

BIOSANTE PHARMACEUTICALS INC

Form 10-Q

May 08, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark one)

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

For the quarterly period ended March 31, 2012

**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)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**58-2301143**  
(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  NO

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  NO

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

As of May 10, 2012, 120,826,861 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**FORM 10-Q**

**MARCH 31, 2012**

**TABLE OF CONTENTS**

<b>Description</b>	<b>Page</b>
<b>PART I.</b>	<b>FINANCIAL INFORMATION</b>
<b>ITEM 1.</b>	<b>Financial Statements</b>
	<u>Condensed Balance Sheets as of March 31, 2012 and December 31, 2011 (unaudited)</u>
	3
	<u>Condensed Statements of Operations for the three months ended March 31, 2012 and 2011 (unaudited)</u>
	4
	<u>Condensed Statements of Cash Flows for the three months ended March 31, 2012 and 2011 (unaudited)</u>
	5
	<u>Notes to the Condensed Financial Statements</u>
	6-12
<u>ITEM 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
	13
<u>ITEM 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>
	24
<u>ITEM 4.</u>	<u>Controls and Procedures</u>
	25
<b>PART II.</b>	<b>OTHER INFORMATION</b>
	26
<u>ITEM 1.</u>	<u>Legal Proceedings</u>
	26
<u>ITEM 1A.</u>	<u>Risk Factors</u>
	26
<u>ITEM 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
	26
<u>ITEM 3.</u>	<u>Defaults Upon Senior Securities</u>
	26
<u>ITEM 4.</u>	<u>Mine Safety Disclosures</u>
	26
<u>ITEM 5.</u>	<u>Other Information</u>
	26
<u>ITEM 6.</u>	<u>Exhibits</u>
	27
<u>SIGNATURE PAGE</u>	28
<u>Exhibit Index</u>	29

*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®, GVAX , The Pill-Plus and Elestrin . This report also contains trademarks, trade names and service marks that are owned by other persons or entities*

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Balance Sheets**

March 31, 2012 and December 31, 2011 (Unaudited)

	March 31, 2012	December 31, 2011
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 49,473,732	\$ 57,225,234
Prepaid expenses and other assets	716,920	801,147
	<b>50,190,652</b>	<b>58,026,381</b>
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>884,301</b>	<b>861,364</b>
<b>OTHER ASSETS</b>		
Investments	3,413,762	3,405,807
Deposits	86,203	86,203
	<b>\$ 54,574,918</b>	<b>\$ 62,379,755</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 3,281,705	\$ 3,150,677
Accrued compensation	767,672	1,597,329
Other accrued expenses	2,035,576	2,479,697
	<b>6,084,953</b>	<b>7,227,703</b>
Long-term convertible senior notes	10,493,589	17,336,760
<b>TOTAL LIABILITIES</b>	<b>16,578,542</b>	<b>24,564,463</b>
<b>STOCKHOLDERS EQUITY</b>		
<b>Capital stock</b>		
Issued and outstanding		
2012 - 391,286; 2011 - 391,286 Class C special stock	391	391
2012 - 120,826,861; 2011 - 109,618,529 Common stock	265,499,610	255,054,049
	<b>265,500,001</b>	<b>255,054,440</b>
Accumulated deficit	(227,503,625)	(217,239,148)
	<b>37,996,376</b>	<b>37,815,292</b>
	<b>\$ 54,574,918</b>	<b>\$ 62,379,755</b>

See accompanying notes to the condensed financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Operations****Three months ended March 31, 2012 and 2011 (Unaudited)**

	Three Months Ended March 31,	
	2012	2011
<b>REVENUE</b>		
Royalty revenue	\$ 114,000	\$ 57,000
	<b>114,000</b>	<b>57,000</b>
<b>EXPENSES</b>		
Research and development	5,183,217	14,864,420
General and administration	1,831,852	1,593,557
Depreciation and amortization	30,866	41,944
	<b>7,045,935</b>	<b>16,499,921</b>
<b>OTHER</b>		
Convertible note fair value adjustment	(3,210,338)	(639,000)
Interest expense	(124,196)	(172,000)
Interest income	1,992	3,245
<b>NET LOSS</b>	<b>\$ (10,264,477)</b>	<b>\$ (17,250,676)</b>
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<b>\$ (0.09)</b>	<b>\$ (0.20)</b>
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	<b>116,266,613</b>	<b>84,764,512</b>

