BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 12, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2010

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES o NO o

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company 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, 2010, 70,802,894 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

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As used 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®, LibiGel®, Elestrin , Bio-T-Gel , The Pill-Plus , BioLook and GVAX . This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Balance Sheets

September 30, 2010 and December 31, 2009 (Unaudited)

	September 30, 2010	December 31, 2009
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 35,526,017	$ 29,858,465
Accounts receivable		64,645
Prepaid expenses and other assets	1,150,798	1,487,160
	36,676,815	31,410,270
PROPERTY AND EQUIPMENT, NET	646,500	747,979
OTHER ASSETS		
Investments	3,340,000	3,626,000
Deposits	99,937	652,679
	$ 40,763,252	$ 36,436,928
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 4,522,800	$ 2,440,096
Due to licensor - Antares		18,033
Accrued compensation	1,156,638	529,066
Other accrued expenses	1,415,693	942,922
	7,095,131	3,930,117
Convertible senior notes due 2011 and 2013	18,364,333	16,676,417
TOTAL LIABILITIES	25,459,464	20,606,534
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2010 - 391,286; 2009 - 391,286 Class C special stock	391	391
2010 - 70,802,894; 2009 - 53,262,568 Common stock	167,662,306	135,264,431
	167,662,697	135,264,822
Accumulated deficit	(152,358,909)	(119,434,428)
	15,303,788	15,830,394
	$ 40,763,252	$ 36,436,928

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three and Nine Months Ended September 30, 2010 and 2009 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
REVENUE				
Licensing revenue	$	$	$	$
Grant revenue		10,492	51,870	103,149
Royalty revenue	51,331		2,279,335	90,934
Other revenue				
	51,331	10,492	2,331,205	194,083
EXPENSES				
Research and development	9,716,091	3,371,217	27,800,567	9,937,033
General and administration	1,534,417	1,506,056	4,572,869	3,744,214
Acquisition related costs		1,470,467		1,470,467
Licensing expense			268,750	
Depreciation and amortization	41,000	33,308	128,967	95,887
	11,291,508	6,381,048	32,771,153	15,247,601
OTHER				
Fair value adjustment	103,000		(1,687,916)	
Investment impairment loss	(286,000)		(286,000)	
Interest expense	(172,000)		(516,083)	
Interest income	5,466		5,466	11,648
NET LOSS	$ (11,589,711)	$ (6,370,556)	$ (32,924,481)	$ (15,041,870)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.16)	$ (0.21)	$ (0.51)	$ (0.53)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	71,194,180	30,434,050	64,092,806	28,445,039

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Nine Months Ended September 30, 2010 and 2009 (Unaudited)

	Nine Months Ended September 30, 2010	2009
CASH FLOWS USED IN OPERATING ACTIVITIES		
Net loss	$ (32,924,481)	$ (15,041,870)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	128,967	95,887
Employee & director stock-based compensation	751,790	946,517
Stock warrant expense - noncash	57,195	34,734
Mark-to-market of convertible senior notes	1,687,916	
Acquisition related costs		1,470,467
Investment impairment loss - noncash	286,000	
Other noncash charges		75,342
Gain on disposal of fixed assets	(804)	
Changes in other assets and liabilities affecting cash flows from operations:		
Prepaid expenses, deposits and other assets	889,104	(183,607)
Accounts receivable	64,645	191,504
Accounts payable and accrued liabilities	3,183,045	114,268
Due to licensor - Antares	(18,033)	2,478
Net cash used in operating activities	(25,894,656)	(12,294,280)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES		
Redemption of short term investments		3,037,982
Purchase of short term investments		(11,648)
Proceeds from sale of fixed assets	2,250	
Purchase of capital assets	(28,934)	(153,415)
Net cash (used in) provided by investing activities	(26,684)	2,872,919
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Cash paid for acquisition related costs		(510,918)
Proceeds from sale or conversion of shares	31,588,892	11,340,617
Net cash provided by financing activities	31,588,892	10,829,699
NET INCREASE CASH AND CASH EQUIVALENTS	5,667,552	1,408,338
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,858,465	11,760,920
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 35,526,017	$ 13,169,258
SUPPLEMENTARY INFORMATION		
Other information:		
Cash paid for interest	$ 344,000	$
Accrued liabilities for acquisition related costs, noncash	$	$ 959,549

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
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NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. DESCRIPTION OF BUSINESS

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The Company s lead products include LibiGel (transdermal testosterone gel) in Phase III clinical development by the Company under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD), and Elestrin (estradiol gel) developed through FDA approval by the Company, indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, currently marketed in the U.S. Also in development is a portfolio of cancer vaccines (GVAX), several of which are currently in Phase II clinical trials at minimal cost to the Company. Three of these vaccines have been granted FDA orphan drug designation. Other products in development are Bio-T-Gel, a testosterone gel for male hypogonadism, which is licensed to Teva Pharmaceuticals, and an oral contraceptive in Phase II clinical development using the Company s patented technology. The Company also is developing its calcium phosphate technology (CaP) for aesthetic medicine (BioLook), among other potential uses, as well as seeking opportunities for its 2A/Furin and other technologies.

2. BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of September 30, 2010 and December 31, 2009, the results of operations for the three and nine months ended September 30, 2010 and 2009, and the cash flows for the nine months ended September 30, 2010 and 2009, 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, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010.

These unaudited interim condensed financial statements should be read in conjunction with the financial statements and related notes contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2009.

