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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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 x 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 November 7, 2011, 109,618,529 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™ and The Pill-Plus™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Balance Sheets
September 30, 2011 and December 31, 2010 (Unaudited)

	September 30, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 69,600,199	$ 38,155,251
Prepaid expenses and other assets	943,710	2,469,879
	70,543,909	40,625,130
PROPERTY AND EQUIPMENT, NET	854,989	635,776
OTHER ASSETS		
Investments	3,405,807	3,405,807
Deposits	86,203	99,937
	$ 74,890,908	$ 44,766,650
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 6,041,891	$ 4,864,217
Accrued compensation	1,476,036	526,022
Other accrued expenses	2,747,791	1,681,956
Current portion of convertible senior notes	1,234,000	1,111,132
	11,499,718	8,183,327

Long-term convertible senior notes	**19,242,333**	**17,436,201**
TOTAL LIABILITIES	**30,742,051**	**25,619,528**
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and outstanding		
2011 - 391,286; 2010 - 391,286 Class C special stock	**391**	**391**
2011 - 109,618,529; 2010 - 81,391,130 Common stock	**254,738,709**	**184,777,375**
	254,739,100	**184,777,766**
Accumulated deficit	**(210,590,243)**	**(165,630,644)**
	44,148,857	**19,147,122**
	$ 74,890,908	**$ 44,766,650**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Statements of Operations
Three and Nine Months Ended September 30, 2011 and 2010 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	**2010**	**2011**	**2010**
REVENUE				
Grant revenue	**$ —**	**$ —**	**$ —**	**$ 51,870**
Licensing revenue	**100,000**	**—**	**100,000**	**—**
Royalty revenue	**82,784**	**51,331**	**220,787**	**2,279,335**
	182,784	**51,331**	**320,787**	**2,331,205**
EXPENSES				
Research and development	**11,500,053**	**9,716,091**	**37,480,873**	**27,800,567**
General and administration	**1,675,268**	**1,534,417**	**5,257,853**	**4,841,619**
Depreciation and amortization	**35,670**	**41,000**	**118,132**	**128,967**
	13,210,991	**11,291,508**	**42,856,858**	**32,771,153**
OTHER				
Convertible note fair value adjustment	**463,000**	**103,000**	**(1,929,000)**	**(1,687,916)**
Investment impairment loss	**—**	**(286,000)**	**—**	**(286,000)**
Interest expense	**(172,000)**	**(172,000)**	**(516,000)**	**(516,083)**
Other income	**2,000**	**—**	**15,000**	**—**
Interest income	**1,516**	**5,466**	**6,472**	**5,466**
NET LOSS	**$ (12,733,691)**	**$ (11,589,711)**	**$ (44,959,599)**	**$ (32,924,481)**
BASIC AND DILUTED NET LOSS PER SHARE	**$ (0.12)**	**$ (0.16)**	**$ (0.48)**	**$ (0.51)**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**104,439,220**	**71,194,180**	**94,468,428**	**64,092,806**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Statements of Cash Flows
Nine Months Ended September 30, 2011 and 2010 (Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	**$ (44,959,599)**	**$ (32,924,481)**
Adjustments to reconcile net loss to net cash (used in) operations		
Depreciation and amortization	**118,132**	**128,967**
Loss on write-down of fixed assets	**367,274**	**(804)**

Employee & director stock-based compensation	886,564	751,790
Stock warrant expense - noncash	180,759	57,195
Convertible note fair value adjustment	1,929,000	1,687,916
Investment impairment loss - noncash	—	286,000
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other assets	1,539,903	953,749
Accounts payable and accrued liabilities	2,993,059	3,165,012
Net cash (used in) operating activities	(36,944,908)	(25,894,656)
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Proceeds from sale of fixed assets	—	2,250
Purchase of fixed assets	(645,603)	(28,934)
Net cash (used in) investing activities	(645,603)	(26,684)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from common stock option exercised	32,442	—
Proceeds from warrants exercised	24,063	—
Proceeds from issuance of common stock by underwritten public offering	45,102,584	—
Proceeds from issuance of common stock by registered direct offerings	23,876,370	31,588,892
Net cash provided by financing activities	69,035,459	31,588,892
NET INCREASE CASH AND CASH EQUIVALENTS	31,444,948	5,667,552
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	38,155,251	29,858,465
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 69,600,199	$ 35,526,017
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Interest paid	$ 344,000	$ 344,000
Noncash investing and financing activities		
Unpaid costs associated with underwritten public offering	$ 141,447	
Purchase of fixed assets on account, non-cash investing activity	$ 59,016	$ —

See accompanying notes to the condensed financial statements.

