the nine months ended September 30, 2006, we had net investment activity of $6,909,815 (including the investment of $7,233,863 from the proceeds of our July 2006 equity offering) in auction rate securities. During the nine months ended September 30, 2005, we received $6,350,149 from the net sale of auction rate securities. We used $39,254 for the purchase of computer equipment during the nine months ended September 30, 2006 and $45,916 for the purchase of computer, lab and office equipment during the nine months ended September 30, 2005. We entered into an irrevocable letter of credit with UBS AG in the amount of $780,000 supported by our short term investment account with UBS AG. The outstanding balance under the letter of credit is $688,234 as of September 30, 2006 and will continue to decrease as payments are made to a former executive officer pursuant to a settlement agreement through December 2007. Net cash provided by financing activities was $7,384,289 for the nine months ended September 30, 2006, which consisted of cash received as a result of our July 2006 private placement and stock option exercises, versus $197,768 for the nine months ended September 30, 2005, which was due to option and warrant exercises.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of September 30, 2006. We have, however, several financial commitments, including certain contractual obligations, product development milestone payments to the licensors of our hormone therapy products, payments under our license agreement with Wake Forest University, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of September 30, 2006:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating Leases	$ 195,142	$ 187,353	$ 7,789	$ 0	$ 0
Obligation for Settlement Agreement	688,235	550,588	137,647	0	0
Commitments Under License Agreement with Wake Forest	720,000	40,000	160,000	160,000	360,000
Total Contractual Cash Obligations	$ 1,603,377	$ 777,941	$ 305,436	$ 160,000	$ 360,000

In August 2006, we entered into a Fourth Amendment to Exclusive License Agreement for patents related to the Company’s CaP technology with The Regents of the University of California. Under the terms of the amendment, we amended certain terms of our agreement, including the elimination of future specified minimum annual royalties which equal in excess of $3 million owed to the University of California in exchange for an immediate payment of $100,000. Under the terms of the original agreement, $75,000 would have been due on February 28, 2007 for which we had accrued $37,500 at the time of the amendment.

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;
- establishment of our own marketing capabilities or a search for third party sales and marketing partners to sell and market our products for us; and
- the licensure or acquisition of new products or sublicensing of our products.

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 establish our own sales and marketing capabilities or 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 our hormone therapy products requires us to make certain payments as development milestones are achieved. Our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future based on annual usage and subject to cancellation upon our request, 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, 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. Pursuant to an amendment entered into with the University of California in August 2006, our license agreement with the University of California no longer requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve specific research and development milestones within a specified time period.

Off-Balance Sheet Arrangements

Except for operating leases entered in the ordinary course of business and customary indemnification obligations under our license, financing and other agreements, we do not have any off-balance sheet arrangements.

Critical Accounting Policies

The discussion and analysis of our financial statements and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these 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, 2005. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, other than our adoption of SFAS No. 123(R), as described herein. Although we believe that our estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109 (FIN 48), which clarifies the accounting for uncertainty in tax positions. 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 provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We have not yet determined the impact, if any, that the implementation of FIN 48 will have on our results of operations and financial condition.

In September 2006, the FASB issued SFAS 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 September 2006, the SEC issued Staff Accounting Bulletin No. 108 *"Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements"* (SAB 108). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 is effective for fiscal years ending on or after November 15, 2006, with early application encouraged. We have not yet determined the impact, if any, that the implementation of SAB 108 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, including the licensing of our Bio-E-Gel, approval of our Bio-E-Gel NDA and the commencement of our Phase III clinical trials for LibiGel;

- 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;

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

- our need and ability 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:

- Failure to obtain and maintain required regulatory approvals for our proposed products in a timely and cost-effective manner or at all;

- FDA requirements regarding size and duration of clinical trials required to obtain and maintain regulatory approvals for our proposed products;

- Failure of our proposed products to perform as expected in clinical trials;

- Our understanding that although Procter & Gamble (P&G) has obtained approval and is planning to launch Intrinsa, P&G's testosterone patch, in Europe, P&G has recently put Intrinsaon hold in the United States and is considering its options in the United States, which decision, if true, may have an adverse effect on the potential size of the U.S. female sexual dysfunction market, the potential market for our LibiGel product and our ability to find a development partner to share in the cost of such development if we choose to seek such a partner;