See accompanying notes to the condensed financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Cash Flows****Three months ended March 31, 2012 and 2011 (Unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>		
Net loss	\$ (10,264,477)	\$ (17,250,676)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	30,866	41,944
Loss on disposal of fixed assets	432	2,099
Employee and director stock-based compensation	313,027	300,385
Stock warrant expense - noncash		50,410
Convertible note fair value adjustment	3,210,338	639,000
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	84,227	1,332,339
Accounts payable and accrued liabilities	(1,063,726)	4,410,871
<b>Net cash (used in) operating activities</b>	<b>(7,689,313)</b>	<b>(10,473,628)</b>
<b>CASH FLOWS (USED IN) INVESTING ACTIVITIES</b>		
Purchase of fixed assets	(54,234)	(221,229)
Purchase of investment	(7,955)	
<b>Net cash (used in) investing activities</b>	<b>(62,189)</b>	<b>(221,229)</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock by registered direct offerings		23,888,627
<b>Net cash provided by financing activities</b>		<b>23,888,627</b>
<b>NET (DECREASE)/INCREASE CASH AND CASH EQUIVALENTS</b>	<b>(7,751,502)</b>	<b>13,193,770</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>57,225,234</b>	<b>38,155,251</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 49,473,732</b>	<b>\$ 51,349,021</b>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION</b>		
<b>Noncash investing and financing activities</b>		
Shares issued for convertible senior notes and accrued interest	\$ 10,132,534	\$
Purchase of fixed assets on account, non-cash investing activity	\$	\$ 38,386

See accompanying notes to the condensed financial statements.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**FORM 10-Q**

**MARCH 31, 2012**

**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 products, either approved or in human clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III clinical development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva); (3) GVAX cancer vaccines, a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and are currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers; (4) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (5) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals), our licensee.

**2. BASIS OF PRESENTATION**

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of March 31, 2012 and December 31, 2011, the results of operations for the three months ended March 31, 2012 and 2011, and the cash flows for the three months ended March 31, 2012 and 2011, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2012 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2012. The Company does not have items of other comprehensive income for either of the three periods ended March 31, 2012 or 2011; and therefore, has not presented comprehensive income.

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, 2011.

**3. LIQUIDITY AND CAPITAL RESOURCES**

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

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

Table of Contents

As of March 31, 2012, the Company had \$49.5 million of cash and cash equivalents. As of March 31, 2012, the Company had outstanding \$11.8 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional significant licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as the Company continues to use cash to fund its operations, including in particular its LibiGel Phase III cardiovascular events and breast cancer safety study. The Company expects its cash and cash equivalents as of March 31, 2012 to meet its liquidity requirements through mid 2013. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing arrangements. If the Company raises additional funds by issuing equity securities, the Company's stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company's operations or the Company's ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to license one or more of its products or technologies 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 the Company's existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. In addition, from time to time, the Company may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. In February 2012, the Company issued an aggregate of approximately 11.2 million shares of its common stock to one of the holders of the Company's 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of \$9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company's available cash and cash equivalents, the Company's liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company's stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company's existing stockholders and/or decrease the Company's cash balance. A significant decrease in the Company's cash balance may impair the Company's ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the future value of the Company, the Company loses the NASDAQ listing of its common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to cut its operating costs further or the Company may be forced to explore other strategic alternatives, such as selling or merging the Company or winding down its operations and liquidating the Company. In such case, the Company's stockholders could lose some or all of their investment.

**4. BASIC AND DILUTED NET LOSS PER SHARE**

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential

Table of Contents

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, such securities are excluded from the computation of diluted net loss per share and there is no difference between basic and diluted net loss per share amounts.

**5. CONVERTIBLE SENIOR NOTES**

The Company has outstanding 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes). The aggregate principal amount of the 2013 Notes outstanding at March 31, 2012 and December 31, 2011 was \$11,782,000 and \$20,782,000, respectively. In February 2012, the Company issued 11.2 million shares of its common stock to one of the holders of the 2013 Notes in exchange for cancellation of \$9,000,000 in aggregate principal amount of such notes and the related accrued and unpaid interest on such notes. A non-cash fair value adjustment of \$(2,545,530) was recorded as a result of the cancellation of such notes. The remaining \$11,782,000 aggregate principal amount of the 2013 Notes are exchangeable at the option of the holder or upon certain specified events into an aggregate of approximately 3.2 million shares of the Company's common stock at a conversion price of \$3.72 per share.

The 2013 Notes are general, unsecured obligations of the Company and are described in Note 7 to the Company's financial statements for the year ended December 31, 2011. As of March 31, 2012, 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 the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company's 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 the Company except in certain circumstances specified in the indenture.

