BIOSANTE PHARMACEUTICALS INC
Form 10-Q
May 14, 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 March 31, 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 May 14, 2010, 63,667,194 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 , BioVant , BioOral , BioAir 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

March 31, 2010 and December 31, 2009 (Unaudited)

	March 31, 2010	December 31, 2009
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 41,163,001	$ 29,858,465
Accounts receivable	132,748	64,645
Prepaid expenses and other assets	1,156,514	1,487,160
	42,452,263	31,410,270
PROPERTY AND EQUIPMENT, NET	710,395	747,979
OTHER ASSETS		
Investments	3,626,000	3,626,000
Deposits	527,463	652,679
	$ 47,316,121	$ 36,436,928
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 4,002,557	$ 2,440,096
Due to licensor - Antares	11,889	18,033
Accrued compensation	602,346	529,066
Other accrued expenses	1,608,223	942,922
	6,225,015	3,930,117
Convertible senior notes due 2011 and 2013	18,085,417	16,676,417
TOTAL LIABILITIES	24,310,432	20,606,534
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2010 - 391,286; 2009 - 391,286 Class C special stock	391	391
2010 - 63,667,194; 2009 - 53,262,568 Common stock	152,980,145	135,264,431
	152,980,536	135,264,822
Accumulated deficit	(129,974,847)	(119,434,428)
	23,005,689	15,830,394
	$ 47,316,121	$ 36,436,928

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three months ended March 31, 2010 and 2009 (Unaudited)

	Three Months Ended March 31,	
	2010	**2009**
REVENUE		
Licensing revenue	**$**	**$**
Grant revenue	**51,870**	**62,943**
Royalty revenue	**2,228,004**	**5,485**
Other revenue		
	2,279,874	**68,428**
EXPENSES		
Research and development	**9,426,870**	**3,072,240**
General and administration	**1,498,252**	**1,029,202**
Licensing expense	**268,750**	
Depreciation and amortization	**45,421**	**29,246**
	11,239,293	**4,130,688**
OTHER		
Fair value adjustment	**(1,409,000)**	
Interest expense	**(172,000)**	
Interest income		**11,648**
NET LOSS	**$ (10,540,419)**	**$ (4,050,612)**
BASIC AND DILUTED NET LOSS PER SHARE	**$ (0.19)**	**$ (0.15)**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**56,312,814**	**27,434,050**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Three months ended March 31, 2010 and 2009 (Unaudited)

	Three Months Ended March 31, 2010	2009
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (10,540,419)	$ (4,050,612)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	45,421	29,246
Employee & director stock-based compensation	204,971	336,119
Stock warrant expense - noncash	37,436	11,657
Mark-to-market of convertible senior notes	1,409,000	
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	455,862	(62,961)
Accounts receivable	(68,103)	(126,976)
Accounts payable and accrued liabilities	2,301,042	(595,701)
Due to licensor - Antares	(6,144)	(506)
Net cash (used in) operating activities	(6,160,934)	(4,459,734)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES		
Redemption of short term investments		3,037,982
Purchase of short term investments		(11,648)
Purchase of capital assets	(7,837)	(152,674)
Net cash (used in) provided by investing activities	(7,837)	2,873,660
CASH FLOWS PROVIDED BY (USED IN) FINANCING ACTIVITIES		
Proceeds from sale or conversion of shares, net	17,473,307	(12,500)
Net cash provided by (used in) financing activities	17,473,307	(12,500)
NET INCREASE (DECREASE) CASH AND CASH EQUIVALENTS	11,304,536	(1,598,574)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,858,465	11,760,920
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 41,163,001	$ 10,162,346

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q

MARCH 31, 2010

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) SPA (Special Protocol Assessment) 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. Two of these vaccines have been granted 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), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery 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 March 31, 2010, the results of operations for the three months ended March 31, 2010 and 2009, and the cash flows for the three months ended March 31, 2010 and 2009, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 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. Early adoption is permitted. 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 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, and the Company expects to continue this practice for the foreseeable future.

On March 8, 2010, the Company completed an additional 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. For additional discussion regarding the March 2010 registered direct offering, see Note 9 entitled Stockholders Equity.

