BIOSANTE PHARMACEUTICALS INC
Form 10-Q
May 10, 2011
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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, 2011

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 x
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company o

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

As of May 10, 2011, 93,593,945 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 and BioLook . 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, 2011 and December 31, 2010 (Unaudited)

	March 31, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 51,349,021**	**$ 38,155,251**
Prepaid expenses and other assets	**1,137,540**	**2,469,879**
	52,486,561	**40,625,130**
PROPERTY AND EQUIPMENT, NET	**812,962**	**635,776**
OTHER ASSETS		
Investments	**3,405,807**	**3,405,807**
Deposits	**99,937**	**99,937**
	$ 56,805,267	**$ 44,766,650**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 8,503,790**	**$ 4,864,217**
Accrued compensation	**743,643**	**526,022**
Other accrued expenses	**2,235,633**	**1,681,956**
Current portion of convertible senior notes	**1,149,820**	**1,111,132**
	12,632,886	**8,183,327**
Long-term convertible senior notes	**18,036,513**	**17,436,201**
TOTAL LIABILITIES	**30,669,399**	**25,619,528**
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2011 - 391,286; 2010 - 391,286 Class C special stock	**391**	**391**
2011 - 93,590,612; 2010 - 81,391,130 Common stock	**209,016,797**	**184,777,375**
	209,017,188	**184,777,766**
Accumulated deficit	**(182,881,320)**	**(165,630,644)**
	26,135,868	**19,147,122**
	$ 56,805,267	**$ 44,766,650**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three months ended March 31, 2011 and 2010 (Unaudited)

	Three Months Ended March 31,	
	2011	**2010**
REVENUE		
Grant revenue	**$**	**$ 51,870**
Royalty revenue	**57,000**	**2,228,004**
	57,000	**2,279,874**
EXPENSES		
Research and development	**14,864,420**	**9,426,870**
General and administration	**1,593,557**	**1,767,002**
Depreciation and amortization	**41,944**	**45,421**
	16,499,921	**11,239,293**
OTHER		
Convertible note fair value adjustment	**(639,000)**	**(1,409,000)**
Interest expense	**(172,000)**	**(172,000)**
Interest income	**3,245**	
NET LOSS	**$ (17,250,676)**	**$ (10,540,419)**
BASIC AND DILUTED NET LOSS PER SHARE	**$ (0.20)**	**$ (0.19)**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**84,764,512**	**56,312,814**

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, 2011 and 2010 (Unaudited)

	Three Months Ended March 31, 2011	2010
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	**$ (17,250,676)**	**$ (10,540,419)**
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	**41,944**	**45,421**
Loss on disposal of fixed assets	**2,099**	
Employee and director stock-based compensation	**300,385**	**204,971**
Stock warrant expense - noncash	**50,410**	**37,436**
Convertible note fair value adjustment	**639,000**	**1,409,000**
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	**1,332,339**	**455,862**
Accounts receivable		**(68,103)**
Accounts payable and accrued liabilities	**4,410,871**	**2,294,898**
Net cash (used in) operating activities	**(10,473,628)**	**(6,160,934)**
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Purchase of fixed assets	**(221,229)**	**(7,837)**
Net cash (used in) investing activities	**(221,229)**	**(7,837)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from issuance of common stock by registered direct offerings	**23,888,627**	**17,473,307**
Net cash provided by financing activities	**23,888,627**	**17,473,307**
NET INCREASE CASH AND CASH EQUIVALENTS	**13,193,770**	**11,304,536**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**38,155,251**	**29,858,465**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 51,349,021**	**$ 41,163,001**

See accompanying notes to the condensed financial statements.

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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) for the treatment of female sexual dysfunction (FSD) which is in Phase III clinical development under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). The Company s first FDA-approved product is Elestrin (estradiol gel) indicated for the treatment of hot flashes associated with menopause, marketed in the U.S. by Azur Pharma International II Limited, BioSante s licensee. BioSante also is developing a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and are currently in several Phase II clinical trials at minimal cost to the Company. Other products are Bio-T-Gel, a testosterone gel for male hypogonadism, licensed to Teva Pharmaceuticals USA, Inc., for which a New Drug Application (NDA) is pending with the FDA with a Prescription Drug User Fee Act (PDUFA) date of November 14, 2011, and an oral contraceptive in Phase II clinical development using the Company s patented technology.