As described in Note 3, from time to time, the Company may purchase, exchange or restructure its outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer.

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of March 31, 2012, with changes in the fair value of the Notes occurring since December 31, 2011, reflected in fair value adjustment in the statements of operations. The fair value of the Notes is based on Level 2 inputs. The recorded fair value of the Notes of an aggregate of \$10,493,589 as of March 31, 2012 differs from their total stated aggregate principal amount of \$11,782,000 as of such date by \$1,288,411. The recorded fair value of the Notes of an aggregate of \$17,336,760 as of December 31, 2011 differed from their total stated aggregate principal amount of \$20,782,000 as of such date by \$3,445,240. During the three months ended March 31, 2012, the Company recorded a fair value adjustment of \$(664,808) related to the 2013 Notes that remained outstanding as of March 31, 2012, that increased the recorded liability and corresponding expense. For the three months ended March 31, 2011, the Company recorded a fair value adjustment of \$(639,000).

For the three months ended March 31, 2012 and 2011, approximately \$293,000 and \$287,000, respectively, of the fair value adjustment was attributable to the change in instrument specific credit risk. The change in the aggregate fair value of the Notes due to instrument specific credit risk for the three months ended March 31, 2012 was estimated by calculating the difference between the March 31, 2012 fair value of the Notes as recorded and what the fair value of the Notes would have been on March 31, 2012 if the December 31, 2011 discount rate continued to be used in the calculation. The instrument



Table of Contents

specific credit risk for both periods has increased the fair value of the Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk-free borrowing rate.

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

The assumptions as of March 31, 2012 were:

	<b>2013 Notes</b>
Average risk-free rate	0.19%
Volatility of BioSante common stock	88.9%
Discount rate for principal payments in cash	15.4%

The assumptions as of December 31, 2011 were:

	<b>2013 Notes</b>
Average risk-free rate	0.19%
Volatility of BioSante common stock	77.4%
Discount rate for principal payments in cash	18.5%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a Ca and Caa3 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.

**6. STOCK-BASED COMPENSATION**

On March 21, 2012, the Board of Directors of the Company approved a third amended and restated BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the Third Amended and Restated 2008 Plan), subject to approval by the Company's stockholders at its next annual meeting of stockholders, which, among other things, increases the number of shares authorized for issuance under the plan from 6,000,000 to 11,000,000 plus the number of shares subject to stock options outstanding under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of the date of stockholder approval of the Third Amended and Restated 2008 Plan but only to the extent that such outstanding awards are forfeited, expire or otherwise terminate without the issuance of such shares. If the Company's stockholders do not approve the Third Amended and Restated 2008 Plan, the current plan will remain in effect until the plan expires or is terminated in accordance with its terms.

During the three months ended March 31, 2012, the Company granted options to purchase an aggregate of 2,123,800 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 \$0.68

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

per share under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan. The exercise price of all options is equal to the fair market value of BioSante's common stock on the date of grant. Options to purchase an aggregate of 289,071 shares of the Company's common stock expired and were cancelled during the three months ended March 31, 2012. No options were exercised during the three months ended March 31, 2012.

Table of Contents

No warrants were granted or exercised during the three months ended March 31, 2012.

**7. STOCKHOLDERS EQUITY**

During the three months ended March 31, 2012, the Company issued 11,208,332 shares of its common stock to one of the holders of the 2013 Notes in exchange for cancellation of \$9,000,000 in aggregate principal amount of such notes, including accrued and unpaid interest. See Note 5, Convertible Senior Notes for information regarding the 2013 Notes.

On March 21, 2012, the Board of Directors of the Company approved an amendment to the Company's Restated Certificate of Incorporation to effect a reverse split of the Company's outstanding shares of common stock and class C special stock in the discretion of the Company's Board of Directors at an exchange ratio of not less than 1-for-2 and not more than 1-for-10. If such reverse split proposal is approved by the Company's stockholders, the Company's Board of Directors will have the authority, but not the obligation, in its sole discretion and without any further action on the part of the Company's stockholders, to effect the reverse stock split, at any time prior to the Company's 2013 annual meeting of stockholders that the Board of Directors believes to be most advantageous to the Company and its stockholders. The reverse stock split amendment, if approved and implemented, would not change the number of authorized shares of the Company's common stock or class C special stock or the par value of the Company's common stock or class C special stock, but because the number of authorized shares of the Company's common stock and class C special stock would not be affected, the effect of the reverse stock split amendment would be an increase in the authorized but unissued shares of the Company's common stock and class C special stock. The primary purpose of the reverse stock split, if implemented, would be to increase the Company's ability to maintain the listing of its common stock on The NASDAQ Global Market.