As of March 31, 2010, the Company had $41.2 million of cash and cash equivalents. 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 clinical study program. The Company expects that its current cash resources will provide it sufficient capital to maintain its projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. Although the Company believes it has sufficient cash resources for the next 12 months, this estimate may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier. The Company 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.

As of March 31, 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 Company is unable to raise additional financing when needed or secure another funding source for its clinical study program, the Company may need to delay its Phase III clinical study program for LibiGel 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 sublicensed) 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

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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 March 31, 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 months ended March 31, 2010 does not include options to purchase an aggregate of 3,596,120 shares of common stock with exercise prices ranging from $1.27 to $36.82 per share, warrants to purchase an aggregate of 10,789,361 shares of common stock with exercise prices of $2.00 to $39.27 per share, or outstanding debt of $22.0 million that is convertible into an aggregate of 5,611,348 shares of common stock at conversion prices ranging from $3.72 to $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 months ended March 31, 2009 does not include options to purchase an aggregate of 2,770,025 shares of common stock with exercise prices ranging from $1.27 to $6.70 per share, and warrants to purchase an aggregate of 2,698,705 shares of common stock with exercise prices of $2.75 to $8.00 per share, because of their antidilutive effect on net loss per share.

6. LICENSE AGREEMENTS

Azur Pharma International II Limited (Azur) is marketing Elestrin in the U.S. using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur which reduced permanently the royalty percentage due to BioSante related to Azur s sales of Elestrin. During 2009 and 2010, BioSante 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 due to us 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.

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7. 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 $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), 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 value of the 2011 Notes and the 2013 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 convertible senior notes to their fair value as of March 31, 2010, with changes in the fair value of the notes occurring since December 31, 2009, reflected in fair value adjustment in the statements of operations. The recorded fair value of the 2011 Notes and 2013 Notes of $18,085,417 as of March 31, 2010 differs from their total stated principal amount of $22,016,000 by $3,930,583. The recorded fair value of the 2011 Notes and 2013 Notes 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 recorded fair value adjustments of $1,409,000 related to the convertible senior notes for the three months ended March 31, 2010 to increase its recorded liability and corresponding expense.

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

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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 March 31, 2010 were:

	2013 Notes	2011 Notes
Average risk free rate	1.6%	0.7%
Volatility of BioSante common stock	76.9%	85.3%
Discount rate for principal payments in cash	15.8%	15.8%

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.

At December 31, 2009, the Fair Value of the two convertible notes excluding accrued interest was $16,676,417. At March 31, 2010, the Fair Value of the two convertible notes excluding accrued interest was $18,085,417, a difference of $1,409,000. Of that difference, approximately $680,000 is related to the change in instrument specific credit risk. The change in the fair value of the two convertible notes due to instrument specific credit risk was estimated by calculating the difference between the March 31, 2010 fair value of the two convertible notes as recorded and what the fair value of the two convertible notes would have been on March 31, 2010 if the December 31, 2009 discount rate continued to be used in the calculation. The instrument specific credit risk has increased the fair value of the two convertible 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.

8. STOCK-BASED COMPENSATION

On March 15, 2010, the Board of Directors of the Company approved an amended and restated BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the Amended and Restated 2008 Plan), subject to approval by the Company s stockholders at the next annual meeting of stockholders, which, among other things, increases the number of shares authorized for issuance under the 2008 Plan from 2,000,000 to 4,000,000 plus the number of shares subject to stock options outstanding under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of the date of stockholder approval of the Amended and Restated 2008 Plan but only to the extent that such outstanding awards are forfeited, expire or otherwise terminate without the issuance of such shares.

During the three months ended March 31, 2010, the Company granted options to purchase an aggregate of 590,000 shares 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 $1.64 per option. No warrants were granted during the period other than the warrants issued in conjunction with our March 8, 2010 share offering

described in Note 9 entitled Stockholders Equity . No stock options or warrants were exercised during the period.

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9. 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.

10. CONTINGENCIES

The Company presently is involved in the following legal action and from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its financial statements for costs related to claims, including future legal costs, settlements and judgments, where the Company has assessed that a loss is probable and an amount can be reasonably estimated.

