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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 June 30, 2012

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)	(I.R.S. Employer Identification No.)

111 Barclay Boulevard
Lincolnshire, Illinois 60069
(Address of principal executive offices) (Zip Code)

(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 July 31, 2012, 21,921,596 shares of common stock and 65,211 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®, GVAX™, The Pill-Plus™ and Elestrin™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

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All share and per share amounts have been adjusted to reflect the one-for-six reverse split of BioSante's outstanding common stock and class C special stock effective June 1, 2012.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Balance Sheets
June 30, 2012 and December 31, 2011 (Unaudited)

	June 30, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 42,417,045	$ 57,225,234
Prepaid expenses and other assets	512,640	801,147
	42,929,685	58,026,381
PROPERTY AND EQUIPMENT, NET	862,439	861,364
OTHER ASSETS		
Investments	3,413,762	3,405,807
Deposits	88,793	86,203
	$ 47,294,679	$ 62,379,755

LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 3,835,756**	**$ 3,150,677**
Accrued compensation	**1,031,624**	**1,597,329**
Other accrued expenses	**1,028,623**	**2,479,697**
Current portion of convertible senior notes	**10,477,635**	**—**
	16,373,638	**7,227,703**
Long-term convertible senior notes	**—**	**17,336,760**
TOTAL LIABILITIES	**16,373,638**	**24,564,463**
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and outstanding		
2012 - 65,211; 2011 - 65,214 Class C special stock	**65**	**65**
2012 - 20,137,526 ; 2011 - 18,269,755 Common stock	**265,768,717**	**255,054,375**
	265,768,782	**255,054,440**
Accumulated deficit	**(234,847,741)**	**(217,239,148)**
	30,921,041	**37,815,292**
	$ 47,294,679	**$ 62,379,755**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Statements of Operations
Three and Six Months Ended June 30, 2012 and 2011 (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	**2011**	**2012**	**2011**
REVENUE				
Royalty revenue	**$ 108,780**	**$ 81,003**	**$ 222,780**	**$ 138,003**
	108,780	**81,003**	**222,780**	**138,003**
EXPENSES				
Research and development	**5,398,305**	**11,116,323**	**10,581,522**	**25,980,744**
General and administration	**1,948,995**	**1,989,103**	**3,780,847**	**3,582,659**
Depreciation and amortization	**30,933**	**40,519**	**61,799**	**82,463**
	7,378,233	**13,145,945**	**14,424,168**	**29,645,866**
OTHER				
Convertible note fair value adjustment	**15,953**	**(1,753,000)**	**(3,194,385)**	**(2,392,000)**
Interest expense	**(92,047)**	**(172,000)**	**(216,243)**	**(344,000)**
Other income	**—**	**13,000**	**—**	**13,000**
Interest income	**1,431**	**1,711**	**3,423**	**4,956**
NET LOSS	**$ (7,344,116)**	**$ (14,975,231)**	**$ (17,608,593)**	**$ (32,225,907)**
BASIC AND DILUTED NET LOSS PER SHARE	**$ (0.36)**	**$ (0.96)**	**$ (0.89)**	**$ (2.16)**
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**20,202,737**	**15,664,225**	**19,790,109**	**14,900,067**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Condensed Statements of Cash Flows
Six Months Ended June 30, 2012 and 2011 (Unaudited)