**8. COMMITMENTS AND CONTINGENCIES**

*Aptar Pharma Gel Filling Machine*

The Company has a commitment with Aptar Pharma to purchase a gel filling machine for \$842,740. As of March 31, 2012, the Company had paid \$337,096 resulting in a remaining obligation of \$505,644 as of such date.

*Pending Litigation*

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming the Company and the Company's President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company's disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company's securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

plaintiff seeks to represent a class of persons who purchased the Company's securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. The Company believes the action is without merit and intends to defend the action vigorously.

Table of Contents

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption *Weinstein v. BioSante Pharmaceuticals, Inc. et al.*, naming the Company's directors as defendants and the Company as a nominal defendant. The suit is generally related to the same events that are the subject of the class action litigation described above. The complaint alleges breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaint seeks unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in the Company's corporate governance and internal control procedures. Additional lawsuits may be filed by other purported stockholders of the Company.

The lawsuits are in their early stages; and, therefore, the Company is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on the Company's operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on the Company's financial condition, results of operations, cash flows or its operations.

The Company is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

**9. FAIR VALUE MEASUREMENTS**

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

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

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

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

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

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Financial assets and liabilities recorded at fair value on a recurring basis as of March 31, 2012 and December 31, 2011 are classified in the tables below in one of the three categories described above:

Description	March 31, 2012 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market fund	\$ 47,467,278		\$ 47,467,278	
<b>Total assets</b>	<b>\$ 47,467,278</b>		<b>\$ 47,467,278</b>	
<b>Liabilities:</b>				
2013 Notes	10,493,589		10,493,589	
<b>Total liabilities</b>	<b>\$ 10,493,589</b>		<b>\$ 10,493,589</b>	

Table of Contents

Description	December 31, 2011 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Money market fund	\$ 55,465,507		\$ 55,465,507	
Total assets	\$ 55,465,507		\$ 55,465,507	
<b>Liabilities:</b>				
2013 Notes	17,336,760		17,336,760	
Total liabilities	\$ 17,336,760		\$ 17,336,760	

The Company made an election to record the values of the 2013 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 are estimated based on the risk-free borrowing rate, the volatility of the Company's stock, and the current borrowing rates for similar companies. See Note 5, "Convertible Senior Notes" for more information and disclosures regarding key assumptions used in this fair value determination.

Table of Contents

**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 or in human clinical development, include:

- LibiGel – once daily transdermal testosterone gel in Phase III clinical development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).
- Male testosterone gel – once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).
- GVAX cancer vaccines – a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.
- The Pill-Plus (triple component contraceptive) – once daily use of various combinations of estrogens, progestogens and androgens in Phase II development.
- Elestrin – once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals), our licensee.

Our corporate strategy always has included product development of high value medically-needed pharmaceutical products. In light of the top-line results from our two pivotal LibiGel Phase III efficacy trials as described below, management continues to assess LibiGel's path forward and potential alternative strategies to utilize the continuing LibiGel Phase III cardiovascular events and breast cancer safety study. We also have

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

expanded our efforts to explore new product development projects through in-licensing and mergers and acquisitions. In addition, a full review of our GVAX cancer vaccine portfolio is underway.

Our lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. As reported in mid-December 2011, data from the two pivotal LibiGel Phase III efficacy trials show that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD. However, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel's results were not shown to be statistically

Table of Contents

different from placebo. The LibiGel Phase III safety study, which completed enrollment in June 2011, continues and will continue until a final strategic decision about LibiGel has been made. It is our objective to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study. In the meantime, we have instituted certain cost savings measures to minimize the continuing cost of the safety study and our operating expenses overall, including the termination of several of our independent contractor arrangements and a reduction in our total employee headcount. In February 2012, we announced that based upon the eighth unblinded review of 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 5,800 subject-years of exposure. If we continue the safety study, the primary analysis of the safety data will be conducted in the second half of 2012.

Our male testosterone gel is our second FDA approved product. This product initially was developed by BioSante, and then licensed by us to Teva for late stage clinical development. Teva submitted a new drug application (NDA) to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed.

Our GVAX cancer vaccines, which are designed to stimulate a patient's immune system to fight effectively the patient's own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving our GVAX cancer vaccines ongoing, primarily being conducted at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland. The studies are being funded by various sources, including certain foundations and our licensees. Our objective with respect to our GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes seeking additional licensees to fund and develop the cancer vaccines.