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, 2011 and December 31, 2010, the results of operations for the three months ended March 31, 2011 and 2010, and the cash flows for the three months ended March 31, 2011 and 2010, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2011 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2011.

To maintain consistency and comparability, certain amounts from previously reported condensed financial statements have been reclassified to conform to the current-year presentation. Specifically, in the condensed statement of operations, Licensing expense of $268,750 has been combined into General and administration expense for the three months ended March 31, 2010. Similarly, in the condensed statements of cash flows, Due to licensor Antares in the amount of ($6,144) has been combined into Accounts payable and accrued liabilities for the three months ended March 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, 2010.

3. 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

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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 2009 merger with Cell Genesys, Inc. (Cell Genesys), to fund its ongoing business operations and short-term liquidity needs. In March 2011, the Company completed an offering of an aggregate of 12,199,482 shares of the Company s common stock and warrants to purchase an aggregate of 4,025,827 shares of the Company s common stock, resulting in net proceeds of approximately $23.9 million, after deducting placement agent fees and other offering expenses. See Note 8, Stockholders Equity, for additional discussion regarding the March 2011 registered direct offering.

As of March 31, 2011, the Company had $51.3 million of cash and cash equivalents, including $49.9 million invested in a U.S. Treasury money market fund. 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. The Company expects its cash and cash equivalents to meet its liquidity requirements through at least the next 12 to 15 months. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier. Exactly how long the Company s cash resources will last will depend upon several factors, including the number of subjects enrolled and the pace and timing of enrollment in the LibiGel safety study. According to the study s protocol, the maximum number of subjects to be enrolled is 4,000. As of April 1, 2011, over 3,000 subjects were enrolled in the safety study equating to over 3,300 subject-years of exposure.

As of March 31, 2011, the Company did not have any existing credit facilities under which it could borrow funds. The Company does have a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) 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. The term of the CEFF runs through December 2011. If the Company accessed capital under the CEFF, it would do so 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. As of March 31, 2011, the Company had not sold any shares to Kingsbridge under the CEFF.

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 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.

4. 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;

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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, 2011 does not include options to purchase an aggregate of 5,420,186 shares of common stock with exercise prices ranging from $1.41 to $36.82 per share, warrants to purchase an aggregate of 23,688,407 shares of common stock with exercise prices of $2.00 to $39.27 per share, or outstanding debt of $22,016,000 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, 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, and 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 $22,016,000 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.

5. INVESTMENTS

The Company s investments balance of $3,405,807 as of March 31, 2011 and December 31, 2010 consists of the Company s investments that are recorded using the cost method, and substantially represents the Company s investment in Ceregene, Inc., a privately held biotechnology company (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.

6. CONVERTIBLE SENIOR NOTES

The Company has two series of convertible senior notes outstanding. 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), convertible at the option of the holder into an aggregate of 5,586,559 shares of the Company s common stock at a conversion price of $3.72 per share. Under certain circumstances, 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 repurchase 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), convertible at the option of the holder into an aggregate of 24,789 shares of the Company s common stock at a conversion price of $49.78 per share. Under certain circumstances, the Company has the right to redeem the 2011 Notes for cash as a whole or

in part. The Company may be

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obligated to repurchase 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 percent 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 at a repurchase price equal to 100 percent of the principal amount of the Notes plus accrued and unpaid interest if certain changes in control occur or upon termination of trading of the Company s common stock.

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 March 31, 2011, with changes in the fair value of the Notes occurring since December 31, 2010, reflected in convertible note 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 $19,186,333 as of March 31, 2011 differs from their total stated principal amount of $22,016,000 by $2,829,667. The recorded fair value of the Notes of an aggregate of $18,547,333 as of December 31, 2010 differs from their total stated principal amount of $22,016,000 by $3,468,667. The Company recorded a fair value adjustment of $639,000 related to the Notes for the three months ended March 31, 2011 to increase its recorded liability and corresponding expense.