	Six Months Ended June 30,	
	2012	**2011**

CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	**$ (17,608,593)**	**$ (32,225,907)**
Adjustments to reconcile net loss to net cash (used in) operations		
Depreciation and amortization	**61,799**	**82,463**
Loss on disposal of fixed assets	**432**	**2,099**
Employee & director stock-based compensation	**582,466**	**581,402**
Stock warrant expense - noncash	**—**	**152,554**
Convertible note fair value adjustment	**3,194,385**	**2,392,000**
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other assets	**285,917**	**1,470,298**
Accounts payable and accrued liabilities	**(1,252,676)**	**3,183,419**
Net cash (used in) operating activities	**(14,736,270)**	**(24,361,672)**
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Purchase of investment	**(7,955)**	**—**
Purchase of fixed assets	**(63,306)**	**(542,919)**
Net cash (used in) investing activities	**(71,261)**	**(542,919)**
CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES		
Fractional share payout	**(658)**	**—**
Proceeds from common stock option exercises	**—**	**16,391**
Proceeds from issuance of common stock by registered direct offerings	**—**	**23,858,955**
Net cash (used in) provided by financing activities	**(658)**	**23,875,346**
NET (DECREASE) CASH AND CASH EQUIVALENTS	**(14,808,189)**	**(1,029,245)**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**57,225,234**	**38,155,251**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 42,417,045**	**$ 37,126,006**
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Interest paid	**$ 184,094**	**$ 344,000**
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.

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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 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 which 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 June 30, 2012 and December 31, 2011, the results of operations for the three and six months ended June 30, 2012 and 2011, and the cash flows for the six months ended June 30, 2012 and 2011, in conformity with accounting principles generally accepted in the United States of America (GAAP). Operating results for the three and six month periods ended June 30, 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 or six month periods ended June 30, 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.

On June 1, 2012, the Company effected a one-for-six reverse split of its outstanding common stock and class C special stock. These unaudited interim condensed financial statements give retroactive effect to the reverse stock split.

3. LIQUIDITY AND CAPITAL RESOURCES

Substantially all of the Company's revenue to date has been derived from upfront, milestone and royalty payments earned on licensing transactions and from subcontracts. The Company's business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. The Company itself 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,

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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.

As of June 30, 2012, the Company had $42,417,045 of cash and cash equivalents. As of June 30, 2012, the Company had outstanding $11,782,000 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. In July 2012, the Company issued an aggregate of 1,784,070 shares of its common stock to two of the holders of the Company's 3.125% convertible senior notes due May 1, 2013 in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. As a result of such exchange, as of July 31, 2012, the Company had outstanding $8,277,850 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013.

Absent the receipt of any additional 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 the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, assuming the Company continues to fund its LibiGel Phase III clinical development program. Based on these assumptions, and after considering the July 2012 exchange of $3,504,150 of the Company's convertible senior notes into common stock, the Company expects its cash and cash equivalents as of June 30, 2012 to meet the Company's liquidity requirements until approximately the third quarter of 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 a possible sale or merger 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. Such 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 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, together with an inability to raise additional financing when needed, 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 our LibiGel Phase III clinical development program, the future value of the Company and/or economic and

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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 reduce its operating costs or the Company may be forced to complete 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 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 July 31, 2012, June 30, 2012 and December 31, 2011 was $8,277,850, $11,782,000 and $20,782,000, respectively. In February 2012, the Company issued 1,868,055 shares of its common stock to one of the holders of the 2013 Notes in exchange for the 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 during the first quarter of 2012 as a result of the cancellation of such notes. The fair value adjustment recorded upon the cancellation of the notes is primarily attributable to the time value effect of settling these obligations at a date prior to the stated maturity of the notes. In July 2012, the Company issued an aggregate of 1,784,070 shares of its common stock to two of the holders of the 2013 Notes in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. It is anticipated that an additional non-cash fair value adjustment of $(611,621) will be recorded during the third quarter of 2012 as a result of the July 2012 cancellation of such notes.

The remaining $8,277,850 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 370,871 shares of the Company's common stock at a conversion price of $22.32 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 June 30, 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.