3. NEW ACCOUNTING PRONOUNCEMENTS

In March 2010, the Financial Accounting Standard Board ratified the consensus reached by the Emerging Issues Task Force on Issue 08-9 (EITF 08-9), which was codified in Accounting Standards Update 2010-17. EITF 08-9 establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, for research and development

arrangements in which one or more payments are contingent upon achieving uncertain future events or circumstances. EITF 08-9 is effective for fiscal years beginning on or after June 15, 2010, and will be adopted by the Company in the fiscal year beginning January 1, 2011. The impact of EITF 08-9 on the Company s financial position and operations is dependent on the nature and structure of the Company s future arrangements.

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4. LIQUIDITY AND CAPITAL RESOURCES

Substantially all of the Company s revenue to date has been derived from upfront, milestone and royalty payments earned on licensing transactions and from subcontracts. The Company s business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. The Company has not introduced commercially any products. If and when the Company s products for which it has not entered into marketing relationships receive FDA approval, the Company may begin to incur other expenses, including sales and marketing related expenses if it chooses to market the products itself. The Company currently does not have sufficient resources to obtain regulatory approval of LibiGel or any of its other products or to complete the commercialization of any of its products for which the Company has not entered into marketing relationships.

To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its merger with Cell Genesys, Inc. (Cell Genesys) to fund its ongoing business operations and short-term liquidity needs.

On March 8, 2010, the Company completed an offering of an aggregate of 10,404,626 shares of the Company s common stock and warrants to purchase an aggregate of 5,202,313 additional shares of its common stock, resulting in net proceeds to the Company of approximately $17.5 million, after deducting placement agent fees and other offering expenses. On June 23, 2010, the Company completed an additional offering of an aggregate of 7,134,366 shares of the Company s common stock and warrants to purchase an aggregate of 3,567,183 additional shares of its common stock, resulting in net proceeds to the Company of approximately $14.1 million, after deducting placement agent fees and other offering expenses. For additional discussion regarding these registered direct offerings, see Note 10, Stockholders Equity.

As of September 30, 2010, the Company had $35.5 million of cash and cash equivalents. Cash and cash equivalents includes $31.7 million in a money market fund, which is recorded at fair value based on level 2 inputs. Absent the receipt of any additional significant licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as the Company continues to use cash to fund its operations, including in particular its LibiGel Phase III clinical development program. How long the Company s current cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel Phase III clinical studies and perhaps more importantly, the number of women the Company will enroll in the LibiGel safety study, which number cannot be determined at this time. According to the study s protocol, the minimum number of enrolled women is 2,500 women and the maximum number is 4,000 women. The greater the number of enrolled women, the more the Company will be required to use its cash to conduct the study. As of October 25, 2010, approximately 2,500 women were enrolled in the safety study. The number of women enrolled in the LibiGel safety study will be determined based on statistical methods contained in the study s FDA-agreed protocol as analyzed by the study s independent Data Monitoring Committee (DMC). If enrollment in the safety study is completed in the near term, the Company believes it has sufficient cash resources to maintain its projected business operations, including continued Phase III clinical development of LibiGel, for approximately the next nine months. If, however, enrollment is not completed until the number of women enrolled is at, or about, 4,000 women, the Company believes its cash will last less than nine months, assuming the Company maintains its projected business operations, including the current pace of Phase III clinical development of LibiGel. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

As of September 30, 2010, the Company did not have any existing credit facilities under which it could borrow funds, other than the Committed Equity Financing Facility described below. If the

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Company is unable to raise additional financing when needed or secure another funding source for its clinical development program, the Company may need to slow temporarily or delay new enrollment in its LibiGel Phase III clinical study program or otherwise make changes to its operations to reduce costs. As an alternative to raising additional financing, the Company may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product (e.g. one or more of the Company s GVAX cancer vaccines) to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under its existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company.

In December 2008, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at the Company s sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of the Company s common stock through the end of December 2010. The Company may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of the Company s common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for the Company s common stock of $1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of common stock issued or issuable to Kingsbridge; and the continued listing of the Company s common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting the Company s business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides the Company notice of such material and adverse event. As of September 30, 2010, the Company had not sold any shares to Kingsbridge under the CEFF.

5. 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, warrants and convertible debt 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, 2010 does not include options to purchase an aggregate of 3,680,703 and 3,660,245, respectively, shares of common stock with exercise prices ranging from $1.27 to $36.82 per share, warrants to purchase an aggregate of 14,390,575 and 14,480,575, respectively, shares of common stock with exercise prices of $2.00 to $39.27 per share, or outstanding convertible debt of an aggregate of $22.0 million principal amount that is convertible into an aggregate of 5,611,348 shares of common stock at conversion prices of either $3.72 or $49.78 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, 2009 does not include options to purchase an aggregate of 2,736,691 shares of common stock with exercise prices ranging from $1.27 to $6.70 per share, and warrants to purchase an aggregate of 3,841,207 and 4,983,709, respectively, shares of common stock with exercise prices of $2.00 to $8.00 per share, because of their antidilutive effect on net loss per share.

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6. LICENSE AGREEMENTS

Azur Pharma International II Limited (Azur), BioSante s licensee, is marketing Elestrin in the U.S. using Azur s women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, the Company entered into an amendment to its original licensing agreement with Azur which reduced permanently the royalty percentage due to the Company related to Azur s sales of Elestrin. During 2009 and 2010, the Company received approximately $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments that the Company would not be required to pay to Antares under a separate agreement and certain future milestone payments due to the Company under the terms of the original license. Pursuant to a separate agreement with Antares and related to the Azur royalty stream buydown, the Company paid Antares an aggregate $268,750 in February 2010. As a result of the amendment to the Company s license agreement with Azur, all royalty payments from Azur equal the royalties due to Antares under the Company s separate license agreement with Antares. Accordingly, the Company records an equal amount of revenue and corresponding royalty expense each period related to sales of Elestrin.