Elestrin is our first FDA approved product. Jazz Pharmaceuticals, Inc. (which recently acquired Azur Pharma International II Limited (Azur), our prior licensee), is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to sales of Elestrin. We maintain the right to receive up to \$140 million in sales-based milestone payments from Jazz Pharmaceuticals 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, but not our male testosterone gel, from Antares Pharma, Inc. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by us or a licensee. Our male testosterone gel was developed and is fully-owned by us and licensed to Teva. We license the technology underlying The Pill Plus from

Table of Contents

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.

One of our strategic goals has been, and continues to be, 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. In particular, as mentioned above, in light of the results from our two pivotal LibiGel Phase III efficacy trials, we have expanded our exploration of new product development projects through in-licensing and mergers and acquisitions. 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 the products and technologies of others 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. 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. 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.

As of March 31, 2012, we had \$49.5 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 safety study. In February 2012, we issued an aggregate of approximately 11.2 million shares of our common stock to one of the holders of our 3.125% convertible senior notes in exchange for cancellation of \$9.0 million in aggregate principal amount of such notes and the related accrued and unpaid interest on such notes. As of March 31, 2012, we had \$11.8 million in aggregate principal amount of 3.125% convertible senior notes outstanding that mature on May 1, 2013. We expect our cash and cash equivalents as of March 31, 2012 to meet our liquidity requirements through mid 2013. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of \$5.2 million on research and development activities during the three months ended March 31, 2012, which is a 65% percent decrease compared to the same period in 2011, primarily as a result of the conclusion of our two LibiGel Phase III efficacy trials at the end of 2011. Our research and development expenses for the remainder of 2012 will depend significantly upon the continuation of our LibiGel Phase III safety study and if we in-license additional products and technologies requiring additional development. We expect to spend approximately \$2.0 million per month on research and development activities during the remainder of 2012, assuming continuation of the LibiGel safety study. If we discontinue our LibiGel Phase III safety study and assuming we do not in-license additional products and technologies requiring additional development, we expect to spend a minimal amount on research and development activities thereafter during the remainder of 2012.

Our general and administrative expenses for the three months ended March 31, 2012 increased 15% percent compared to the same period in 2011 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and administrative expenses for the remainder of 2012 will depend upon continuation of our LibiGel Phase III safety study and if we in-





Table of Contents

license additional products and technologies requiring additional development. 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 months ended March 31, 2012 of \$10.3 million compared to a net loss of \$17.3 million for the three months ended March 31, 2011. This decrease was due primarily as a result of the conclusion of our two LibiGel Phase III efficacy trials at the end of 2011 offset by an increase in the fair value adjustment relating to the cancellation of \$9.0 million in aggregate principal amount of our convertible senior notes and an increase in general and administrative expenses. We recognized a net loss per share for the three months ended March 31, 2012 of \$0.09 compared to a net loss per share of \$0.20 for the three months ended March 31, 2011. The decrease in net loss per share was the result of the significantly higher weighted average number of shares outstanding, partially offset by the lower net loss described above, in each case in the three months ended March 31, 2012 as compared to the same period in 2011. We expect to continue to incur substantial and continuing losses for the foreseeable future.

**Results of Operations*****Three Months Ended March 31, 2012 Compared to Three Months Ended March 31, 2011***

The following table sets forth our results of operations for the three months ended March 31, 2012 and 2011.

	<b>Three Months Ended</b>				
	<b>March 31,</b>		<b>\$ Change</b>	<b>% Change</b>	
	<b>2012</b>	<b>2011</b>			
Revenue	\$ 114,000	\$ 57,000	\$ 57,000	100.0%	
Expenses					
Research and development	5,183,217	14,864,420	(9,681,203)	(65.1)%	
General and administrative	1,831,852	1,593,557	238,295	15.0%	
Other expense - Convertible note fair value adjustment	(3,210,338)	(639,000)	2,571,338	402.4%	
Other expense - Interest expense	(124,196)	(172,000)	(47,804)	(27.8)%	
Other income - Interest income	1,992	3,245	(1,253)	(38.6)%	
Net loss	\$ (10,264,477)	\$ (17,250,676)	(6,986,199)	(40.5)%	
Net loss per common share (basic and diluted)	\$ (0.09)	\$ (0.20)	\$ (0.11)	(55.0)%	
Weighted average number of common shares and common equivalent shares outstanding	116,266,613	84,764,512	31,502,101	37.2%	

The only revenue recognized during the three months ended March 31, 2012 and 2011 consisted of the royalty revenue from Jazz Pharmaceuticals (formerly Azur Pharma International II Limited) 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 \$114,000 during the three months ended March 31, 2012 and \$57,000 during the three months ended March 31, 2011, is recorded within general and administrative expenses in our statements of operations.