On July 1, 2009, a putative shareholder class action lawsuit concerning the Company s then proposed merger with Cell Genesys was filed in California Superior Court in San Mateo County naming Cell Genesys, its officers and directors, and the Company as defendants. On July 6, 2009, a second putative shareholder class action lawsuit naming the same parties and containing essentially identical allegations was filed in California Superior Court in San Mateo County. On July 8, 2009, a third putative shareholder class action lawsuit was filed in California Superior Court in San Mateo County, which also named the same parties and contained essentially identical allegations as the two prior lawsuits. On July 15, 2009, the Court consolidated these three lawsuits into one action and appointed interim lead counsel. On August 13, 2009, plaintiffs filed a consolidated class action complaint alleging that defendants breached their fiduciary duties and/or aided and abetted the breach of fiduciary duties owed to Cell Genesys stockholders in connection with the then proposed merger, including by failing to engage in a fair sales process, failing to obtain a fair price for the sale of Cell Genesys, and failing to provide Cell Genesys stockholders with material information regarding the merger. Plaintiffs sought an order certifying the lawsuit as a class action, injunctive relief to enjoin the merger or, in the event the then pending merger was completed, a rescission of the merger or rescissory damages. Plaintiffs further sought an accounting for all damages and an award of attorneys fees and costs.

Solely to avoid the costs, risks and uncertainties inherent in litigation, on September 18, 2009, the Company and Cell Genesys entered into a memorandum of understanding with plaintiffs counsel in the San Mateo County action pursuant to which the Company, Cell Genesys, the other named defendants and the plaintiffs agreed to settle the lawsuits subject to court approval. If the Court approves the settlement, the lawsuits will be dismissed with prejudice. Pursuant to the memorandum of understanding, Cell Genesys agreed to pay to plaintiffs counsel an amount not more than $240,000 as is approved by Court order for plaintiffs attorneys fees, costs and expenses in the San Mateo County action and to make additional disclosures in a current report on Form 8-K, without admitting in any way that the certain disclosures are material or otherwise required by law. Cell Genesys filed the Form 8-K on

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September 21, 2009. Pursuant to the memorandum of understanding, plaintiffs counsel conducted confirmatory discovery to confirm the fairness and adequacy of the settlement. The parties filed a stipulation of settlement with the Court and moved the Court for preliminary approval of the settlement, which was granted. Pursuant to the Preliminary Approval Order of Class Action Settlement dated April 1, 2010, notice of the settlement was provided to all persons or entities of record who bought or held shares of Cell Genesys common stock between June 30, 2009 and October 14, 2009. The Court set a hearing to consider final approval of the settlement on June 9, 2010. During the June 9, 2010 hearing, the Court will consider any properly asserted objections to the settlement and rule whether final judgment will be entered under the terms of the parties stipulated settlement and all claims dismissed with prejudice. The Company assumed Cell Genesys s rights and obligations relative to this lawsuit as a result of its merger with Cell Genesys, and accordingly has recorded a liability of $240,000 for the potential settlement. The Company believes that the resolution of this matter will not have a material impact on its financial position, cash flows or results of operations.

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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. We also are developing our calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery as well as seeking opportunities for our 2A/Furin and other technologies.

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 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 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. 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 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 and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,500 and 4,000 women exposed to LibiGel or placebo for 12 months after which time we

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intend to submit an NDA to the FDA. In February 2010, we announced that based upon the second review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee (DMC) unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. As of such date, there had been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. In view of DMC recommendation, we will continue the LibiGel Phase III development program as planned. We continue to target submission to the FDA of an NDA by the second half of 2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur) is marketing Elestrin in the U.S. using its women s health sales force that 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 permanently reduced 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 4.5 percent of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. 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 include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and is subsequently marketed.

GVAX cancer vaccines are designed to stimulate the patient s immune system to effectively fight 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 prostate cancer, pancreatic cancer, leukemia, breast and prostate (expected to begin in the fourth quarter 2010) cancer. Two of these vaccines have been granted 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 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

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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, to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future.