7. INVESTMENTS

The Company s investments balance of $3,340,000 and $3,626,000 as of September 30, 2010 and December 31, 2009, respectively, consists of investments in private companies recorded using the cost method, the substantial portion of which relates to the Company s investment in Ceregene. The Company has recorded its investment in Ceregene using the cost method, as no active market exists for this investment, and the Company does not possess significant influence over operating and financial policies of Ceregene, although the Company by virtue of its stock ownership of Ceregene has the right to designate one member on the Ceregene board of directors. The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest the investment may not be recoverable. The fair value of the cost method investments are not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investments and it is not practicable to estimate the fair value of the investments. Cost method investments with a carrying value of $140,000 were not evaluated for impairment during the three months ended September 30, 2010.

During the three months ended September 30, 2010, the Company recorded an impairment loss of $286,000 based on its determination that an other-than-temporary loss had occurred with respect to the Company s investment in Ceregene. Such loss was determined based on a recent third-party investment in Ceregene.

8. CONVERTIBLE SENIOR NOTES

As a result of the Company s merger with Cell Genesys, the Company assumed liabilities related to two series of convertible senior notes of Cell Genesys. The conversion features of the convertible senior notes have been adjusted for the exchange ratio used in the merger. The terms of the convertible senior notes are as follows:

- $20,782,000 principal amount of 3.125% Convertible Senior Notes due May 1, 2013 (the 2013 Notes), exchangeable at the option of the holder or upon certain specified events into an aggregate of 5,586,559 shares of the Company s common stock at a conversion price of

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$3.72 per share. The Company has the right to redeem the 2013 Notes for cash as a whole or in part after May 1, 2011. The Company may be obligated to redeem the 2013 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.

- $1,234,000 principal amount of 3.125% Convertible Senior Notes due November 1, 2011 (the 2011 Notes and collectively with the 2013 Notes, the Notes), exchangeable at the option of the holder or upon certain specified events into an aggregate of 24,789 shares of the Company s common stock at a conversion price of $49.78 per share. The Company has the right to redeem the 2011 Notes for cash as a whole or in part after November 1, 2009. The Company may be obligated to redeem the 2011 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.

Interest on both series of Notes is payable on May 1 and November 1 each year through maturity. Under certain circumstances, the Company may redeem some or all of the Notes on or after specified dates at a redemption price equal to 100% of the principal amount of the Notes plus accrued and unpaid interest. Holders of the Notes may require the Company to purchase some or all of their Notes if certain changes in control occur at a repurchase price equal to 100% of the principal amount of the Notes plus accrued and unpaid interest.

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of September 30, 2010, with changes in the fair value of the Notes occurring since December 31, 2009, reflected in fair value adjustment in the condensed statements of operations. The fair value of the Notes is based on Level 2 inputs. The recorded fair value of the Notes of an aggregate of $18,364,333 as of September 30, 2010 differs from their total stated principal amount of $22,016,000 by $3,651,667. The recorded fair value of the Notes of an aggregate of $16,676,417 as of December 31, 2009 differs from their total stated principal amount of $22,016,000 by $5,339,583.

The Company establishes the value of the Notes based upon contractual terms of the notes, as well as certain key assumptions.

The assumptions as of December 31, 2009 were:

	2013 Notes	2011 Notes
Average risk free rate	1.7%	1.1%
Volatility of BioSante common stock	81.4%	89.8%
Discount rate for principal payments in cash	17.6%	17.6%

The assumptions as of September 30, 2010 were:

	2013 Notes	2011 Notes
Average risk free rate	0.53%	0.27%
Volatility of BioSante common stock	81.5%	55.9%
Discount rate for principal payments in cash	17.0%	17.0%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a C and Ca rating for long-term corporate obligations as assigned by Moody s Investors Service.

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At December 31, 2009, the fair value of the Notes excluding accrued interest was an aggregate of $16,676,417. At September 30, 2010, the fair value of the Notes excluding accrued interest was an aggregate of $18,364,333. The Company recorded fair value adjustments of $(103,000) and $1,687,916 related to the Notes for the three and nine months ended September 30, 2010, respectively, to decrease its recorded liability and corresponding expense for the three months ended September 30, 2010 and to increase its recorded liability and corresponding expense for the nine months ended September 30, 2010. For the three months and nine months ended September 30, 2010, approximately ($337,000) and $198,000 of the fair value adjustment related to the change in instrument specific credit risk. The change in the aggregate fair value of the Notes due to instrument specific credit risk was estimated by calculating the difference between the September 30, 2010 fair value of the Notes as recorded and what the fair value of the convertible notes would have been on September 30, 2010 if the December 31, 2009 or June 30, 2010 discount rate continued to be used in the calculation. The instrument specific credit risk for the nine months ended September 30, 2010 has increased the fair value of the Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk free borrowing rate. The instrument specific credit risk for the three months ended September 30, 2010 has decreased the fair value of the Notes as market borrowing rates have increased for similarly rated companies and are estimated to have increased for the Company as well, indicating a higher credit spread assuming no significant changes in the risk free borrowing rate.

9. STOCK-BASED COMPENSATION

During the three and nine month periods ended September 30, 2010, the Company granted options to purchase an aggregate of 51,250 and 706,250 shares, respectively, of the Company s common stock to certain employees of the Company and the Company s non-employee directors with a weighted average exercise price of $1.65 per share under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan. Options to purchase an aggregate of 1,334 shares of the Company s common stock at an exercise price of $1.51 per share were exercised during the nine months ended September 30, 2010. Options to purchase an aggregate of 30,333 shares of the Company s common stock were cancelled during the nine months ended September 30, 2010.