For the three months ended March 31, 2011 and 2010, approximately $287,000 and $680,000, respectively, of the fair value adjustment was attributable to the change in instrument specific credit risk. The change in the aggregate fair value of the Notes due to instrument specific credit risk for the three months ended March 31, 2011 was estimated by calculating the difference between the March 31, 2011 fair value of the Notes as recorded and what the fair value of the Notes would have been on March 31, 2011 if the December 31, 2010 discount rate continued to be used in the calculation. The change in the aggregate fair value of the Notes due to instrument specific credit risk for the three months ended March 31, 2010 was estimated by calculating the difference between the March 31, 2010 fair value of the Notes as recorded and what the fair value of the 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 for both periods 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 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, 2010 were:

	2013 Notes	2011 Notes
Average risk-free rate	0.82%	0.29%
Volatility of BioSante common stock	78.7%	61.0%
Discount rate for principal payments in cash	17.0%	17.0%

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The assumptions as of March 31, 2011 were:

	2013 Notes	2011 Notes
Average risk-free rate	0.80%	0.30%
Volatility of BioSante common stock	63.5%	64.8%
Discount rate for principal payments in cash	16.0%	16.0%

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. Volatility is based on the historical fluctuations in the Company s stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate is based on observed yields as of the measurement date of one-year, two-year and three-year U.S. Treasury Bonds.

7. STOCK-BASED COMPENSATION

On February 23, 2011, the Board of Directors of the Company approved a second amended and restated BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the Second Amended and Restated 2008 Plan), subject to approval by the Company s stockholders at its next annual meeting of stockholders, which, among other things, increases the number of shares authorized for issuance under the plan from 4,000,000 to 6,000,000 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 Second 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, 2011, the Company granted options to purchase an aggregate of 1,759,250 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 $1.70 per share under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan. Options to purchase an aggregate of 56,500 shares of the Company s common stock expired and were cancelled during the three months ended March 31, 2011. No options were exercised during the three months ended March 31, 2011.

No warrants were granted during the period other than the warrants issued in conjunction with the Company s March 8, 2011 share offering described in Note 8, Stockholders Equity . No warrants were exercised during the three months ended March 31, 2011.

8. STOCKHOLDERS EQUITY

On March 8, 2011, the Company completed an offering of 12,199,482 shares of its common stock and warrants to purchase an aggregate of 4,025,827 shares of its common stock at a purchase price of $2.0613 per share to institutional investors for gross proceeds of $25.1 million. The offering resulted in net proceeds to the Company of approximately $23.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of $2.25 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 243,990 shares of the Company s common stock at an exercise price of $2.58, which warrants are exercisable immediately 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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9. FAIR VALUE MEASUREMENTS

The Company accounts for its convertible debt and U.S. Treasury money market fund at fair value. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, a fair value hierarchy has been established that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk.

Financial assets and liabilities recorded at fair value on a recurring basis as of March 31, 2011 and December 31, 2010 are classified in the tables below in one of the three categories described above:

Description	March 31, 2011 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 49,880,019		$ 49,880,019	
Total assets	$ 49,880,019		$ 49,880,019	
Liabilities:				
2011 Senior Notes	$ 1,149,820		$ 1,149,820	
2013 Senior Notes	18,036,513		18,036,513	
Total liabilities	$ 19,186,333		$ 19,186,333	

Description	December 31, 2010 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 21,729,230		$ 21,729,230	

Total assets	$	21,729,230	$	21,729,230
Liabilities:				
2011 Senior Notes	$	1,111,132	$	1,111,132
2013 Senior Notes		17,436,201		17,436,201
Total liabilities	$	18,547,333	$	18,547,333

The Company made an election to record the values of the 2011 and 2013 Senior Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earning immediately. The fair values of the 2011 and 2013 Senior Notes are estimated based on the risk-

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free borrowing rate, the volatility of the Company s stock, and the current borrowing rates for similar companies. See Note 6, Convertible Senior Notes for more information and disclosures regarding key assumptions used in this fair value determination.

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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 heading Forward-Looking Statements below. The following discussion of our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report.

Business Overview

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

Our products, either approved, awaiting approval or in human clinical 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.

- Bio-T-Gel once daily transdermal testosterone gel for the treatment of hypogonadism, or testosterone deficiency in men, for which a New Drug Application (NDA) is pending with a Prescription Drug User Fee Act (PDUFA) date of November 14, 2011 and which is licensed to Teva Pharmaceuticals USA, Inc.