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

1. DESCRIPTION OF BUSINESS

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The Company's lead products include LibiGel (transdermal testosterone gel) for the treatment of female sexual dysfunction (FSD) which is in Phase III clinical development according to 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, and an oral contraceptive in Phase II clinical development.

2. BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of September 30, 2011 and December 31, 2010, the results of operations for the three and nine months ended September 30, 2011 and 2010, and the cash flows for the nine months ended September 30, 2011 and 2010, in conformity with accounting principles generally accepted in the United States of America (GAAP). Operating results for the three and nine month periods ended September 30, 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 nine months ended September 30, 2010. Similarly, in the condensed statements of cash flows, Due to licensor — Antares in the amount of $(18,033) has been combined into Accounts payable and accrued liabilities, and Accounts receivable in the amount of $64,645 has been combined into Prepaid expenses, deposits and other assets for the nine months ended September 30, 2010.

Included within research and development expense for the three and nine month periods ended September 30, 2011 is a loss of $367,274 resulting from the write-down of equipment no longer in use in the Company's clinical development activities.

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.

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3. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-04, "*Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS)*." This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. The Company will adopt this guidance at the beginning of its first quarter of 2012. Adoption of this guidance is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, "*Presentation of Comprehensive Income*" which was issued to enhance comparability between entities that report under U.S. GAAP and IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. The Company will adopt this guidance at the beginning of its first quarter of 2012. To the extent the Company has components of other comprehensive income, the Company will report comprehensive income and its components pursuant to the requirements of this guidance.

In September 2011, the FASB issued Accounting Standards Update, *Testing Goodwill for Impairment* (the revised standard). The revised standard is intended to reduce the cost and complexity of the annual goodwill impairment test by providing entities an option to perform a "qualitative" assessment to determine whether further impairment testing is necessary. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. An entity can choose to early adopt if its annual test date is before the issuance of the final standard, provided that the entity has not yet performed its 2011 annual impairment test or issued its financial statements. Entities considering early adoption should begin assessing relevant factors for the qualitative assessment. An entity has the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The Company does not expect the adoption of this update to have any impact on the Company's financial position, results of operations or cash flows.

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 primarily 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.

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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 approximately 12.2 million shares of the Company's common stock and warrants to purchase an aggregate of approximately 4.0 million shares of the Company's common stock, resulting in net proceeds of $23.9 million, after deducting placement agent fees and other offering expenses. In August 2011, the Company completed an underwritten public offering of an aggregate of 16.0 million shares of common stock, resulting in net proceeds of approximately $45.1 million, after underwriters' discounts, commissions and offering expenses. See Note 9, "Stockholders' Equity," for additional discussion regarding the March 2011 registered direct offering and the August 2011 underwritten public offering. As of September 30, 2011, the Company had $69.6 million of cash and cash equivalents, including $67.0 million invested in a U.S. Treasury money market fund.

Absent the receipt of any additional licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations, including in particular its LibiGel Phase III clinical development program. The Company expects its ongoing LibiGel Phase III clinical development program to continue to require significant resources. The Company's future capital requirements will depend upon numerous factors, including: the progress, timing, cost and results of its LibiGel Phase III clinical development program; the progress, timing, cost and outcome of regulatory reviews of the Company's products; the Company's ability to license LibiGel or its other products for development and commercialization; the rate of technological advances; the commercial success of the Company's products; the Company's general and administrative expenses; and the progress, timing, cost and success of the Company's business development efforts to implement business collaborations, licenses and other business combinations or transactions and its efforts to continue to evaluate various strategic alternatives available with respect to its products and the company, itself.

The Company expects its cash and cash equivalents as of September 30, 2011 to meet the Company's liquidity requirements through at least the next 18 months. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

As of September 30, 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 approximately 5.4 million shares of the Company's common stock. The CEFF term runs through December 2011, and the Company currently does not intend to extend or renew such facility. If the Company accessed capital under the CEFF, it would do so by providing Kingsbridge with the Company's 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 September 30, 2011, the Company had not accessed

capital from or sold any shares to Kingsbridge under the CEFF, and the Company has no intention of doing so prior to the CEFF's expiration in December 2011.

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.