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As described in Note 3, "Liquidity and Capital Resources," 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 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 otherwise would require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the 2013 Notes to their fair value as of June 30, 2012, with changes in the fair value of the 2013 Notes occurring since December 31, 2011, reflected in fair value adjustment in the unaudited condensed statements of operations. As described in Note 9, "Fair Value Measurements," the fair value of the 2013 Notes is based on Level 2 inputs. The recorded fair value of the 2013 Notes of an aggregate of $10,477,635 as of June 30, 2012 differs from their total stated aggregate principal amount of $11,782,000 as of such date by $1,304,365. The recorded fair value of the 2013 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 and six months ended June 30, 2012, the Company recorded a fair value adjustment of $15,953 and $(3,194,385) related to the 2013 Notes that remained outstanding as of June 30, 2012, that for the three months ended June 30, 2012 decreased the recorded liability and corresponding expense and for the six months ended June 30, 2012 increased the recorded liability and corresponding expense. For the three and six months ended June 30, 2011, the Company recorded a fair value adjustment of $(1,753,000) and $(2,392,000) that increased the recorded liability and corresponding expense.

For the six months ended June 30, 2012 and 2011, approximately $(22,000) and $415,000, 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 2013 Notes due to instrument specific credit risk for the six months ended June 30, 2012 was estimated by calculating the difference between the June 30, 2012 fair value of the 2013 Notes as recorded and what the fair value of the 2013 Notes would have been on June 30, 2012 if the December 31, 2011 discount rate continued to be used in the calculation. The instrument specific credit risk for both periods has increased the fair value of the 2013 Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk-free borrowing rate.

The Company establishes the value of the 2013 Notes based upon contractual terms of the 2013 Notes, as well as certain key assumptions.

The assumptions as of June 30, 2012 were:

Average risk-free rate	0.19%
Volatility of BioSante common stock	86.6%
Discount rate for principal payments in cash	18.8%

The assumptions as of December 31, 2011 were:

Average risk-free rate	0.19%
Volatility of BioSante common stock	77.4%
Discount rate for principal payments in cash	18.5%

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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 six month and one-year U.S. Treasury Bonds.

6. STOCK-BASED COMPENSATION

At the annual meeting of the Company's stockholders held on May 30, 2012, the Company's stockholders approved a third amended and restated BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the 2008 Plan), which, among other things, increased the number of shares of the Company's common stock authorized for issuance under the plan from 1.0 million to approximately 1.8 million plus the number of shares subject to stock options outstanding under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of May 30, 2012 but only to the extent that such outstanding awards are forfeited, expire or otherwise terminate without the issuance of such shares. As of June 30, 2012, approximately 945,391shares of the Company's common stock remain available for issuance under the 2008 Plan.

During the six months ended June 30, 2012, the Company granted options under the 2008 Plan to purchase an aggregate of 354,782 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 $4.10 per share. Options to purchase an aggregate of 86,994 shares of the Company's common stock expired and were cancelled during the six months ended June 30, 2012. Options are granted at an exercise price equal to the closing price of the Company's common stock on the date of the grant. No options were exercised during the six months ended June 30, 2012.

During the six months ended June 30, 2012, no warrants were granted or exercised and warrants to purchase an aggregate of 65,872 shares of the Company's common stock at an exercise price of $235.62 per share expired on April 11, 2012.

7. STOCKHOLDERS' EQUITY

During the six months ended June 30, 2012, the Company issued an aggregate of 1,868,055 shares of its common stock to one of the holders of the 2013 Notes in exchange for the cancellation of $9,000,000 in aggregate principal amount of such notes, including accrued and unpaid interest. In July 2012, the Company issued 1,784,070 shares of its common stock to two of the holders of the 2013 Notes in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. See Note 5, "Convertible Senior Notes" for information regarding the 2013 Notes.

On May 30, 2012, the Company's stockholders 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. On June 1, 2012, the Board of Directors of the Company effected a 1-for-6 reverse split of the Company's outstanding shares of common stock and class C special stock. The reverse stock split did 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

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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 was not affected, the effect of the reverse stock split was to increase the number of authorized but unissued shares of the Company's common stock and class C special stock. The primary purpose of the reverse stock split was to increase the Company's ability to maintain the listing of its common stock on The NASDAQ Global Market.