No warrants were granted during the three and nine month periods ended September 30, 2010, other than the warrants issued in conjunction with the Company s March 2010 and June 2010 registered direct offerings, respectively, described in Note 10, Stockholders Equity . No warrants were exercised during the nine months ended September 30, 2010. Warrants to purchase 180,000 shares of the Company s common stock expired during the nine months ended September 30, 2010.

10. STOCKHOLDERS EQUITY

On March 8, 2010, the Company completed an offering of 10,404,626 shares of its common stock and warrants to purchase an aggregate of 5,202,313 shares of its common stock at a purchase price of $1.73 per share to funds affiliated with two institutional investors for gross proceeds of $18.0 million. The offering resulted in net proceeds to the Company of approximately $17.5 million, after deducting placement agent fees and offering expenses. The warrants are exercisable beginning on September 9, 2010 and continuing for a period of five years, at an exercise price of $2.08 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 208,093 shares of the Company s common stock at an exercise price of $2.16, which warrants are exercisable beginning on September 8, 2010 and will expire on June 9, 2014. 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.

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On June 23, 2010, the Company completed an offering of 7,134,366 shares of its common stock and warrants to purchase an aggregate of 3,567,183 shares of its common stock at a purchase price of $2.1025 per share to funds affiliated with certain institutional investors for gross proceeds of $15.0 million. The offering resulted in net proceeds to the Company of approximately $14.1 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of five years, at an exercise price of $2.45 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 214,031 shares of the Company s common stock at an exercise price of $2.63, which warrants are exercisable immediately and will expire on June 9, 2015. 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.

11. SUBSEQUENT EVENT

On October 29, 2010, the Company was notified that it has received a grant of approximately $244,000 under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

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

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

Business Overview

We are a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

Our products, either approved or in development, include:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD).

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.

- The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development for the treatment of FSD in women using oral or transdermal contraceptives.

- Bio-T-Gel once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.

- GVAX cancer vaccines a portfolio of cancer vaccines in Phase II clinical development for the treatment of various cancers.

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need, for which presently there is no FDA approved pharmaceutical product. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety

study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women.

Currently, three LibiGel Phase III studies are underway and enrolling women: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are randomized, double-blind, placebo-controlled, multi-center trials that will enroll up to approximately 500 surgically menopausal women each, exposed to LibiGel or placebo for six months. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular and breast cancer safety study of between 2,500 and 4,000 women exposed to LibiGel or placebo for an average of 12 months after which time we

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plan to submit an NDA to the FDA. Following NDA submission and potential FDA approval and product launch, we will continue to follow the women in the safety study for an average of 60 months of exposure.

In October 2010, we announced that based upon the fourth review of study conduct and unblinded safety data from the LibiGel Phase III cardiovascular and breast cancer safety study by the study s independent data monitoring committee (DMC), as well as the first unblinded statistical analysis by the DMC, the DMC unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The unblinded review of the cardiovascular events and breast cancer events by the DMC showed no safety signals. The review and statistical analysis were based on 2,500 subjects who have been enrolled in the study. Another unblinded statistical analysis will be conducted by the DMC each time there is an additional adjudicated cardiovascular event. As of the date of the DMC s review, there had been only 14 adjudicated cardiovascular (CV) events, a rate of approximately 0.65 percent, compared to an expected rate of CV events for this study of approximately two percent. Moreover, there have been only seven diagnoses of breast cancer, a rate of approximately 0.32 percent, compared to an expected rate of approximately 0.35 percent, after approximately 2,300 women-years of exposure in the study. The data analyses of the CV events are based on predefined statistical methods, in accordance with our agreement with the FDA, to determine if LibiGel is safe for menopausal women. At each of these analyses the trial potentially could be fully enrolled. If enrollment is not completed sooner, enrollment will continue until the study reaches its predetermined maximum of 4,000 women. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit a NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women. It is our objective to submit the LibiGel NDA to the FDA in late 2011.

In July 2010, we announced the initiation of a LibiGel clinical trial to evaluate its effect on cognitive function in menopausal women. The trial is a randomized, double-blind, placebo-controlled six-month comparison in 120 women of the effect of LibiGel compared to placebo treatment on a variety of learning and memory tasks. The study is being conducted by Dr. Susan Davis, Professor of Women s Health, Department of Medicine, Monash University Women s Health Program in Australia.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), BioSante s licensee, is marketing Elestrin in the U.S. using Azur s women s health sales force which targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an amendment to our original licensing agreement with Azur which reduced permanently the royalty percentage due to us related to Azur s sales of Elestrin. During 2009 and 2010 we received approximately $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments that BioSante would not be required to pay to Antares under a separate agreement and certain future milestone payments. We maintain the right to receive up to $140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year.

We license the technology underlying certain of our gel products, including LibiGel and Elestrin, from Antares Pharma, Inc. 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 licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a 4.5 percent royalty on net sales of product by us or a licensee. Bio-T-Gel was developed and is fully-owned by us and licensed to Teva for further development and commercialization. We license the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license

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include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

In June 2010, we announced positive results in a Phase II study of the Pill-Plus triple component oral contraceptive. The study was a Phase II double-blind, randomized clinical trial in 82 women comprising a cross-over design of two treatment periods of five months each. The study compared use of an oral contraceptive alone to the same oral contraceptive with the addition of an oral androgen (DHEA). The study was performed by the Department of Sexology of the Academic Medical Center in Amsterdam, The Netherlands in close collaboration with Pantarhei Bioscience B.V. in The Netherlands, our licensee.

GVAX cancer vaccines are designed to stimulate the patient s immune system to fight effectively the patient s own cancer. Multiple Phase II trials of these vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia, breast and prostate (expected to begin in the fourth quarter 2010) cancer. Three of these vaccines have been granted FDA orphan drug designation. We license our GVAX cancer vaccine technology from Johns Hopkins University. Under various agreements, we are required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the in-licensed technology.