- 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.

- 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. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months 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 an NDA for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. We have completed enrollment in the two efficacy trials. The Phase III safety study currently is enrolling subjects, and as of April 1, 2011 had enrolled over 3,000 subjects. In February 2011, we announced that based upon the fifth review of study conduct and unblinded safety data from the safety study by the study s independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If

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enrollment is not completed sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 subjects. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit an 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 2012.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), our licensee, is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur s sales of Elestrin. 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, although based on current sales levels, we believe our receipt of such payments unlikely in the near term, if at all.

We license the technology underlying certain of our gel products, including LibiGel and Elestrin, from Antares Pharma, Inc. (Antares). 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 upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by us or a licensee.

Bio-T-Gel was developed initially by BioSante, and then it was licensed to Teva for late stage clinical development. Teva has filed the Bio-T-Gel NDA and the PDUFA date is November 14, 2011. In April 2011, Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement with respect to Bio-T-Gel. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent listed in the FDA Orange Book related to Abbott s testosterone gel for men. Although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

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 subsequently is marketed.

Our portfolio of cancer vaccines is 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 and breast cancer. Four of these vaccines have been granted FDA orphan drug designation. We license our cancer vaccine technology from Johns Hopkins University and The Whitehead Institute for Biomedical Research. Under various agreements, we are required to pay Johns Hopkins University 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.

In March 2011, we licensed our Pancreas Cancer Vaccine and Prostate Cancer Vaccine to Aduro BioTech, a clinical-stage immunotherapy company, solely for use in combination with Aduro s proprietary vaccine platform based on *Listeria monocytogenes* (Lm). Under the agreement, we are entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using our cancer vaccine technology.

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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 2009 merger with Cell Genesys, Inc., to fund our ongoing business operations and short-term liquidity needs.

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 March 31, 2011, we had $51.3 million of cash and cash equivalents. Absent the receipt of any additional 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. We expect our current cash and cash equivalent to meet our liquidity requirements through at least the next 12 to 15 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. Exactly how long our cash resources will last will depend upon several factors, including the number of subjects enrolled and the pace and timing of enrollment in the LibiGel safety study.

We incurred expenses of approximately $14.9 million on research and development activities during the three months ended March 31, 2011, which is a 58 percent increase, compared to the same period in 2010, primarily as a result of the conduct of the three LibiGel Phase III clinical studies. We anticipate spending on research and development activities approximately $3.0 million to $4.0 million per month until enrollment is completed in the safety study. The amount of our actual research and development expenditures 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 safety study; (4) the amount of our clinical recruitment expenditures intended to complete enrollment in our LibiGel safety study; (5) whether we or our licensees are funding the development of our products; and (6) competitive developments.

Our general and administrative expenses for the three months ended March 31, 2011 decreased 10 percent compared to the same period in 2010 due primarily to a decrease in licensing expense, partially offset by 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 months ended March 31, 2011 of approximately $17.3 million compared to a net loss of approximately $10.5 million for the three months ended March 31,

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2010. This increase was due primarily to the increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for the three months ended March 31, 2011 of $0.20 compared to a net loss of $0.19 for the three months ended March 31, 2010. This slight increase in net loss per share was the result of the higher net loss described above, partially offset by a significantly higher weighted average number of shares outstanding during the three months ended March 31, 2011. We expect to continue to incur substantial and continuing losses for at least the next 18 to 24 months.

Results of Operations

Three Months Ended March 31, 2011 Compared to Three Months Ended March 31, 2010

The following table sets forth our results of operations for the three months ended March 31, 2011 and 2010.