- Our dependence upon Bradley Pharmaceuticals, Inc. to market and sell our Bio-E-Gel product, if and when it is approved by the FDA;

- Slow patient enrollment in our clinical trials, untimely completion of clinical site protocol approval and obtaining informed consent form subjects, longer treatment time required to demonstrate efficacy or safety of our proposed products, adverse medical events or side effects in patients treated with our proposed products, lack of effectiveness of our proposed product and other risks associated with clinical trials;

- Failure of our proposed products if commercially introduced to obtain market acceptance and generate any revenues;

- Uncertainties associated with the impact of published studies and research regarding the adverse health effects of certain forms of hormone therapy;

- Highly competitive nature of the markets in which we intend to sell our products and the introduction of competing products;

- Failure to maintain our rights to license our licensed technology;

- Exposure to assertions of intellectual property claims and failure to protect our intellectual property;

- Our lack of experience and dependence upon others for clinical testing and manufacturing and sales and marketing functions;

- Failure to obtain additional capital when needed or on acceptable terms;

- Failure to comply with applicable laws and regulations;

- Failure to retain senior management and other key personnel or replace lost senior management or key personnel;

- Effects of any litigation of which we may be subject, including threatened or pending litigation;

- Adverse changes in applicable laws or regulations;

- Changes in generally accepted accounting principles; or

- Conditions and changes in pharmaceutical industry or in general economic and 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, 2005 under the heading "Part I - Item 1A. Risk Factors" on pages 22 through 34 of such report and "Part II - Item 1A. Risk Factors" included 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, 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. 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, 2006 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our annual report on Form 10-K for the fiscal year ended December 31, 2005 under the heading "Part I - Item 1A. Risk Factors," and the additional and revised risk factors below, which could materially adversely affect our business, financial condition or operating results.

It is our understanding that although Procter & Gamble (P&G) has obtained approval and is planning to launch Intrinsa, P&G's testosterone patch, in Europe, P&G recently has put Intrinsa on hold in the United States, which decision, if true, may have an adverse effect on the potential size of the U.S. female sexual dysfunction market, the potential market for our LibiGel product and our ability to find a development partner to share in the cost of such development if we choose to seek such a partner.

In December 2004, the FDA's Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of P&G's Intrinsa testosterone patch for hypoactive sexual desire disorder. The panel's main concern was the desire to have long-term safety data particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Currently, the FDA has not explicitly publicly stated nor set any type of public policy or guidance document as to what size or duration of a safety trial would be required for approval.

It is our understanding that although Procter & Gamble (P&G) has obtained approval and is planning to launch Intrinsa, P&G's testosterone patch, in Europe, P&G recently has put Intrinsa on hold in the United States and is considering its options with respect to the product in the United States. Since P&G has not said anything publicly it is hard for us to determine why it may have made this decision or what the future of the product in the U.S. will be. It is possible that P&G's decision to put Intrinsa on hold in the U.S. will adversely affect the potential size of the U.S. female sexual dysfunction market and the potential for our LibiGel product. In addition, it may adversely effect our ability to find a development partner to share in the cost of development if we decide to seek such a partner.

Several pharmaceutical products have been found to have potentially life threatening side effects and have been subsequently removed from the market. These drugs had been previously approved for sale by the FDA. The withdrawals of approved drugs from the market create an increased risk for the pharmaceutical industry in general in that certain proposed products may not receive the required regulatory approval on a timely basis or ever. The withdrawal of Vioxx by Merck & Co., Inc. has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, these withdrawals have resulted and may continue to result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilence after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians' desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

We have recently entered into a marketing agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel® (transdermal estradiol gel) in the United States as a result of which we are dependent upon Bradley for the marketing and sale of our Bio-E-Gel product, if and when it is approved by the FDA.

In November 2006, BioSante signed an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel® (transdermal estradiol gel) in the United States. Upon execution of the agreement, BioSante received an upfront payment of $2.625 million. In addition, if and when Bio-E-Gel is approved by the U.S. Food and Drug Administration (FDA), Bradley has agreed to pay BioSante $10 to $10.5 million, $7 million of which would be due upon the earlier of 14 weeks after obtaining such approval or the first commercial sale of Bio-E-Gel by Bradley in the U.S. and up to an additional $3.5 million which would be due on the one-year anniversary of such approval,. Upon receipt of these payments, BioSante will be obligated to pay Antares Pharma IPL AG, BioSante's licensor of the transdermal estradiol gel formulation in Bio-E-Gel, 25 percent of such payments resulting in BioSante receiving an aggregate of $7.5 million to $7.875 million from Bradley. Bradley also has agreed to pay BioSante additional sales based milestone payments, as well as royalties on sales of Bio-E-Gel.