Our strategy with respect to our CaP technology is to continue development (at minimal cost to us) 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, we have entered into a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial line filler in aesthetic medicine (BioLook). Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received an ownership position in MATC of approximately five percent of the common stock of MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

One of our strategic goals is to continue to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, we may engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger or sale of our company.

Financial Overview

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our merger with Cell Genesys, Inc., to fund our ongoing business operations and short-term liquidity needs.

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We have not introduced commercially any products. Azur, our marketing licensee for Elestrin, commercially launched Elestrin in April 2009. In December 2009, we entered into an amendment to our original licensing agreement with Azur which reduced permanently the royalty percentage due to us related to Azur s sales of Elestrin to only that portion we are required to pay Antares under a separate agreement. We received approximately $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments that we would not be required to pay to Antares under a separate agreement and certain future milestone payments. We recognized $51,331 and $2,279,335 in royalty revenue from sales of Elestrin during the three and nine months ended September 30, 2010. The royalty revenue during the nine month period includes $129,335 in royalty payments pursuant to our original agreement with Azur, and $2,150,000 of additional royalty income from payments received as a result of the receipt of non-refundable payments from Azur in exchange for the elimination of all remaining future royalty payments that we would not be required to pay to Antares under a separate agreement and certain future milestone payments due us under the terms of the original license. This royalty revenue amount represents the gross royalty revenue we received from Elestrin through September 30, 2010 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $51,331 and $129,335 for the three and nine months ended September 30, 2010, is recorded within general and administrative expenses in our condensed statements of operations. Pursuant to a separate agreement with Antares and related to the Azur royalty stream and milestone buydown, we paid Antares an aggregate of $268,750 in February 2010.

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 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 obtain regulatory approval of LibiGel or any of our other products or to complete the commercialization of any of our products for which we have not entered into marketing relationships. As of September 30, 2010, we had $35.5 million of cash and cash equivalents. Absent the receipt of any additional significant licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. How long our current cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel Phase III clinical studies and perhaps more importantly, the number of women we will enroll in the LibiGel safety study, which number cannot be determined at this time. According to the study s protocol, the minimum number of enrolled women is 2,500 women and the maximum number is 4,000 women. The greater the number of enrolled women, the more we will be required to use our cash to conduct the study. As of October 25, 2010, approximately 2,500 women were enrolled in the safety study. The number of women enrolled in the LibiGel safety study will be determined based on statistical methods contained in the study s FDA-agreed protocol as analyzed by the study s independent DMC. If enrollment in the safety study is completed in the near term, we believe we have sufficient cash resources to maintain our projected business operations, including continued Phase III clinical development of LibiGel, for approximately the next nine months. If, however, enrollment is not completed until the number of women enrolled is at, or about, 4,000 women, we believe our cash will last less than nine months, assuming we maintain our projected business operations, including the current pace of Phase III clinical development of LibiGel. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of approximately $3.1 million per month on research and development activities during the nine months ended September 30, 2010, which is a 180 percent increase, compared to the same period in 2009, primarily as a result of the conduct of the LibiGel Phase III clinical studies. In April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study in order

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to conserve cash; however, in January 2010, we reinitiated screening and enrollment in our safety study. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash available; (2) our development schedule, including the timing and scope of our clinical trials; (3) results of studies, clinical trials and regulatory decisions, including in particular the number of subjects required in our LibiGel Phase III cardiovascular and breast cancer safety study; (4) the amount of our clinical recruitment expenditures intended to complete enrollment in our LibiGel Phase III studies; (5) whether we or our licensees are funding the development of our products; and (6) competitive developments.

Our general and administrative expenses for the nine months ended September 30, 2010 increased 22 percent compared to the same period in 2009 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and administrative expenses may fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, business development, accounting, corporate governance and other fees and expenses incurred.

We recognized a net loss for the three and nine months ended September 30, 2010 of approximately $11.6 million and $32.9 million, respectively, compared to a net loss of approximately $6.4 million and $15.0 million, respectively, for the three and nine months ended September 30, 2009. These increases were primarily due to the increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for the three and nine months ended September 30, 2010 of $0.16 and $0.51, respectively, compared to a net loss per share of $0.21 and $0.53, respectively, for the three and nine months ended September 30, 2009. These decreases in net loss per share were the result of a significantly higher weighted average number of shares outstanding during the three and nine months ended September 30, 2010, partially offset by increases in net loss as described above. We expect to continue to incur substantial and continuing losses for the foreseeable future. This is true especially as our product development programs expand and various clinical studies continue, in particular the three LibiGel Phase III studies.

Results of Operations

Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009

The following table sets forth our results of operations for the three months ended September 30, 2010 and 2009.

	Three Months Ended September 30,			
	2010	**2009**	**$ Change**	**% Change**
Revenue	$ 51,331	$ 10,492	$ 40,839	389.2%
Expenses				
Research and development	9,716,091	3,371,217	6,344,874	188.2%
General and administrative	1,534,417	1,506,056	28,361	1.9%
Acquisition related costs		1,470,467	(1,470,467)	N/A
Other expense Fair value adjustment	(103,000)		(103,000)	N/A
Other expense Investment impairment loss	286,000		286,000	N/A
Other expense Interest expense	172,000		172,000	N/A
Other income - Interest income	5,466		5,466	N/A
Net loss	$ (11,589,711)	$ (6,370,556)	$ 5,219,155	81.9%

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Revenue recognized in 2010 is the result of the recognition of Elestrin revenue. However, as a result of the amendment to our license agreement with Azur signed in December 2009, all royalty payments from Azur equal the royalty due to Antares under our separate license agreement with Antares. Accordingly, we recorded a corresponding royalty expense of $51,331 within general and administrative expenses in our condensed statements of operations. Revenue recognized in 2009 was from a grant.