Table of Contents

Research and development expenses for the three months ended March 31, 2012 decreased 65 percent compared to the three months ended March 31, 2011 primarily as a result of the conclusion of our two LibiGel Phase III efficacy trials at the end of 2011.

General and administrative expenses for the three months ended March 31, 2012 increased 15 percent compared to the three months ended March 31, 2011 primarily as a result of an increase in personnel-related costs, professional fees and other administrative expenses.

The convertible note fair value adjustment for the three months ended March 31, 2012 increased primarily as a result of a \$2,545,530 non-cash fair value adjustment recorded upon cancellation of \$9.0 million in aggregate principal amount of our convertible senior notes in February 2012. The convertible note fair value adjustment for the three months ended March 31, 2012 also included an adjustment of \$664,808 to increase the recorded liability and corresponding expense of the remaining \$11.8 million in aggregate principal amount of our convertible senior notes due to a decline in the discount rate during the current year period. The convertible fair value adjustment for the three months ended March 31, 2011 increased the recorded liability and corresponding expense by \$639,000 and included the 2011 and 2013 Notes.

Interest expense was \$124,196 and \$172,000 for the three months ended March 31, 2012 and 2011, respectively, as a result of our convertible senior notes. Interest expense decreased during the most recent current year period as a result of the repayment of our convertible senior notes due November 1, 2011 during the fourth quarter of 2011 and the cancellation of \$9.0 million in aggregate principal amount of our convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first quarter of 2012 in exchange for the issuance of approximately 11.2 million in shares of our common stock.

Interest income decreased \$1,253 for the three months ended March 31, 2012 compared to the three months ended March 31, 2011 as a result of lower average interest rates during the current year period.

**Liquidity and Capital Resources**

The following table highlights several items from our balance sheets:

<b>Balance Sheet Data</b>	<b>March 31, 2012</b>	<b>December 31, 2011</b>
Cash and cash equivalents	\$ 49,473,732	\$ 57,225,234
Total current assets	50,190,652	58,026,381
Investments	3,413,762	3,405,807
Total assets	54,574,918	62,379,755
Total current liabilities	6,084,953	7,227,703
Convertible senior notes due 2013	10,493,589	17,336,760
Total liabilities	16,578,542	24,564,463
Total stockholders' equity	37,996,376	37,815,292

**Liquidity**

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of \$227.5 million as of March 31, 2012. 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.

Table of Contents

As of March 31, 2012, we had \$49.5 million of cash and cash equivalents. As of March 31, 2012, we had outstanding \$11.8 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. 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 safety study. We expect our cash and cash equivalents as of March 31, 2012 to meet our liquidity requirements through mid 2013. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our clinical development programs, including in particular continuation of our LibiGel Phase III safety study;
- whether we in-license additional new products and technologies that require further development;
- the cost, timing and outcome of regulatory actions with respect to our products;
- our ability to obtain value from our current products and technologies and our ability to out-license our products and technologies to third parties for development and commercialization and the terms of such out-licensings;
- our ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;
- the timing and amount of any royalties, milestone or other payments we may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;
- the emergence of competing products and technologies, and other adverse market developments;
- the perceived, potential and actual commercial success of our products;

- the outstanding principal amount of our 3.125% convertible senior notes due May 1, 2013 that are scheduled to mature and become due and payable on May 1, 2013 and our ability to avoid a fundamental change or an event of default under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;
- our operating expenses;
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, and our efforts to evaluate various strategic alternatives available with respect to our products and our company; and
- the resolution of our pending purported class action and shareholder derivative litigation and any amount we may be required to pay in excess of our directors and officers liability insurance.

Table of Contents

We do not have any existing credit facilities under which we could borrow funds. In the event that we would require additional working capital to fund future operations, we could seek to acquire such funds through additional equity or debt financing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to us, or at all. As an alternative to raising additional financing, we may choose to license one or more of our products or technologies 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. In addition, from time to time, we may purchase, exchange or restructure our outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of our company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, our available cash and cash equivalents, our liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of our stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of our existing stockholders and/or decrease our cash balance. A significant decrease in our cash balance may impair our ability to execute strategic alternatives or leave us without sufficient cash remaining for operations.