We have not introduced commercially any products. Azur, our marketing licensee for Elestrin, commercially launched Elestrin in April 2009. As a result, we received royalties on net sales of Elestrin from Azur through February 22, 2010. We recognized $2,228,004 in royalty revenue from sales of Elestrin during the three months ended March 31, 2010, which includes $78,004 in royalty payments pursuant to our original agreement with Azur, and $2.15 million 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, as permitted by the amendment to our license agreement signed in December 2009. This royalty revenue amount represents the gross royalty revenue we received from Elestrin through March 31, 2010 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $11,889 for the three months ended March 31, 2010, is recorded within general and administrative expenses in our statements of operations. Upon receiving the final payment from Azur in February 2010, our future Elestrin royalty stream was reduced to zero. 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 complete the commercialization of any of our products for which we have not entered into marketing relationships. We believe that our cash and cash equivalents of $41.2 million at March 31, 2010 will be sufficient to meet our liquidity requirements through at least the next 12 months.

We incurred expenses of approximately $3.1 million per month on research and development activities during the first quarter of 2010, which is a 207 percent increase, compared to the same period in 2009, primarily as a result of the conduct of the LibiGel Phase III clinical trials. In April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study in order to conserve cash; however, in January 2010, we reinitiated screening and enrollment in our safety study, and we expect our

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monthly research and development expenses to increase significantly in 2010 compared to 2009. 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 of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our products; and (5) competitive developments.

Our general and administrative expenses for the first quarter of 2010 increased 46% compared to the first quarter of 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, legal, public and investor relations, business development, accounting and corporate governance and other fees and expenses incurred.

We recognized a net loss for the first quarter of 2010 of approximately $10.5 million compared to a net loss of approximately $4.1 million for the first quarter of 2009. This increase was primarily due to the increased LibiGel clinical development expenses discussed above. We expect to continue to incur substantial and continuing losses for the foreseeable future. This is true especially as our own product development programs expand and various clinical trials continue, including in particular the Phase III clinical study program for LibiGel.

Results of Operations

Three Months Ended March 31, 2010 Compared to Three Months Ended March 31, 2009

The following table sets forth our results of operations for the three months ended March 31, 2010 and 2009.

	Three Months Ended March 31,			
	2010	**2009**	**$ Change**	**% Change**
Revenue	$ 2,279,874	$ 68,428	$ 2,211,446	3,231.8%
Expenses				
Research and development	9,426,870	3,072,240	6,354,630	206.8%
General and administrative	1,498,252	1,029,202	469,050	45.5%
Licensing expense	268,750		268,750	N/A
Other expense Fair value adjustment	1,409,000		1,409,000	N/A
Other expense Interest expense	172,000		172,000	N/A
Other income - Interest income		11,648	(11,648)	(100.0)%
Net loss	$ (10,540,419)	$ (4,050,612)	$ 6,489,807	160.2%

Revenue increased $2.2 million primarily as a result of the recognition of royalty revenue resulting 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.

Research and development expenses for the three months ended March 31, 2010 increased 207 percent compared to the three months ended March 31, 2009 primarily as a result of the conduct of the

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two LibiGel Phase III safety and efficacy clinical trials and the LibiGel Phase III cardiovascular safety study.

General and administrative expenses for the three months ended March 31, 2010 increased 46 percent compared to the three months ended March 31, 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 first quarter of 2010.

Interest income for the three months ended March 31, 2010 decreased 100 percent compared to interest income for the three months ended March 31, 2009 as a result of our decision to keep cash in a 100% FDIC-insured non-interest bearing checking account for all of the first quarter of 2010, in order to ensure maximum safety of principal.

We recognized other expenses of $1.6 million during the first quarter of 2010 compared to $0 during the first quarter of 2009. This increase was the result of a non-cash mark-to-market fair value adjustment related to our convertible senior notes and to a lesser extent, the accrual of interest expense on those convertible senior notes. The mark-to-market adjustment was driven by a lower assumed discount rate due to changes in market borrowing rates and our higher stock price.

Liquidity and Capital Resources

Working Capital

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, and we expect to continue this practice for the foreseeable future. As of March 31, 2010, we had $41.2 million of cash and cash equivalents. In March 2010, we completed a registered direct offering of approximately 10.4 million shares of our common stock and warrants to purchase an aggregate of approximately 5.2 million shares of our common stock at a purchase price of $1.73 per share. The offering resulted in net proceeds of approximately $17.5 million, after deduction of placement agent fees and offering expenses.