Research and development expenses for the three months ended September 30, 2010 increased 188 percent compared to the three months ended September 30, 2009 primarily as a result of the conduct of the three LibiGel Phase III clinical studies compared to the temporary delay in the screening and enrollment in our safety study which was in place during the three months ended September 30, 2009.

General and administrative expenses for the three months ended September 30, 2010 increased two percent compared to the three months ended September 30, 2009 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during the third quarter of 2010.

For the three months ended September 30, 2009, we recognized acquisition related costs of $1,470,467 related to our merger with Cell Genesys, which was completed on October 14, 2009.

We have elected to record our convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, we have adjusted the carrying value of the convertible senior notes to their fair value as of September 30, 2010, with changes in the fair value of the notes occurring since December 31, 2009, reflected in fair value adjustment in our condensed statements of operations. The fair value adjustment on our convertible senior notes for the three months ended September 30, 2010 was $103,000 to decrease the recorded liability and corresponding expense compared to no similar expense for the three months ended September 30, 2009 since we assumed the convertible senior notes during the fourth quarter of 2009.

During the three months ended September 30, 2010, we recorded an investment impairment loss of $286,000 based on our determination that an other-than-temporary loss had occurred with respect to our investment in Ceregene, Inc. based on a recent third-party investment in Ceregene.

Interest expense for the three months ended September 30, 2010 was $172,000 compared to no similar expense for the three months ended September 30, 2009 as a result of our convertible senior notes which we assumed during the fourth quarter of 2009.

Interest income for the three months ended September 30, 2010 was $5,466 compared to no interest income for the three months ended September 30, 2009 as a result of the placement of a portion of our cash in an institutional U.S. Treasury money fund for most of the three month period ended September 30, 2010, compared to 100% of our cash being in a non-interest bearing checking account for the entire three month period ended September 30, 2009, in order to ensure maximum safety of principal.

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Nine Months Ended September 30, 2010 Compared to Nine Months Ended September 30, 2009

The following table sets forth our results of operations for the nine months ended September 30, 2010 and 2009.

	Nine Months Ended September 30,			
	2010	**2009**	**$ Change**	**% Change**
Revenue	$ 2,331,205	$ 194,083	$ 2,137,122	1,101.1%
Expenses				
Research and development	27,800,567	9,937,033	17,863,534	179.8%
General and administrative	4,572,869	3,744,214	828,655	22.1%
Acquisition related costs		1,470,467	(1,470,467)	N/A
Licensing expense	268,750		268,750	N/A
Other expense Fair value adjustment	1,687,916		1,687,916	N/A
Other expense Investment impairment loss	286,000		286,000	
Other expense Interest expense	516,083		516,083	N/A
Other income - Interest income	5,466	11,648	(6,182)	(53.1)%
Net loss	$ (32,924,481)	$ (15,041,870)	$ 17,882,611	118.9%

Revenue increased $2.1 million primarily as a result of a significant increase in royalty revenue, partially offset by a decrease in grant revenue. Of the $2.3 million in royalty and grant revenue during the nine months ended September 30, 2010, $2.2 million resulted from the receipt of non-refundable upfront payments from Azur in exchange for the elimination of all remaining future royalty payments that we are not required to pay to Antares under a separate agreement, and certain future milestone payments due us under the terms of the original license, as permitted by the amendment to our license agreement signed in December 2009. Pursuant to a separate agreement with Antares and related to the Azur royalty stream and milestone buydown, we paid Antares an aggregate of $268,750 in February 2010. In addition, for the nine months ended September 30, 2010, we recorded royalty revenue and corresponding royalty expense of $129,335 within general and administrative expenses in our condensed statements of operations to reflect the Antares portion of Elestrin sales in royalty revenue.

Research and development expenses for the nine months ended September 30, 2010 increased 180 percent compared to the nine months ended September 30, 2009 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

General and administrative expenses for the nine months ended September 30, 2010 increased 22 percent compared to the nine months ended September 30, 2009 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during the nine months ended September 30, 2010.

For the nine months ended September 30, 2009, we recognized acquisition related costs of $1,470,467 related to our merger with Cell Genesys, which was completed on October 14, 2009.

For the nine months ended September 30, 2010, we recognized licensing expense of $268,750 related to our payment to Antares as a result of the Azur royalty stream and milestone buydown described above.

The fair value adjustment on our convertible senior notes for the nine months ended September 30, 2010 was $1,687,916 compared to no similar expense for the nine months ended September 30, 2009 since we assumed the convertible senior notes during the fourth quarter of 2009.

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During the nine months ended September 30, 2010, we recorded an investment impairment loss of $286,000 based on our determination that an other-than-temporary loss had occurred with respect to our investment in Ceregene, Inc. based on a recent third-party investment in Ceregene.

Interest expense for the nine months ended September 30, 2010 was $516,083 compared to no similar expense for the nine months ended September 30, 2009 as a result of our convertible senior notes which we assumed during the fourth quarter of 2009.

Interest income for the nine months ended September 30, 2010 decreased $6,182, or 53 percent, compared to interest income for the nine months ended September 30, 2009 primarily as a result of our cash being in a non-interest bearing checking account for more of the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009.