The announcement of the results of our LibiGel Phase III efficacy trials significantly depressed the trading price of our common stock and if we terminate development of LibiGel, the trading price of our common stock could be depressed further and affect adversely our ability to raise additional capital. The decrease in the trading price of our common stock has resulted in the bid price for our common stock failing to meet the minimum \$1.00 per share required for continued inclusion on The NASDAQ Global Market. We have until July 30, 2012 to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum bid closing price of at least \$1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance by July 30, 2012, we may transfer our common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if we meet the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, we also would need to provide NASDAQ written notice of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not indicate our intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for us to cure the deficiency, we will not be eligible for the second 180-day grace period and our common stock will be subject to delisting, which delisting determination we may appeal to a hearings panel at that time. A delisting of our common stock from NASDAQ or even the transfer of our common stock listing to The NASDAQ Capital Market could result in further decreases in the trading price of our common stock and, among other things, could harm our ability to raise additional financing.

In addition, the announcement of the results of our LibiGel Phase III efficacy trials resulted in pending purported class action and shareholder derivative litigation of which we are involved, which litigation is described in more detail in Note 8 to our unaudited condensed financial statements included in this report. While we believe the class action and shareholder derivative litigation are without merit and intend to defend the litigation vigorously, such litigation could divert management's attention, harm our business and/or reputation and result in significant liabilities, as well as harm our ability to raise additional financing.



Table of Contents

We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, or at all. This is particularly true if investors are not confident in the future value of our company, we lose the NASDAQ listing of our common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to cut our operating costs further or we may be forced to explore other strategic alternatives, such as selling or merging our company or winding down our operations and liquidating our company. In such case, our stockholders could lose some or all of their investment.

*Uses of Cash and Cash Flow*

Net cash used in operating activities was \$7.7 million for the three months ended March 31, 2012 compared to net cash used in operating activities of \$10.5 million for the three months ended March 31, 2011. Net cash used in operating activities for the three months ended March 31, 2012 was primarily the result of the net loss for that period which was lower compared to the prior period due to lower clinical trial related expenses primarily as a result of the conclusion of our two LibiGel Phase III efficacy trials at the end of 2011, partially offset by a decrease in prepaid expenses and other assets and a decrease in accounts payable and other accrued liabilities.

Net cash used in investing activities was \$62,189 for the three months ended March 31, 2012 compared to net cash used in investing activities of \$221,229 for the three months ended March 31, 2011. Net cash used in investing activities for each of the three months ended March 31, 2012 and 2011 was primarily due to the purchase of fixed assets.

Net cash provided by financing activities was \$0 for the three months ended March 31, 2012 compared to net cash provided by financing activities of \$23.9 million for the three months ended March 31, 2011. Net cash provided by financing activities for the three months ended March 31, 2011 was the result of our March 2011 registered direct offering of approximately 12.2 million shares of our common stock and warrants to purchase an aggregate of approximately 4.0 million shares of our common stock at a purchase price of \$2.0613 per share, resulting in net proceeds of approximately \$23.9 million, after deduction of placement agent fees and offering expenses.

*Commitments and Contractual Obligations*

We did not have any material commitments for capital expenditures as of March 31, 2012 other than a purchase obligation relating to a gel filling machine of \$505,644. 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, 2011 as set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. There were no material changes to such information since that date through March 31, 2012.

*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.

Table of Contents

**Critical Accounting Policies**

The discussion and analysis of our condensed financial statements and results of operations are based upon our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified certain of our accounting policies as critical accounting policies. Our critical accounting policies are described in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. 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, 2011.

**Recently Issued Accounting Pronouncements**

We do not expect the adoption of any recent accounting pronouncements to have a material effect 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, expect, intend, plan, predict, anticipate, estimate, hope, approximate, contemplate or continue, the negative of these words, or 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 status of our LibiGel Phase III clinical development program and the timing of our decision whether to continue our LibiGel Phase III safety study;
- our future operating expenses, anticipated burn rate and whether and how long our existing cash and cash equivalents will be sufficient to fund our operations;

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

Table of Contents

- the market size and market acceptance of our approved products and products in development;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- 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 future of our LibiGel Phase III clinical development program and the possibility that we may terminate it depending upon our ultimate strategic direction;
- our ability to generate significant revenues and obtain profitability;
- our ability to obtain additional capital when needed or on acceptable terms and the effect of any future equity or debt financings or debt restructurings on our stockholders;
- our substantial indebtedness and our ability to repay such debt when it becomes due and payable and the effect of such debt on our ability to operate our business;
- the resolution of our pending purported class action and shareholder derivative litigation and the effect of such resolution on our business, operating results and financial condition;