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8. COMMITMENTS AND CONTINGENCIES

Aptar Pharma — Gel Packaging Machine

The Company has a commitment with Aptar Pharma to purchase a gel packaging machine for $847,532. As of June 30, 2012, the Company had paid $337,096 resulting in a remaining obligation of $510,436 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 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.

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. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits are generally related to the same events that are the subject of the class action litigation described above. The complaints allege 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 complaints seek 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 operations, including its financial condition, results of operations, or cash flows.

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.

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9. FAIR VALUE MEASUREMENTS

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

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

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

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

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

Financial assets and liabilities recorded at fair value on a recurring basis as of June 30, 2012 and December 31, 2011 are classified in the tables below in one of the three categories described above:

Description	June 30, 2012 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	$ 41,468,496	—	$ 41,468,496	—
Total assets	$ 41,468,496	—	$ 41,468,496	—
Liabilities:				
2013 Notes	10,477,635	—	10,477,635	—
Total liabilities	$ 10,477,635	—	$ 10,477,635	—

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)
Assets:				
Money market fund	$ 55,465,507	—	$ 55,465,507	—
Total assets	$ 55,465,507	—	$ 55,465,507	—
Liabilities:				
2013 Notes	17,336,760	—	17,336,760	—
Total liabilities	$ 17,336,760	—	$ 17,336,760	—

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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 earning 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 6, "Convertible Senior Notes" for more information and disclosures regarding key assumptions used in this fair value determination.

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

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

Business Overview

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

Our products, either approved 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 is to develop high value medically-needed pharmaceutical products. As a part of our corporate strategy, we continue to seek and 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. Therefore, as a matter of course, from time to time, 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, with the goal of maximizing stockholder value.

Our lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, we have focused our efforts on two Phase III LibiGel efficacy trials and our ongoing LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, we announced results from our two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the

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two efficacy trials was greater than expected, and LibiGel's results were not shown to be statistically different from use of the placebo.

Beginning in December 2011, we analyzed the data from our Phase III LibiGel efficacy trials, consulted with key opinion leaders (KOLs) in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 we announced a plan to initiate two new LibiGel Phase III efficacy trials. We subsequently began the process of developing a protocol for the two new efficacy trials and applying for an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials. We also announced in June 2012 the continuation of the LibiGel Phase III cardiovascular and breast cancer safety study per the protocol.

We expect that any potential new LibiGel Phase III efficacy trials would include the same FDA-required efficacy endpoints as our prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire. We estimate that the cost of the two new LibiGel Phase III efficacy trials would be similar to the cost of the previous trials, approximately $15-$18 million each, or a combined $30-$36 million spread over 18 months. No assurance can be provided that these cost estimates will be correct or that we will be able to obtain the necessary working capital to fund the trials. In addition, no assurance can be provided that we will be able to design the two new efficacy trials to the FDA's satisfaction or to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. If we are not successful in this regard, our business may be harmed and we likely would disappoint our stockholders and may experience a decline in our stock price.

With respect to our LibiGel Phase III safety study, 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. We anticipate that the DMC will perform another unblinded review of safety data from the safety study during the third quarter of 2012. Currently, we anticipate that top-line safety data of the safety study on an unblinded basis will be available during the fourth quarter 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. No launch date for this product has been announced by Teva.

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

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therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines.

Elestrin was our first FDA approved product and now is one of our two FDA approved products. Jazz Pharmaceuticals, Inc. (which 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 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.

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., to fund our ongoing business operations and short-term liquidity needs.