Liquidity and Capital Resources

The following table highlights several items from our balance sheets (in thousands):

Balance Sheet Data	September 30, 2010	December 31, 2009
Cash and cash equivalents	$ 35,526,017	$ 29,858,465
Total current assets	36,676,815	31,410,270
Investments	3,340,000	3,626,000
Total assets	40,763,252	36,436,928
Total current liabilities	7,095,131	3,930,117
Convertible senior notes due 2011 and 2013	18,364,333	16,676,417
Total liabilities	25,459,464	20,606,534
Total stockholders equity	15,303,788	15,830,394

Working Capital

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $152.4 million as of September 30, 2010. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our merger with Cell Genesys, to fund our ongoing business operations and short-term liquidity needs. As of September 30, 2010, we had $35.5 million of cash and cash equivalents. During the first nine months of 2010, we raised approximately $31.6 million, net of offering expenses, through the sale of common stock and warrants.

We expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our LibiGel Phase III clinical development;

- subject recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical development program for LibiGel, and the amount of our clinical recruitment expenditures intended to encourage enrollment in such studies;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our products;

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- the rate of technological advances;

- the commercial success of our products;

- our general and administrative expenses; and

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

If and when our products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing and other expenses if we choose to market the products ourselves. We currently do not have sufficient resources to obtain regulatory approval of LibiGel or any of our other products, to establish our own sales and marketing function or complete the commercialization of any of our products that are not licensed to others for development and marketing. We expect the ongoing LibiGel Phase III clinical development program to continue to require significant resources.

As of September 30, 2010, we had $35.5 million of cash and cash equivalents. Absent the receipt of any additional significant licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. How long our current cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel Phase III clinical studies and perhaps more importantly, the number of women we will enroll in the LibiGel safety study, which number cannot be determined at this time. According to the study s protocol, the minimum number of enrolled women is 2,500 women and the maximum number is 4,000 women. The greater the number of enrolled women, the more we will be required to use our cash to conduct the study. As of October 25, 2010, approximately 2,500 women were enrolled in the safety study. The number of women enrolled in the LibiGel safety study will be determined based on statistical methods contained in the study s FDA-agreed protocol as analyzed by the study s independent DMC. If enrollment in the safety study is completed in the near term, we believe we have sufficient cash resources to maintain our projected business operations, including continued Phase III clinical development of LibiGel, for approximately the next nine months. If, however, enrollment is not completed until the number of women enrolled is at, or about, 4,000 women, we believe our cash will last less than nine months, assuming we maintain our projected business operations, including the current pace of Phase III clinical development of LibiGel. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

As of September 30, 2010, we did not have any existing credit facilities under which we could borrow funds, other than our committed equity financing facility described below. If we are unable to raise additional financing when needed or secure another funding source for our clinical study program, we may need to temporarily slow or delay new enrollment in our LibiGel Phase III clinical development program or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product (e.g. one or more of our GVAX cancer vaccines) to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

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Committed Equity Financing Facility with Kingsbridge Capital Limited

In December 2008, we entered into a committed equity financing facility with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of our common stock through the end of December 2010. Under the terms of the facility, we are not obligated to utilize any of the $25.0 million available under the facility and there are no minimum commitments or minimum use penalties. We have access, at our discretion, to the funds through the sale of newly-issued shares of our common stock. The funds that can be raised under the facility over the two-year term set to expire in December 2010, will depend on the then-current price for our common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. We may access capital under the facility by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include a minimum price for our common stock of $1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of common stock issued or issuable to Kingsbridge; and the continued listing of our common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the facility if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. In connection with the committed equity financing facility, we issued a warrant to Kingsbridge to purchase 300,000 shares of our common stock at an exercise price of $4.00. The warrant became exercisable on June 15, 2009 and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys fees and other direct costs related to the registration of these shares, we did not make any other payments to secure the facility. The facility does not impose any material restrictions on our operating or financial activities. During the term of the facility, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to our common stock. As of September 30, 2010, we had not sold any shares to Kingsbridge under the committed equity financing facility. We currently are deciding whether to extend this facility, enter into a new or similar facility or let the facility expire by its terms in December 2010.

Convertible Senior Notes Due November 2011 and May 2013

As a result of our merger with Cell Genesys, we assumed $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the notes is approximately $0.7 million. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between us and the trustees thereunder, the November 2011 convertible notes are convertible into an aggregate of 24,789 shares of our common stock at a conversion price of $49.78 per share and the May 2013 convertible notes are convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of $3.72 per share, in each case subject to adjustments for stock dividends, stock splits and other similar events. The convertible notes are our general, unsecured obligations, ranking equally with all of our existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of our subsidiaries. The convertible notes are subject to repurchase by us at each holder s option, if a fundamental change (as defined in the indentures) occurs, at a repurchase price equal to 100% of the principal amount of the convertible notes, plus accrued and unpaid interest (and additional amounts, if any) through, but not including, the repurchase date and are subject to redemption for cash by us at any time in the case of the convertible notes due in 2011 and

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at any time on or after May 1, 2011, in the case of the convertible notes due in 2013, in whole or in part, at a redemption price equal to 100% of the principal amount of such notes if the closing price of our common stock has exceeded 150% of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. The indentures governing the convertible notes, as supplemented by the supplemental indentures, do not contain any financial covenants and do not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indentures.

We may from time to time seek to retire or purchase our outstanding convertible notes through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material.

We have elected to record our convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, we have adjusted the carrying value of the convertible senior notes to their fair value as of September 30, 2010, with changes in the fair value of the notes occurring since December 31, 2009, reflected in fair value adjustment in our 2010 condensed statements of operations. The recorded fair value of the convertible senior notes of an aggregate of $18,364,333 as of September 30, 2010 differs from their total stated principal amount of $22,016,000 by $3,651,667. The recorded fair value of the convertible senior notes of an aggregate of $16,676,417 as of December 31, 2009 differs from their total stated principal amount of $22,016,000 by $5,339,583.