As a result of this agreement, Bio-E-Gel is subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of the product, but its success is also now dependent upon the success of Bradley in marketing and selling the product. We cannot assure you that Bradley will remain focused on the commercialization of our Bio-E-Gel product or will not otherwise breach the terms of our agreement. Any breach by Bradley of its obligations under our agreement or a termination of the agreement could adversely affect the success of our Bio-E-Gel product if we are unable to sublicense the product to another party on substantially the same or better terms or continue the development and future commercialization of the product ourselves.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2006, we issued to 24 accredited investors, including certain existing stockholders, an aggregate of 3,812,978 shares of common stock and five-year warrants to purchase an aggregate of 1,334,542 shares of common stock. The price of each unit, which consisted of one share of common stock plus a warrant to purchase 0.35 share of common stock was $2.00, the approximate price of BioSante's common stock at the time the subscriptions were entered into, less a slight discount. The exercise price of the warrant is $2.75 per full share. Proceeds of the financing were approximately $7.2 million, net of transaction costs related to the private placement. We filed with the Securities and Exchange Commission a registration statement on Form S-3 on August 23, 2006 registering the offering and resale of 5,147,520 shares of our common stock, including the 3,812,978 outstanding shares of common stock and 1,334,542 shares of common stock issuable upon exercise of the warrants we issued in this private placement. This registration statement was declared effective by the SEC on August 30, 2006.

Commissions and fees were paid to the placement agent in connection with our July 2006 private placement. In addition, all of the above sales were made in reliance on either Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. In all such transactions, certain inquiries were made by BioSante to establish that such sales 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) all offers of sales and sales were made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) each investor made representations that he or she was sophisticated in relation to his or her investment (and BioSante has no reason to believe that such representations were incorrect), (iii) each purchaser gave assurance of investment intent and the certificates for the shares 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

We did not purchase any shares of our common stock or other equity securities during the three months ended September 30, 2006, 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.

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

On August 18, 2006, we entered into a Fourth Amendment to Exclusive License Agreement for patents related to the Company’s CaP technology with The Regents of the University of California. Under the terms of the amendment, we amended certain terms of the agreement, including the elimination of future specified minimum annual royalties which equal in excess of $3 million owed to the University of California in exchange for an immediate payment of $100,000. Under the terms of the original agreement, $75,000 would have been payable on February 28, 2007. The amendment also eliminated provisions that required us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve specific research and development milestones within specified time periods.

ITEM 6. EXHIBITS

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

10.1 Fourth Amendment to Exclusive License Agreement for Selected Applications of Coated Nanocrystalline Particles between The Regents of the University of California and BioSante Pharmaceuticals, Inc. dated as of August 11, 2006

10.2 Form of Subscription Agreement dated as of July 7, 2006 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreements

10.3 Form of Warrant dated as of July 21, 2006 issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the Subscription Agreements dated July 7, 2006

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 14, 2006

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Stephen M. Simes
President and Chief Executive Officer
(principal executive officer)
By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
(principal financial and accounting officer)

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

Exhibit No.	Description	Method of Filing
10.1	Fourth Amendment to Exclusive License Agreement for Selected Applications of Coated Nanocrystalline Particles between The Regents of the University of California and BioSante Pharmaceuticals, Inc. dated as of August 11, 2006 (1)	Filed herewith
10.2	Form of Subscription Agreement dated as of July 7, 2006 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreements	Incorporated by reference to Exhibit 10.1 in BioSante's Current Report on Form 8-K dated July 7, 2006 (File No. 001-31812)
10.3	Form of Warrant dated as of July 21, 2006 issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the Subscription Agreements dated July 7, 2006	Incorporated by reference to Exhibit 10.2 in BioSante's Current Report on Form 8-K dated July 21, 2006 (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

(1) Confidential treatment has been requested with respect to designated portions of this document. Such portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange of 1934, as amended.