As of June 30, 2012, we had $42.4 million of cash and cash equivalents and had outstanding $11,782,000 in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. In July 2012, we issued an aggregate of 1,784,070 shares of our common stock to two of the holders of our 3.125% convertible senior notes due May 1, 2013 in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. As a result of such exchange, we had $8,277,850 in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013 outstanding as of July 31, 2012. 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 the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, assuming we continue to fund our LibiGel Phase III clinical development program. Based on these assumptions, we expect our cash and cash equivalents as of June 30, 2012 to meet our liquidity requirements until approximately the third quarter of 2013. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

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We incurred expenses of $10.6 million on research and development activities during the six months ended June 30, 2012, which is a 59 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of our prior two LibiGel Phase III efficacy trials at the end of 2011. We anticipate that our research and development expenses for the remainder of 2012 will consist primarily of expenses associated with the continuation of the safety study, the primary analysis of the safety study and the planning for the two new LibiGel Phase III efficacy trials. We currently expect to spend approximately $1.7 million per month on research and development activities during the remainder of 2012, assuming we continue the LibiGel Phase III safety study, and do not in-license additional products and technologies requiring additional development.

Our general and administrative expenses for the six months ended June 30, 2012 increased six 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 may fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

We recognized a net loss for the three and six months ended June 30, 2012 of $7.3 million and $17.6 million, respectively, compared to a net loss of $15.0 million and $32.2 million for the three and six months ended June 30, 2011, respectively. These decreases were primarily a result of the conclusion of our prior two LibiGel Phase III efficacy trials at the end of 2011 and were offset in part by an increase in the non-cash 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 and six months ended June 30, 2012 of $0.36 and $0.89, respectively, compared to a net loss per share of $0.96 and $2.16 for the three and six months ended June 30, 2011, respectively. These decreases in net loss per share were the result of the significantly higher weighted average number of shares outstanding, partially offset by the lower net loss described above. We expect to continue to incur substantial and continuing losses for the foreseeable future.

Results of Operations

Three Months Ended June 30, 2012 Compared to Three Months Ended June 30, 2011

The following table sets forth our results of operations for the three months ended June 30, 2012 and 2011.

	Three Months Ended June 30,			
	2012	2011	$ Change	% Change
Revenue	$ 108,780	$ 81,003	27,777	34.3
Expenses				
Research and development	5,398,305	11,116,323	(5,718,018)	(51.4)
General and administrative	1,948,995	1,989,103	(40,108)	(2.0)
Other expense — Convertible note fair value adjustment	15,953	(1,753,000)	1,768,953	100.9
Other expense — Interest expense	(92,047)	(172,000)	(79,953)	(46.5)
Other income	—	13,000	(13,000)	(100.0)
Other income - Interest income	1,431	1,711	(280)	(16.4)
Net loss	$ (7,344,116)	$ (14,975,231)	7,631,115	(51.0)
Net loss per common share (basic and diluted)	$ (0.36)	$ (0.96)	0.60	(62.5)

	Three Months Ended June 30,			
	2012	2011	$ Change	% Change
Weighted average number of common shares and common equivalent shares outstanding	20,202,737	15,664,225	4,538,513	29.0

The only revenue recognized during the three months ended June 30, 2012 and 2011 consisted of royalty revenue from Jazz Pharmaceuticals 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 $108,780 during the three months ended June 30, 2012 and $81,003 during the three months ended June 30, 2011, is recorded within general and administrative expenses in our condensed statements of operations.

Research and development expenses for the three months ended June 30, 2012 decreased 51 percent compared to the three months ended June 30, 2011 primarily as a result of the completion of our prior two LibiGel Phase III efficacy trials at the end of 2011.

General and administrative expenses for the three months ended June 30, 2012 decreased two percent compared to the three months ended June 30, 2011 primarily as a result of a decrease in personnel-related costs, professional fees and other administrative expenses.

The convertible note fair value adjustment to decrease the recorded liability and corresponding expense was $15,953 for the three months ended June 30, 2012 compared to a fair value adjustment to increase the recorded liability and corresponding expense of $1.8 million for the three months ended June 30, 2011.

Interest expense was $92,047 and $172,000 for the three months ended June 30, 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 3.125% 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 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first quarter of 2012 in exchange for the issuance of 1,868,055 shares of our common stock.

Interest income decreased $280 for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 as a result of lower average interest rates during the current year period.