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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 the basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and nine months ended September 30, 2011 does not include options to purchase an aggregate of approximately 5.5 million shares of common stock with exercise prices ranging from $1.41 to $36.82 per share, warrants to purchase an aggregate of approximately 23.6 million 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 approximately 5.6 million shares of common stock at conversion prices of either $3.72 or $49.78 per share, because of their anti-dilutive effect on net loss per share. The computation of diluted net loss per share for the three and nine months ended September 30, 2010 does not include options to purchase an aggregate of approximately 3.7 million shares of common stock with exercise prices ranging from $1.27 to $36.82 per share, and warrants to purchase an aggregate of approximately 14.5 million and 14.4 million shares of common stock, respectively, 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 approximately 5.6 million shares of common stock at conversion prices of either $3.72 or $49.78 per share, because of their antidilutive effect on net loss per share.

6. INVESTMENTS

The Company's investments balance of $3.4 million as of September 30, 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. (Ceregene), 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.

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

7. CONVERTIBLE SENIOR NOTES

As of September 30, 2011, the Company had two series of convertible senior notes outstanding:

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- $20,782,000 principal amount of 3.125% Convertible Senior Notes due May 1, 2013 (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; and

- $1,234,000 principal amount of 3.125% Convertible Senior Notes due November 1, 2011 (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.

Subsequent to the end of the third quarter of 2011 on November 1, 2011, the maturity date of the 2011 Notes, the Company repaid in its entirety the outstanding principal amount of the 2011 Notes, plus all accrued and unpaid interest thereon through such date.

Interest on the 2013 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 2013 Notes at a redemption price equal to 100 percent of the principal amount of the 2013 Notes plus accrued and unpaid interest. The Company may be obligated to repurchase the 2013 Notes at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes plus accrued and unpaid interest if prior to their stated maturity there is an occurrence of a fundamental event, as described in the indenture.

The Company has elected to record 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. The Company has elected to record the 2011 Notes at fair value as of September 30, 2011 but with such fair value being determined as their total stated principal amount of

$1.2 million in light of the proximity of the November 1, 2011 maturity date. Prior to September 30, 2011, the Company recorded the 2011 Notes at fair value but with such fair value being determined in a manner similar to the 2013 Notes. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of September 30, 2011, with changes in the fair value of the Notes occurring since December 31, 2010 reflected in convertible note fair value adjustment in the unaudited condensed statements of operations. The fair value of the Notes are based on Level 2 inputs. The aggregate recorded fair value of the Notes of $20.5 million as of September 30, 2011 differs from their total stated principal amount of $22.0 million as of such date by $1.5 million. The aggregate recorded fair value of the Notes of $18.6 million as of December 31, 2010 differs from their total stated principal amount of $22.0 million as of such date by $3.4 million. The Company recorded a fair value adjustment of ($0.5) million related to the Notes for the three months ended September 30, 2011 to decrease its recorded liability and corresponding expense. The Company recorded a fair value adjustment of $1.9 million related to the Notes for the nine months ended September 30, 2011 to increase its recorded liability and corresponding expense.

The Company establishes the value of the Notes based upon contractual terms of the Notes, as well as, in the case of the 2013 Notes and as of December 31, 2010, the 2011 Notes, 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 September 30, 2011 were:

	2013 Notes
Average risk-free rate	0.19%
Volatility of BioSante common stock	64.6%
Discount rate for principal payments in cash	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.

8. STOCK-BASED COMPENSATION

The Company typically grants options to purchase shares of the Company's common stock to existing employees and non-employee directors on an annual basis during the first quarter of each year and to new employees and non-employee directors throughout the year on or around the date their employment or service with the Company commences. All options are granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the 2008 Plan). During the nine months ended September 30, 2011, the Company granted options under the 2008 Plan to purchase an aggregate of 2,069,250 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 $1.90 per share. Options to purchase an aggregate of 244,788 shares of the Company's common stock expired and were cancelled during the nine months ended September 30, 2011. Options to purchase an aggregate of 19,167 shares of the Company's common stock at a weighted average exercise price of $1.69 per share were exercised during the nine months ended September 30, 2011. Options are granted at an exercise price equal to the closing price of the Company's common stock on the date of the grant. As of September 30, 2011, approximately 2.4 million shares of the Company's common stock remain available for issuance under the 2008 Plan.

No warrants were granted during the nine months ended September 30, 2011, other than the warrants issued in conjunction with the Company's March 8, 2011 offering described in Note 9, "Stockholders' Equity." Warrants to purchase an aggregate of 8,750 shares of common stock were exercised during the nine months ended September 30, 2011 for total cash proceeds of $24,063.