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 clinical study 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 Phase III clinical study program for LibiGel, and our other product development efforts;

- subject recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;

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

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

- the rate of technological advances;

- the commercial success of our products;

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- 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 other 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 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 Phase III clinical study program of LibiGel to continue to require significant resources.

We expect that our current cash resources will provide us sufficient capital to maintain our projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. Although we believe we have sufficient cash resources for the next 12 months, our estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

As of March 31, 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 delay our Phase III clinical study program for LibiGel 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 sublicensed) 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.

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

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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 March 31, 2010, we had not sold any shares to Kingsbridge under the committed equity financing facility. As of the date of this Form 10-Q filing, we did not have an effective registration statement registering the resale of shares of our common stock issue or issuable to Kingsbridge under the facility.

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) to, 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 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.

Uses of Cash and Cash Flow

Net cash used in operating activities was $6.2 million for the three months ended March 31, 2010 compared to net cash used in operating activities of $4.5 million for the three months ended March 31, 2009. Net cash used in operating activities for the three months ended March 31, 2010 was primarily the result of the net loss for that period which was higher compared to the prior period due to higher clinical trial related expenses, partially offset by an increase in accounts payable and other accrued liabilities. Net cash used in operating activities of $4.5 million for the three months ended March 31, 2009 was

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primarily the result of the net loss for that period which was higher compared to the prior year period due to higher clinical trial related expenses, and to a lesser extent, a decrease in accounts payable and accrued liabilities.

Net cash used in investing activities was $7,837 for the three months ended March 31, 2010 compared to net cash provided by investing activities of $2.9 million for the three months ended March 31, 2009. Net cash used in investing activities for the three months ended March 31, 2010 was due to the purchase of capital assets. Net cash provided by investing activities for the three months ended March 31, 2009 was due to the redemption of approximately $3.0 million in short-term investments, partially offset by purchases of capital assets.

Net cash provided by financing activities was $17.5 million for the three months ended March 31, 2010 compared to net cash used in financing activities of $12,500 for the three months ended March 31, 2009. Net cash provided by financing activities for the three months ended March 31, 2010 was the result of our March 2010 registered direct offering of approximately 10.4 million shares of our common stock and warrants to purchase an aggregate of approximately 5.2 million shares of our common stock at a purchase price of $1.73 per share, resulting in net proceeds of approximately $17.5 million, after deduction of placement agent fees and offering expenses.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of March 31, 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 March 31, 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

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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 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. Early adoption is permitted. 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.

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, 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;

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

- 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;

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

- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and

- our substantial and continuing losses.

Forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors that affect all businesses operating in a global market as well as matters specific to us. These uncertainties and factors are difficult to predict and many of them are beyond our control.

The following are some of the uncertainties and factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements 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 Phase III clinical study program for LibiGel, and the results of such studies;

- our failure to 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 licenses with Antares Pharma IPL AG and 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 and our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 under the heading Part I Item 1A. Risk Factors and included in our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown uncertainties and factors, including those described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 under the heading Part I Item 1A. Risk Factors and included in our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report. The risks and uncertainties described above are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 March 31, 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

A description of our legal proceedings in Note 10 to our financial statements included within this report is incorporated herein by reference.

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 March 31, 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, other than a warrant to purchase 208,093 shares of common stock to the placement agent in connection with our March 2010 registered direct offering, which warrant was issued in reliance upon Section 4(2) 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 March 31, 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.

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ITEM 6. EXHIBITS

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

Exhibit No.	Description
1.1	Placement Agent Agreement dated as of March 4, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC (Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812))
4.1	Form of Common Stock Purchase Warrant to be issued by BioSante Pharmaceuticals, Inc. to the investors and the placements agent in the March 2010 registered direct offering (Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812))
10.1	Form of Securities Purchase Agreement, dated March 4, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the March 2010 registered direct offering (Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812))
10.2	Amendment No. 1 to Common Stock Purchase Agreement dated as of March 24, 2010 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited (Incorporated by reference to Exhibit 10.39 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812))
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)

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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.

May 14, 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
Chief Financial Officer, Treasurer and Secretary
(principal financial and accounting officer)

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BIOSANTE PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

EXHIBIT INDEX

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