Uses of Cash and Cash Flow

Net cash used in operating activities was $25.9 million for the nine months ended September 30, 2010 compared to net cash used in operating activities of $12.3 million for the nine months ended September 30, 2009. Net cash used in operating activities for the nine months ended September 30, 2010 was primarily the result of the net loss for that period which was higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities, the non-cash mark-to-market expense for our convertible senior notes and a decrease in prepaid expenses, deposits and other assets. Net cash used in operating activities for the nine months ended September 30, 2009 was primarily the result of the net loss for that period, and to a lesser extent, changes in prepaid expenses, deposits and other assets and accounts payable and accrued liabilities.

Net cash used in investing activities was $26,684 for the nine months ended September 30, 2010 compared to net cash provided by investing activities of $2.9 million for the nine months ended September 30, 2009. Net cash used in investing activities for the nine months ended September 30, 2010 was primarily due to the purchase of capital assets. Net cash provided by investing activities for the nine months ended September 30, 2009 was due to the redemption of approximately $3.0 million in short-term investments, partially offset by the purchase of capital assets and, to a lesser extent, short-term investments.

Net cash provided by financing activities was $31.6 million for the nine months ended September 30, 2010 compared to net cash provided by financing activities of $10.8 million for the nine months

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ended September 30, 2009. Net cash provided by financing activities for the nine months ended September 30, 2010 was the result of our March 2010 and June 2010 registered direct offerings, which resulted in net proceeds of approximately $17.5 million and $14.1 million, respectively, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2009 was the result of our August 2009 registered direct offering, which resulted in net proceeds of approximately $11.4 million, after deduction of placement agent fees and offering expenses, partially offset by the payment of certain acquisition related costs during that same period. Accrued liabilities for acquisition related costs were $959,549 as of September 30, 2009.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of September 30, 2010. We have, however, several financial commitments, including our convertible senior notes, product development milestone payments to the licensors of certain of our products, payments under our license agreements with Johns Hopkins University and Wake Forest University Health Sciences, as well as minimum annual lease payments.

We refer you to the description of our contractual obligations and commitments as of December 31, 2009 as set forth in our annual report on Form 10-K for the year ended December 31, 2009. There were no material changes to such information since that date through September 30, 2010.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies

The discussion and analysis of our condensed financial statements and results of operations are based upon our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company s most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified certain of our accounting policies as critical accounting policies. Our critical accounting policies are described in Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2009**.**

Recently Issued Accounting Pronouncements

In March 2010, the Financial Accounting Standard Board ratified the consensus reached by the Emerging Issues Task Force on Issue 08-9 (EITF 08-9), which was codified in Accounting Standards Update 2010-17. EITF 08-9 establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, for research and

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development arrangements in which one or more payments are contingent upon achieving uncertain future events or circumstances. EITF 08-9 is effective for fiscal years beginning on or after June 15, 2010, and will be adopted by us in the fiscal year beginning January 1, 2011. The impact of EITF 08-9 on our financial position and operations is dependent on the nature and structure of our future arrangements.

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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, would, might, possible, potential, project, expect, intend, plan, predict, anticipate, estimate, hope, approximate, contemplate or continue, the negative of these words, ot terms of similar meaning or the use of future dates. These forward-looking statements may be contained in the notes to our condensed financial statements and elsewhere in this report, including under the heading Part I. Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations. Our forward-looking statements generally relate to:

- the timing of the commencement, enrollment and successful completion of our clinical studies and the submission of new drug applications and other regulatory status of our products in development;

- approval by the FDA of our products that are currently in clinical development and other regulatory decisions and actions;

- our spending on research and development programs, pre-clinical studies and clinical studies, regulatory processes and licensure or acquisition of new products;

- our spending on general and administrative expenses;

- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;

- the future market size and market acceptance of our products;

- the effect of new accounting pronouncements and future health care, tax and other legislation;

- 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

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- 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 or otherwise could materially adversely affect our business, financial condition or operating results:

- subject recruitment and enrollment in our current and future clinical studies, including in particular our LibiGel Phase III clinical development program, and the results of such studies;

- the results of our clinical studies and the actions of the independent DMC or certain regulatory bodies, including the FDA;

- our failure to submit applications for and obtain and maintain required regulatory approvals on a timely basis or at all;

- the failure of certain of our products to be introduced commercially for several years or at all;

- the level of market acceptance of our products if and when they are commercialized;

- our dependence upon the maintenance of our license with Antares Pharma IPL AG and, to a lesser extent, other licensors;

- our dependence upon our licensees for the development, marketing and sale of certain of our products;

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

- our ability to implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;

- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;

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

- our ability to compete in a competitive industry;

- 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;

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- changes in generally accepted accounting principles and the effect of new accounting pronouncements; 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, 2009 under the heading Part I Item 1A. Risk Factors on pages 22 through 36 of such 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, 2009 under the heading Part I Item 1A. Risk Factors 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, 2009 under the heading Part I Item 1A. Risk Factors . The risks and uncertainties described above are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This Item 3 is not applicable to BioSante as a smaller reporting company and has been omitted pursuant to Item 305(e) of SEC Regulation S-K.

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

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

This Item 1A is not applicable to BioSante as a smaller reporting company.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 2010, we did not issue or sell any shares of our common stock or other equity securities of ours that were not registered under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended September 30, 2010. Our Board of Directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. **[REMOVED AND RESERVED]**

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) (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)

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SIGNATURES

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

November 12, 2010

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
Senior Vice President of Finance, Chief Financial Officer and Secretary
(principal financial and accounting officer)

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

Exhibit No.	Description	Method of Filing
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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