9. STOCKHOLDERS' EQUITY

On March 8, 2011, the Company completed an offering of approximately 12.2 million shares of its common stock and warrants to purchase an aggregate of approximately 4.0 million 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 $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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On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 16.0 million shares of common stock at a purchase price of $3.00 per share, resulting in net proceeds of approximately $45.1 million, after underwriters' discounts, commissions and offering expenses.

10. FAIR VALUE MEASUREMENTS

The Company accounts for the Notes and its 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 September 30, 2011 and December 31, 2010 are classified in the tables below in one of the three categories described above:

Description	September 30, 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	$ 67,041,874	—	$ 67,041,874	—
Total assets	$ 67,041,874	—	$ 67,041,874	—
Liabilities:				
2011 Notes	$ 1,234,000	—	$ 1,234,000	—
2013 Notes	19,242,333	—	19,242,333	—
Total liabilities	$ 20,476,333	—	$ 20,476,333	—

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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 Notes	$ 1,111,132	—	$ 1,111,132	—
2013 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 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately. The fair values of the 2013 Notes as of September 30, 2011 and December 31, 2010 and the fair value of the 2011 Notes as of December 31, 2010 are estimated based on the risk-free borrowing rate, the volatility of the Company's common stock, and the current borrowing rates for similar companies. The fair value of the 2011 Notes as of September 30, 2011 was determined based on their total stated principal amount of $1.2 million in light of the proximity of the November 1, 2011 maturity date. See Note 7, "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 according to a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).

- 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. by Azur Pharma International II Limited (Azur).

- 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 and which is licensed to Teva Pharmaceuticals USA, Inc. (Teva).

- The Pill-Plus (triple component contraceptive) — once daily oral contraceptive composed of various combinations of estrogens, progestogens and androgens in Phase II development.

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

We believe LibiGel remains the most clinically advanced pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder 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 discussions with the FDA, including an SPA relating to the design of our two LibiGel Phase III safety and efficacy trials, that these trials and our Phase III cardiovascular and breast cancer safety study 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.

Subjects completed therapy in the two LibiGel safety and efficacy trials in the third quarter of 2011. Data are being collected from the 141 investigative sites in the U.S. and Canada that participated in the two trials, and we expect to announce top-line LibiGel efficacy results in December 2011. The third and last pivotal study for the LibiGel clinical development program is the ongoing LibiGel Phase III cardiovascular and breast cancer safety study, which completed enrollment of 3,656 subjects in June 2011. In October 2011, we announced that based upon the seventh 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. At the time of such announcement, 3,656 subjects were enrolled in the safety study resulting in over 4,800 subject-years of exposure. According to the protocol, the cardiovascular and breast cancer safety study will continue for 12 months of therapy from June 2011, the date the last subject was enrolled before the primary analysis will be conducted, which will provide data for our NDA submission. In total, subjects will be in the safety study for five years each. Therefore, the study will continue until June 2016. The primary analysis of safety data is targeted for the third quarter of 2012. The LibiGel NDA submission will include data from the two efficacy trials as well as the safety study and is targeted for the fourth quarter of 2012.

In September 2011, we successfully completed our principal LibiGel pharmacokinetic study, a required study for the submission of the LibiGel NDA, indicating that LibiGel increases levels of free testosterone, bioavailable testosterone and total testosterone in the serum of postmenopausal women to within normal ranges for younger premenopausal women. There were no differences in blood levels of testosterone regardless of the absence or presence of estrogen therapy, whether transdermal or oral.

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 $3.15 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 initially developed by BioSante, and then it was licensed to Teva for late stage clinical development. Teva has filed a Bio-T-Gel NDA and the Prescription Drug User Fee Act (PDUFA) date has been extended from November 14, 2011 to February 14, 2012 as a result of an additional information request by the FDA and submission by Teva. 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 cancer vaccine technology is designed to stimulate the patient's immune system to fight effectively the patient's own cancer. Multiple Phase II trials of our 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. In June 2011, we announced that the FDA's clinical hold on the GVAX Prostate Cancer Vaccine (GVAX Prostate) for the treatment of prostate cancer was lifted by the FDA.