	Three Months Ended March 31,			
	2011	**2010**	**$ Change**	**% Change**
Revenue	$ 57,000	$ 2,279,874	$ (2,222,874)	(97.5)%
Expenses				
Research and development	14,864,420	9,426,870	5,437,550	57.7%
General and administrative	1,593,557	1,767,002	(173,445)	(9.8)%
Other expense Convertible note fair value adjustment	(639,000)	(1,409,000)	770,000	54.6%
Other expense Interest expense	(172,000)	(172,000)		0.0%
Other income - Interest income	3,245		3,245	N/A
Net loss	$ (17,250,676)	$ (10,540,419)	$ 6,710,257	63.7%
Net loss per common share (basic and diluted)	$ (0.20)	$ (0.19)	$ 0.01	5.3%
Weighted average number of common shares and common equivalent shares outstanding	84,764,512	56,312,814	28,451,698	50.5%

Revenue decreased $2.2 million, or 98 percent, primarily as a result of the recognition of $2,228,004 in royalty revenue during the three months ended March 31, 2010 resulting primarily 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. The only revenue recognized during the three months ended March 31, 2011 consisted of the royalty revenue from Azur for Elestrin sales, which royalty revenue is offset by our corresponding obligation to pay Antares royalties representing the same amount. Of the $2,228,004 in royalty revenue recognized during the three months ended March 31, 2010, $2,150,000 was received as a result of the December 2009 amendment. The remaining royalty revenue amounts represent the gross royalty revenue we received from Elestrin during the three months ended March 31, 2011 and 2010 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $57,000 during the three months ended March 31, 2011 and $11,889 during the three months ended March 31, 2010, is recorded within general and administrative expenses in our statements of operations.

Research and development expenses for the three months ended March 31, 2011 increased 58 percent compared to the three months ended March 31, 2010 primarily as a result of the conduct of the

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three LibiGel Phase III clinical studies, including in particular increased amounts spent for recruiting subjects and maintaining the increased number of subjects in the studies during the most recent period.

General and administrative expenses for the three months ended March 31, 2011 decreased 10 percent compared to the three months ended March 31, 2010 primarily as a result of a decrease in licensing expense in 2010 related to our payment to Antares as a result of expenses associated with the Azur licensing agreement and the termination of our prior licensing agreement for Elestrin, partially offset by an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during the three months ended March 31, 2011. We did not incur any licensing expense during the three months ended March 31, 2011.

The convertible note fair value adjustment to increase the recorded liability and corresponding expense was $639,000 for the three months ended March 31, 2011 compared to a fair value adjustment to increase the recorded liability and corresponding expense of $1,409,000 for the three months ended March 31, 2010. The larger increase in the liability for the three month ended March 31, 2010 was a result of the larger decline in the discount rate during the prior year period.

Interest expense was $172,000 for each of the three months ended March 31, 2011 and 2010 as a result of our convertible senior notes.

Interest income increased $3,245 for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 as a result of our cash being in a U.S. Treasury portfolio during the most recent period compared to our cash being in a non-interest bearing checking account during the prior year period.

Liquidity and Capital Resources

The following table highlights several items from our balance sheets:

Balance Sheet Data	March 31, 2011	December 31, 2010
Cash and cash equivalents	$ 51,349,021	$ 38,155,251
Total current assets	52,486,561	40,625,130
Investments	3,405,807	3,405,807
Total assets	56,805,267	44,766,650
Total current liabilities	12,632,886	8,183,327
Convertible senior notes due 2013	18,036,513	17,436,201
Total liabilities	30,669,399	25,619,528
Total stockholders equity	26,135,868	19,147,122

Liquidity

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $182,881,320 as of March 31, 2011. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our 2009 merger with Cell Genesys, to fund our ongoing business operations and short-term liquidity needs.

In March 2011, we completed an offering of an aggregate of 12,199,482 shares of our common stock and warrants to purchase an aggregate of 4,025,827 shares of our common stock, resulting in net proceeds of approximately $23.9 million, after deducting placement agent fees and other offering expenses.

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As of March 31, 2011, we had $51.3 million of cash and cash equivalents. Absent the receipt of any additional 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. 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 program;

- subject recruitment and enrollment in our current and future clinical studies, including in particular our LibiGel safety study;

- 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;

- 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.

We expect our current cash and cash equivalent to meet our liquidity requirements through at least the next 12 to 15 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. Exactly how long the Company s cash resources will last will depend upon several factors, including the number of subjects enrolled and the pace and timing of enrollment in the LibiGel safety study.