Six Months Ended June 30, 2012 Compared to Six Months Ended June 30, 2011

The following table sets forth our results of operations for the six months ended June 30, 2012 and 2011.

	Six Months Ended June 30,			
	2012	2011	$ Change	% Change
Revenue	$ 222,780	$ 138,003	84,777	61.4
Expenses				
Research and development	10,581,522	25,980,744	(15,399,222)	(59.3)
General and administrative	3,780,847	3,582,659	198,188	5.5
Other expense — Convertible note fair value adjustment	(3,194,385)	(2,392,000)	(802,385)	(33.5)

	Six Months Ended June 30,			
	2012	2011	$ Change	% Change
Other expense — Interest expense	(216,243)	(344,000)	(127,757)	(37.1)
Other income	—	13,000	(13,000)	(100.0)
Other income - Interest income	3,423	4,956	(1,533)	(30.9)
Net loss	$ (17,608,593)	$ (32,225,907)	(14,617,314)	(45.4)
Net loss per common share (basic and diluted)	$ (0.89)	$ (2.16)	(1.27)	(58.8)
Weighted average number of common shares and common equivalent shares outstanding	19,790,109	14,900,067	4,890,042	32.8

The only revenue recognized during the six months ended June 30, 2012 and 2011 consisted of royalty revenue from Jazz Pharmaceuticals 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 $222,780 during the six months ended June 30, 2012 and $138,003 during the six months ended June 30, 2011, is recorded within general and administrative expenses in our condensed statements of operations.

Research and development expenses for the six months ended June 30, 2012 decreased 59 percent compared to the six months ended June 30, 2011 primarily as a result of the completion of our prior two LibiGel Phase III efficacy trials at the end of 2011.

General and administrative expenses for the six months ended June 30, 2012 increased six percent compared to the six months ended June 30, 2011 primarily as a result of an increase in personnel-related costs, professional fees and other administrative expenses.

The fair value adjustment on our convertible senior notes for the six months ended June 30, 2012 was $3.2 million compared to $2.4 million for the six months ended June 30, 2011. The increase in the liability for the six months ended June 30, 2012 was 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 six months ended June 30, 2012 also included an adjustment of $648,855 to increase the recorded liability and corresponding expense of the then remaining $11.8 million in aggregate principal amount of our convertible senior notes due to an increase in the discount

rate in the current year period in comparison to the prior year period. The convertible fair value adjustment for the six months ended June 30, 2011 increased the recorded liability and corresponding expense by $2,392,000 and included the 2011 and 2013 Notes.

Interest expense was $216,243 and $344,000 for the six months ended June 30, 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 3.125% 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 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first quarter of 2012 in exchange for the issuance of 1,868,055 shares of our common stock.

Interest income decreased $1,533 for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 as a result of lower average interest rates during the current year period.

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Liquidity and Capital Resources

The following table highlights several items from our condensed balance sheets:

Balance Sheet Data	June 30, 2012	December 31, 2011
Cash and cash equivalents	$ 42,417,045	$ 57,225,234
Total current assets	42,929,685	58,026,381
Investments	3,413,762	3,405,807
Total assets	47,294,679	62,379,755
Convertible senior notes due 2013	10,477,635	17,336,760
Total liabilities	16,373,638	24,564,463
Total stockholders' equity	30,921,041	37,815,292

Liquidity

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $234.8 million as of June 30, 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.

As of June 30, 2012, we had $42.4 million of cash and cash equivalents and $11,782,000 in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013 (2013 Notes) outstanding. In July 2012, we issued an aggregate of 1,784,070 shares of our common stock to two of the holders of the 2013 Notes in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. As a result of such exchange, $8,277,850 in aggregate principal amount of the 2013 Notes were outstanding as of July 31, 2012. 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 the LibiGel Phase III safety study, and beginning in mid- 2013, the two new LibiGel Phase III efficacy trials, assuming we continue to fund our LibiGel Phase III safety study. Based on these assumptions, and after considering the July 2012 exchange of $3.5 million of the 2013 Notes into our common stock, we expect our cash and cash equivalents as of June 30, 2012 to meet our liquidity requirements until approximately the third quarter of 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 the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, and if we in-license additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to our products;
- 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.