- our ability to maintain the listing of our common stock on The NASDAQ Global Market;
- the significant costs that we may incur in terminating our LibiGel Phase III clinical development program if we decide to do so;
- our ability to acquire or invest in new businesses, products and technologies and the effect of such actions on our business, operating results and financial condition;
- our success in developing new products and technologies, obtaining any required regulatory approvals for such products and technologies and obtaining market acceptance and commercial success with respect to such new products and technologies;
- results of our clinical studies and the actions of the independent DMC or certain regulatory bodies, including the FDA;
- our ability to submit applications for and obtain and maintain required regulatory approvals on a timely basis or at all;

Table of Contents

- the timing of when, if ever, our products will be approved and introduced commercially;
- 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, including in particular Teva Pharmaceuticals USA Inc. with respect to our male testosterone gel and the uncertainty involved in when Teva will launch commercially our male testosterone gel and the commercial success of such product and the amount of revenues we may receive, if any, from such product;
- 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 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 achieve projected goals and objectives within the time periods that we anticipate or announce publicly;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- our ability to compete in a competitive industry;
- our dependence upon key employees;

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- the risk of product liability lawsuits against us or our licensees;
- our ability to maintain effective internal control over financial reporting;
- changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
- changes in generally accepted accounting principles and the effect of new accounting pronouncements; or
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see our



Table of Contents

Annual Report on Form 10-K for the fiscal year ended December 31, 2011 under the heading Part I Item 1A. Risk Factors on pages 20 through 49 of such report.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 under the heading Part I Item 1A. Risk Factors as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown uncertainties and factors, including those described above and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 under the heading Part I Item 1A. Risk Factors. The risks and uncertainties described above are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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

**Interest Rate Sensitivity****Principal Amount by Expected Maturity and Average Interest Rate**

As of March 31, 2012	2012	2013	2014	Total	Fair Value March 31, 2012
Total Cash Equivalents	\$ 47,467,278				\$ 47,467,278
Average Interest Rate	0.01%				
Fixed Interest Rate 2013 Convertible Senior Notes		11,782,000		11,782,000	\$ 10,493,589

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Average Interest Rate	3.125%	3.125%	3.125%	3.125%
-----------------------	--------	--------	--------	--------

Table of Contents

As of December 31, 2011	2012	2013	2014	Total	Fair Value December 31, 2011
Total Cash Equivalents	\$ 55,465,507				\$ 55,465,507
Average Interest Rate	0.02%				
Fixed Interest Rate 2013 Convertible					
Senior Notes		20,782,000		20,782,000	\$ 17,336,760
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 the three months ended March 31, 2012 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

A description of our legal proceedings in Note 8 to our unaudited condensed financial statements included in this report is incorporated herein by reference.

**ITEM 1A. RISK FACTORS**

We are affected by risks specific to us as well as factors that affect all businesses. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our most recent annual report on Form 10-K for the fiscal year ended December 31, 2011 under the heading Part I Item 1A. Risk Factors, which could materially adversely affect our business, financial condition or operating results. There has been no material change to 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 March 31, 2012, 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 (Securities Act), other than the issuance of an aggregate of approximately 11.2 million shares of our common stock to one of the holders of our convertible senior notes in exchange for cancellation of \$9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest, which shares were issued in a transaction exempt from the registration requirements of the Securities Act by virtue of the exemption provided for in Section 3(a)(9) of the Securities Act for securities exchanged by the issuer with an existing security holder. No commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

**Issuer Purchases of Equity Securities**

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended March 31, 2012. 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.        MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5.        OTHER INFORMATION**

Not applicable.

Table of Contents

**ITEM 6. EXHIBITS**

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

<b>Exhibit No.</b>	<b>Description</b>
10.1	Securities Exchange Agreement dated as of February 7, 2012 between BioSante Pharmaceuticals, Inc. and Tang Capital Partners, LP (Filed herewith)
10.2	Securities Exchange Agreement dated as of February 15, 2012 between BioSante Pharmaceuticals, Inc. and Tang Capital Partners, LP (Filed herewith)
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 March 31, 2012, 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.

Table of Contents

**SIGNATURES**

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

May 8, 2012

**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)

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
10.1	Securities Exchange Agreement dated as of February 7, 2012 between BioSante Pharmaceuticals, Inc. and Tang Capital Partners, LP	Filed herewith
10.2	Securities Exchange Agreement dated as of February 15, 2012 between BioSante Pharmaceuticals, Inc. and Tang Capital Partners, LP	Filed herewith
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 March 31, 2012, 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.