As of March 31, 2011, we did not have any existing credit facilities under which we could borrow funds. We have a committed equity financing facility described below. If we are unable to raise additional financing when needed or secure another funding source for our LibiGel Phase III clinical development program, we may need to temporarily slow or delay the 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 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

We have a committed equity financing facility with Kingsbridge Capital Limited (Kingsbridge), under 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 2011. If we choose to access capital under the facility, we can do so 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, among other conditions, a minimum price for our common stock of $1.15 per share, and is permitted to terminate the facility under certain limited circumstances, such as if a material and adverse event has occurred affecting our business, operations, properties or financial condition. As of March 31, 2011, we had not sold any shares to Kingsbridge under the committed equity financing 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 percent of the principal amount of the convertible notes, plus accrued and unpaid interest (which, with respect to the 2011 convertible notes, includes additional amounts, if any) on the repurchase date and are subject to redemption for cash by us at any time in the case of the convertible notes due in November 2011 and at any time on or after May 1, 2011, in the case of the convertible notes due in May 2013, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest (which, with respect to the 2011 convertible notes includes additional amounts, if any) to the redemption date, if the closing price of our common stock has exceeded 150 percent 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.

From time to time, we may 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

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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 March 31, 2011, with changes in the fair value of the notes occurring since December 31, 2010, reflected in convertible note fair value adjustment in our 2011 condensed statements of operations. The recorded fair value of the convertible senior notes of an aggregate of $19,186,333 as of March 31, 2011 differs from their total stated principal amount of $22,016,000 by $2,829,667. The recorded fair value of the convertible senior notes of an aggregate of $18,547,333 as of December 31, 2010 differs from their total stated principal amount of $22,016,000 by $3,468,667.

Uses of Cash and Cash Flow

Net cash used in operating activities was $10.5 million for the three months ended March 31, 2011 compared to net cash used in operating activities of $6.2 million for the three months ended March 31, 2010. Net cash used in operating activities for the three months ended March 31, 2011 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 a decrease in prepaid expenses and other assets and an increase in accounts payable and other accrued liabilities. Net cash used in operating activities of $6.2 million 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 year period due to higher clinical trial related expenses, partially offset by an increase in accounts payable and other accrued liabilities.

Net cash used in investing activities was $221,229 for the three months ended March 31, 2011 compared to net cash used in investing activities of $7,837 for the three months ended March 31, 2010. Net cash used in investing activities for each of the three months ended March 31, 2011 and 2010 was due to the purchase of fixed assets.

Net cash provided by financing activities was $23.9 million for the three months ended March 31, 2011 compared to net cash provided by financing activities of $17.5 million for the three months ended March 31, 2010. Net cash provided by financing activities for the three months ended March 31, 2011 was the result of our March 2011 registered direct offering of approximately 12.2 million shares of our common stock and warrants to purchase an aggregate of approximately 4.0 million shares of our common stock at a purchase price of $2.0613 per share, resulting in net proceeds of approximately $23.9 million, after deduction of placement agent fees and offering expenses. 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, 2011. 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.

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We refer you to the description of our contractual obligations and commitments as of December 31, 2010 as set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There were no material changes to such information since that date through March 31, 2011.

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, 2010. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

Recently Issued Accounting Pronouncements

The Company does not expect the adoption of any recent accounting pronouncements to have a material effect on the Company s financial position, results of operations or cash flows.

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

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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 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 and other regulatory decisions and actions;
- our spending capital 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
- 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;

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- the size of the market and 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 dependence upon certain third parties who assist us in certain aspects of our clinical studies and certain manufacturers who produce 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;

- 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, 2010 under the heading Part I Item 1A. Risk Factors on pages 17 through 38 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

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to the uncertainties and factors described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 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, 2010 under the heading Part I Item 1A. Risk Factors and included in our subsequent quarterly reports on Form 10-Q under the heading Part II Item 1A. Risk Factors, including this report. The risks and uncertainties described above are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to interest rate sensitivity on our cash equivalents in money market funds and our outstanding fixed rate debt. The objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid U.S. Treasury money market funds. Our investments in U.S. Treasury money market funds are subject to interest rate risk. To minimize the exposure due to an adverse shift in interest rates, we invest in short-term securities and our goal is to maintain an average maturity of less than one year. As of the date of this report, all of our cash equivalents are only invested in a U.S. Treasury money market fund and a certificate of deposit.