Manufacturing of new GVAX Prostate is complete, and planning for a Phase II clinical trial, funded by others, at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center is underway. In July 2011, we announced an exclusive worldwide license of our Melanoma Vaccine to The John P. Hussman Foundation (Hussman Foundation), in exchange for our receipt of an upfront license fee, milestone payments, royalties on any sales and a percentage of any sublicense fees. Additionally, the Hussman Foundation has committed up to approximately $11 million in Melanoma Vaccine clinical development funding.

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. (Cell Genesys), to fund our ongoing business operations and short-term liquidity needs.

Our business operations to date have consisted primarily 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. As of September 30, 2011, we had $69.6 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 cash and cash equivalents as of September 30, 2011 to meet our liquidity requirements through at least the next 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of $37.5 million on research and development activities during the nine months ended September 30, 2011, which is a 35 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 of $3.0 million to $4.0 million per month for our LibiGel Phase III clinical development program through the end of 2011, after which time we expect our research and development spending to decrease to $2.0 million to $3.0 million per month. The amount of our actual research and development expenditures may fluctuate depending upon: (1) our development schedule,

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including the timing and scope of our clinical trials and studies; (2) the results of our clinical trials and studies; (3) the timing and results of regulatory actions relating to our products; (4) whether we or our licensees are funding the development of our products; (5) the amount of resources, including cash available; and (6) competitive developments.

Our general and administrative expenses for the nine months ended September 30, 2011 increased 9 percent compared to the same period in 2010 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and administrative expenses may fluctuate depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

We recognized a net loss for the three and nine months ended September 30, 2011 of $12.7 million and $45.0 million, respectively, compared to a net loss of $11.6 million and $32.9 million for the three and nine months ended September 30, 2010, respectively. These increases were due primarily to the increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for the three and nine months ended September 30, 2011 of $0.12 and $0.48, respectively, compared to a net loss per share of $0.16 and $0.51 for the three and nine months ended September 30, 2010, respectively. These changes in net loss per share were the result of the higher net loss described above, partially offset by a significantly higher weighted average number of shares outstanding during the three and nine months ended September 30, 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 September 30, 2011 Compared to Three Months Ended September 30, 2010

The following table sets forth our results of operations for the three months ended September 30, 2011 and 2010.

	Three Months Ended September 30,			
	2011	2010	$ Change	% Change
Revenue	$ 182,784	$ 51,331	$ 131,453	256.1%
Expenses				
Research and development	11,500,053	9,716,091	1,783,962	18.4%
General and administrative	1,675,268	1,534,417	140,851	9.2%
Other income — Convertible note fair value adjustment	463,000	103,000	360,000	349.5%
Other expense — Interest expense	(172,000)	(172,000)	—	N/A
Other expense — Investment impairment loss	—	(286,000)	(286,000)	N/A
Other income	2,000	—	2,000	N/A
Other income - Interest income	1,516	5,466	(3,950)	(72.3)%
Net loss	$ (12,733,691)	$ (11,589,711)	$ 1,143,980	9.9%
Net loss per common share (basic and diluted)	$ (0.12)	$ (0.16)	$ 0.04	25.0%
Weighted average number of common shares and common equivalent shares outstanding	104,439,220	71,194,180	33,245,040	46.7%

Revenue increased $131,453 primarily as a result of our receipt of a $100,000 upfront non-refundable licensing fee from the Hussman Foundation and, to a lesser extent, increased net sales of Elestrin. Of the revenue recognized during the three months ended September 30, 2011 and 2010, $82,784 and $51,331 consisted of royalty revenue from Azur for Elestrin sales, which royalty revenue is offset by our corresponding obligation to pay Antares royalties representing the same amount. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $82,784 during the three months ended September 30, 2011 and $51,331 during the three months ended September 30, 2010, is recorded within general and administrative expenses in our statements of operations.

Research and development expenses for the three months ended September 30, 2011 increased 18.4 percent compared to the three months ended September 30, 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

General and administrative expenses for the three months ended September 30, 2011 increased 9.2 percent compared to the three months ended September 30, 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses.

The convertible note fair value adjustment to decrease the recorded liability and corresponding expense was $463,000 for the three months ended September 30, 2011 compared to a fair value adjustment to decrease the recorded liability and corresponding expense of $103,000 for the three months ended September 30, 2010. The larger decrease in the liability for the three months ended September 30, 2011 was primarily a result of a decrease in our common stock price during the most recent period, which decreased the fair value of the conversion feature in the debt and, to a lesser extent, an increase in the discount rate during the most recent period.

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

Interest expense, as a result of our convertible senior notes, was $172,000 for each of the three months ended September 30, 2011 and 2010.

Nine Months Ended September 30, 2011 Compared to Nine Months Ended September 30, 2010

The following table sets forth our results of operations for the nine months ended September 30, 2011 and 2010.

	Nine Months Ended September 30,			
	2011	2010	$ Change	% Change
Revenue	$ 320,787	$ 2,331,205	$ (2,010,418)	(86.2)%
Expenses				
Research and development	37,480,873	27,800,567	9,680,306	34.8%
General and administrative	5,257,853	4,841,619	416,234	8.6%
Other expense — Convertible note fair value adjustment	(1,929,000)	(1,687,916)	241,084	14.3%
Other expense — Interest expense	(516,000)	(516,083)	(83)	(0.0)%
Other expense — Investment impairment loss	—	(286,000)	286,000	N/A

	Nine Months Ended September 30,			
	2011	2010	$ Change	% Change
Other income	15,000	—	15,000	N/A
Other income - Interest income	6,472	5,466	1,006	18.4%
Net loss	$ (44,959,599)	$ (32,924,481)	$ 12,035,118	36.6%
Net loss per common share (basic and diluted)	$ (0.48)	$ (0.51)	$ 0.03	5.9%
Weighted average number of common shares and common equivalent shares outstanding	94,468,428	64,092,806	30,375,622	47.4%

Revenue decreased $2.0 million, or 86.2 percent, primarily as a result of the recognition of royalty revenue during the nine months ended September 30, 2010 resulting primarily from the receipt of $2.3 million in non-refundable upfront payments from Azur in exchange for the elimination of all remaining future royalty payments that we are not required to pay 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, partially offset by our receipt during the nine months ended September 30, 2011 of $100,000 in a non-refundable upfront licensing fee from the Hussman Foundation. The only other revenue recognized during the nine months ended September 30, 2011 consisted of royalty revenue from Azur for Elestrin sales, which royalty revenue is offset by our corresponding obligation to pay Antares royalties representing the same amount.

Research and development expenses for the nine months ended September 30, 2011 increased 34.8 percent compared to the nine months ended September 30, 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

General and administrative expenses for the nine months ended September 30, 2011 increased 8.6 percent compared to the nine months ended September 30, 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during the nine months ended September 30, 2011 compared to the prior year period.

The fair value adjustment on our convertible senior notes for the nine months ended September 30, 2011 was $1.9 million compared to $1.7 million for the nine months ended September 30, 2010. The increase in the expense for the nine months ended September 30, 2011 was primarily a result of the increase in our common stock price increasing the fair value of the conversion feature in the debt combined with the shortening of the time period remaining until the debt matures.

Interest expense for the nine months ended September 30, 2011 was $516,000 compared to $516,083 for the nine months ended September 30, 2010.

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

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Liquidity and Capital Resources

The following table highlights several items from our balance sheets:

Balance Sheet Data	September 30, 2011	December 31, 2010
Cash and cash equivalents	$ 69,600,199	$ 38,155,251
Total current assets	70,543,909	40,625,130
Total assets	74,890,908	44,766,650
Total current liabilities	11,499,718	8,183,327
Convertible senior notes due 2013	19,242,333	17,436,201
Total liabilities	30,742,051	25,619,528
Total stockholders' equity	44,148,857	19,147,122

Liquidity

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $210.6 million as of September 30, 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 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, resulting in net proceeds of $23.9 million, after deducting placement agent fees and other offering expenses. In August 2011, we completed an underwritten public offering issuing 16.0 million shares of our common stock, resulting in net proceeds of approximately $45.1 million, after underwriters' discounts, commissions and offering expenses. We expect to use the net proceeds from these offerings for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital.

As of September 30, 2011 we had $69.6 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;
- the progress, timing, cost and outcome of certain regulatory actions relating to our products, including in particular LibiGel;
- our ability to license LibiGel or our other products for development and commercialization;
- the rate of technological advances;
- the commercial success of our products;
- our general and administrative expenses; and

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- the progress, timing, cost and success 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.

We expect the ongoing LibiGel Phase III clinical development program to continue to require significant resources. If and when LibiGel or 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 expect our cash and cash equivalents as of September 30, 2011 to meet our liquidity requirements through at least the next 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

As of September 30, 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, we may need to temporarily slow or delay then current programs 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.