The following table provides information about our financial instruments that are sensitive to changes in interest rates.

Interest Rate Sensitivity

Principal Amount by Expected Maturity and Average Interest Rate

As of March 31, 2011	2011	2012	2013	Total	Fair Value March 31, 2011
Total Cash Equivalents	**$ 49,880,019**				**$ 49,880,019**
Average Interest Rate	**0.03%**				
Fixed Interest Rate 2011 Convertible Senior Notes	**$ 1,234,000**			**$ 1,234,000**	**$ 1,149,820**
Average Interest Rate	**3.125%**	**3.125%**	**3.125%**	**3.125%**	
Fixed Interest Rate 2013 Convertible Senior Notes			**20,782,000**	**20,782,000**	**$ 18,036,513**
Average Interest Rate	**3.125%**	**3.125%**	**3.125%**	**3.125%**	

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As of December 31, 2010	2011	2012	2013	Total	Fair Value December 31, 2010
Total Cash Equivalents	**$ 21,729,230**				**$ 21,729,230**
Average Interest Rate	**0.04%**				
Fixed Interest Rate 2011 Convertible Senior Notes	**$ 1,234,000**			**$ 1,234,000**	**$ 1,111,132**
Average Interest Rate	**3.125%**	**3.125%**	**3.125%**	**3.125%**	
Fixed Interest Rate 2013 Convertible Senior Notes			**20,782,000**	**20,782,000**	**$ 17,436,201**
Average Interest Rate	**3.125%**	**3.125%**	**3.125%**	**3.125%**	

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, 2011 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

The significant factors known to us that could materially adversely affect our business, financial condition, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report, are described in our most recently filed annual report on Form 10-K for the fiscal year ended December 31, 2010 under the heading Part I Item 1A. Risk Factors. There has been no material change in those risk factors, other than the risk factor below which we have revised to reflect recent patent infringement litigation involving Bio-T-Gel between Teva Pharmaceuticals and Abbott Laboratories, which, among other things, could delay the FDA approval and commercial launch of Bio-T-Gel and potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva:

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our operating results and financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and also are maintained in secrecy outside the United States until the application is published. Accordingly, we cannot determine whether our technology would infringe on patents arising from these unpublished patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development delays;

- require us to develop non-infringing technology; or

- require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our potential gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results. With respect to products which we have licensed to others, our licensees may be responsible for the defense of any patent infringement claims, which would result in our dependence upon them to defend our intellectual property rights. With respect to Bio-T-Gel, which was developed initially by BioSante and then was licensed to Teva for late stage clinical development, Abbott Laboratories, a marketer of a testosterone gel, in April 2011 filed a complaint against Teva alleging patent infringement. Under our agreement with Teva, Teva

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must assume the direction, control and disposition of the defense of such claims. There can be no assurance that Teva will be successful in the infringement claim. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent owned by Abbott related to testosterone gels for men. In addition, although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

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

Recent Sales of Unregistered Equity Securities

During the three months ended March 31, 2011, 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 243,990 shares of common stock to the placement agent in connection with our March 2011 registered direct offering, which warrant was issued in reliance upon Section 4(2) under the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering or Regulation D of the Securities Act. In such transaction, we made certain inquiries to establish that such sale qualified for such exemption from the registration requirements. In particular, we confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) all offers of sales and sales were made by personal contact from our officers and directors or other persons closely associated with us, (ii) the recipient made representations that such recipient was sophisticated in relation to his, her or its investment (and we had no reason to believe that such representations were incorrect), (iii) the recipient gave assurance of investment intent and the certificates for the shares bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended March 31, 2011. 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 3, 2011 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 4, 2011 (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 2011 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 4, 2011 (File No. 001-31812))
10.1	Ninth Amendment to Lease dated as of January 19, 2011 by and between 111 Barclay Associates, the sole beneficiary under Chicago Title Land Trust Company, as successor trustee to LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago and BioSante Pharmaceuticals, Inc. (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 January 21, 2011 (File No. 001-31812))
10.2	Form of Securities Purchase Agreement, dated March 3, 2011, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the March 2011 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 4, 2011 (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 10, 2011

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

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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