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 approximately 5.4 million shares of our common stock through the end of December 2011. We currently do not intend to extend or renew such facility. If we choose to access capital under the facility prior to its expiration, 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 September 30, 2011, we had not accessed capital from or sold any shares to Kingsbridge under the committed equity financing facility, and we have no intention of doing so prior to the facility's expiration in December 2011.

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 (the 2011 Notes) and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 (the 2013 Notes and together with the 2011 Notes, the Notes) issued by Cell Genesys. On November 1, 2011, we repaid in its entirety the outstanding principal amount of the 2011 Notes and all accrued and unpaid interest thereon through such date. Contractual interest payments on the 2013 Notes are due on May 1 and November 1 of each year through maturity. Annual interest on the Notes was approximately $0.7 million, which will decrease slightly commencing in the fourth quarter of 2011 as a result of the repayment of the 2011 Notes. As a result of the merger and in accordance with the terms of the indenture governing the 2013 Notes as supplemented by a supplemental indenture entered into between us and the trustee thereunder, the 2013 Notes are

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convertible into an aggregate of approximately 5.6 million shares of our common stock at a conversion price of $3.72 per share, subject to adjustments for stock dividends, stock splits and other similar events. The 2013 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 2013 Notes are subject to repurchase by us at each holder's option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by us, 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 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. As of September 30, 2011, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indenture.

From time to time, we may seek to retire or purchase our outstanding 2013 Notes through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material.

We have elected to record 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. We have elected to record the 2011 Notes at fair value as of September 30, 2011 but with such fair value being determined as their total stated principal amount of $1.2 million in light of the proximity of the November 1, 2011 maturity date. Prior to September 30, 2011, we recorded the 2011 Notes at fair value but with such fair value being determined in a manner similar to the 2013 Notes. Accordingly, we have adjusted the carrying value of the Notes to their fair value as of September 30, 2011, with changes in the fair value of the Notes occurring since December 31, 2010 reflected in convertible note fair value adjustment in the unaudited condensed statements of operations. The fair value of the Notes are based on Level 2 inputs. The aggregate recorded fair value of the Notes of $20.5 million as of September 30, 2011 differs from their total stated principal amount of $22.0 million as of such date by $1.5 million. The aggregate recorded fair value of the Notes of $18.6 million as of December 31, 2010 differs from their total stated principal amount of $22.0 million as of such date by $3.4 million. We recorded a fair value adjustment of ($0.5) million related to the Notes for the three months ended September 30, 2011 to decrease its recorded liability and corresponding expense. We recorded a fair value adjustment of $1.9 million related to the Notes for the nine months ended September 30, 2011 to increase its recorded liability and corresponding expense.

Uses of Cash and Cash Flow

Net cash used in operating activities was $36.9 million for the nine months ended September 30, 2011 compared to net cash used in operating activities of $25.9 million for the nine months ended September 30, 2010. Net cash used in operating activities for the nine months ended September 30, 2011

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

Net cash used in investing activities was $645,603 for the nine months ended September 30, 2011 compared to net cash used in investing activities of $26,684 for the nine months ended September 30, 2010. The increase in net cash used in investing activities for the most recent period was due to a

significant increase in the purchase of fixed assets, including in particular machinery, computers and furniture. The machinery purchased during the most recent period relates to new BioSante-owned machinery for LibiGel product manufacturing at our contract manufacturer and the increased amounts spent on computers and furniture during the most recent period is due primarily to our increased number of personnel.

Net cash provided by financing activities was $69.0 million for the nine months ended September 30, 2011 compared to net cash provided by financing activities of $31.6 million for the nine months ended September 30, 2010. Net cash provided by financing activities for the nine months ended September 30, 2011 was the result of our August 2011 underwritten public offering and March 2011 registered direct offering, which resulted in net proceeds of $45.1 million and $23.9 million, respectively, after deduction of underwriter discounts and commissions or placement agent fees and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2010 was the result of our March 2010 and June 2010 registered direct offerings, which resulted in net proceeds of $17.5 million and $14.1 million, respectively, 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 September 30, 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.

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 September 30, 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 unaudited 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

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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

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-04, "*Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS)*." This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. We will adopt this guidance at the beginning of our first quarter of 2012. Adoption of this guidance is not expected to have any impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, "*Presentation of Comprehensive Income*" which was issued to enhance comparability between entities that report under U.S. GAAP and IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity's equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders' equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. We will adopt this guidance at the beginning of our first quarter of 2012. To the extent we have components of other comprehensive income we will report comprehensive income and its components pursuant to the requirements of this guidance.

In September 2011, the FASB issued Accounting Standards Update, *Testing Goodwill for Impairment* (the revised standard). The revised standard is intended to reduce the cost and complexity of the annual goodwill impairment test by providing entities an option to perform a "qualitative" assessment to determine whether further impairment testing is necessary. The revised standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. An entity can choose to early adopt if its annual test date is before the issuance of the final standard, provided that the entity has not yet performed its 2011 annual impairment test or issued its financial statements. Entities considering early adoption should begin assessing relevant factors for the qualitative assessment. An entity has the option to first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. We do not

expect the adoption of this update to have any impact on our 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,” “will,” “should,” “expect,” “intend,” “plan,” “predict,” “anticipate,” “estimate,” “target,” “approximate,” “contemplate” or “continue,” the negative of these words, other words and 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 completion of our LibiGel Phase III clinical studies, the submission of an NDA for LibiGel and other clinical and 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:

- the results of our clinical studies and the actions of the independent DMC or certain regulatory bodies, including the FDA;
- our failure to submit applications for and obtain and maintain required regulatory approvals on a timely basis or at all;
- the failure of certain of our products to be introduced commercially for several years or at all;
- the 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.

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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 the information under the heading "Part II — Item 1A. Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2011.

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 under the heading "Part II — Item 1A. Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2011 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 under the heading "Part II — Item 1A. Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2011. The risks and uncertainties described above and under the heading "Part II — Item 1A. Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2011 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 September 30, 2011	2011	2012	2013	Total	Fair Value September 30, 2011
Money Market Fund	$ 67,041,874	—	—	—	$ 67,041,874
Average Interest Rate	0.03%	—	—	—	—
Fixed Interest Rate 2011 Convertible Senior Notes	$ 1,234,000	—	—	$ 1,234,000	$ 1,234,000

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As of September 30, 2011	2011	2012	2013	Total	Fair Value September 30, 2011
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	
Fixed Interest Rate 2013 Convertible Senior Notes	—	—	$ 20,782,000	$ 20,782,000	$ 19,242,333
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	

As of December 31, 2010	2011	2012	2013	Total	Fair Value December 31, 2010
Money Market Fund	$ 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 September 30, 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

We are affected by risks specific to us as well as factors that affect all businesses operating in a global market. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our most recent quarterly report on Form 10-Q for the quarter ended June 30, 2011 under the heading "Part II — Item 1A. Risk Factors," which could materially adversely affect our business, financial condition or operating results. There has been no material change in those risk factors.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 30, 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 (the Securities Act), other than an aggregate of 8,750 shares of common stock issued to two investors in our 2006 private placement upon the exercise of warrants. Such shares were issued in reliance upon Section 4(2) under the Securities Act 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 September 30, 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
10.1	Underwriting Agreement, dated July 28, 2011 by and between BioSante Pharmaceuticals, Inc. and Jefferies & Company, Inc., as Representative of the Several Underwriters Named in Schedule A Thereto ((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 July 28, 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)
101	The following materials from BioSante Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Balance Sheets, (ii) the unaudited Condensed Statements of Operations, (iii) the unaudited Condensed Statements of Cash Flows, and (iv) Notes to Condensed Financial Statements.*

* Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this quarterly report on Form 10-Q shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under Section 11 or 12 of the Securities Act of 1933, as amended, or otherwise subject to the liability of those sections, except as shall be expressly set forth by specific reference in such filings.

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SIGNATURES

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

November 9, 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

Exhibit No.	Description	Method of Filing
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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
101	The following materials from BioSante Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Balance Sheets, (ii) the unaudited Condensed Statements of Operations, (iii) the unaudited Condensed Statements of Cash Flows, and (iv) Notes to Condensed Financial Statements.*	Furnished herewith

* Pursuant to Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this quarterly report on Form 10-Q shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be deemed part of a registration statement, prospectus or other document filed under Section 11 or 12 of the Securities Act of 1933, as amended, or otherwise subject to the liability of those sections, except as shall be expressly set forth by specific reference in such filings.

Exhibit 31.1

CERTIFICATION OF CEO PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Stephen M. Simes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

/s/ Stephen M. Simes

Stephen M. Simes
Vice Chairman, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CFO PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Phillip B. Donenberg, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2011

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary

Exhibit 32.1

CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen M. Simes, Vice Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer
November 9, 2011

Exhibit 32.2

CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip B. Donenberg, Senior Vice President of Finance, Chief Financial Officer and Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary
November 9, 2011