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- 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-licenses;
- 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 (convertible senior notes) 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; 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.

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 a possible merger or 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. In February 2012, we issued an aggregate of 1,868,055 shares of our common stock to one of the holders of our 2013 Notes in exchange for the cancellation of $9,000,000 in aggregate principal amount of such notes, including accrued and unpaid interest, and in July 2012, we issued an aggregate of 1,784,070 shares of our common stock to two of the holders of our 2013 Notes in exchange for the cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of our common stock, the willingness of the note holders to sell, exchange or restructure their notes, our available cash and cash equivalents, our liquidity requirements, regulatory limitations, contractual

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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, together with an inability to raise additional financing when needed, may impair our ability to execute strategic alternatives or leave us without sufficient cash remaining for operations.

We are subject to pending purported class action and shareholder derivative litigation, which litigation is described in more detail in Note 8, "Commitments and Contingencies" to our unaudited condensed financial statements included in this report. 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 and execute certain strategic alternatives.

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 our LibiGel clinical development program, the future value of our company 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 reduce 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 $14.7 million for the six months ended June 30, 2012 compared to net cash used in operating activities of $24.4 million for the six months ended June 30, 2011. Net cash used in operating activities for the six months ended June 30, 2012 was primarily the result of the net loss for that period which was lower compared to the prior year period due to lower clinical trial related expenses primarily as a result of the completion of our prior two LibiGel Phase III efficacy trials at the end of 2011. Net cash used in operating activities for the six months ended June 30, 2011 was primarily the result of the net loss for that period which was higher compared to the prior year period due to higher clinical trial related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities.

Net cash used in investing activities was $71,261 for the six months ended June 30, 2012 compared to net cash used in investing activities of $542,919 for the six months ended June 30, 2011. Net cash used in investing activities for each of the six months ended June 30, 2012 and 2011 was due primarily to the purchase of fixed assets.

Net cash used in financing activities was $658 for the six months ended June 30, 2012 compared to net cash provided by financing activities of $23.9 million for the six months ended June 30, 2011. Net cash provided by financing activities for the six months ended June 30, 2011 was the result of our March 2011 registered direct offering, which resulted in net proceeds of $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 June 30, 2012. The Company has a significant purchase obligation relating to a gel packaging machine of $510,436. We also have several financial commitments, including our 2013 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

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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 June 30, 2012, except for the $12,504,150

reduction in the aggregate principal amount outstanding under the 2013 Notes as a result of the share exchanges in February 2012 and July 2012, as previously described.

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 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," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue," the negative of these words, other words and terms of similar meaning and the use of future dates. These forward-looking statements may be contained in the

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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 and conduct of our LibiGel Phase III clinical development program and the timing of certain events related thereto;
- 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 explore and evaluate various strategic alternatives with respect to our products and our company and the possible effect such strategic alternatives may have on our business, including in particular our LibiGel Phase III clinical development program;
- 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 and success of our LibiGel Phase III clinical development program;
- 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;

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- 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 acquire or invest in new businesses, products and technologies by way of a license, acquisition or merger transaction and the effect of such a transaction on our stockholders, 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 and receive an FDA SPA agreement and other applications for and obtain and maintain required regulatory approvals on a timely basis or at all;
- 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 or if 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 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;
- the risk of product liability lawsuits against us or our licensees;

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- 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 the risk factors described later in this report under the heading “Part II — Item 1A. Risk Factors.”

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 later in this report under the heading “Part II — 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 later in this report under the heading "Part II — Item 1A. Risk Factors." The risks and uncertainties described above and later in this report 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.

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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 June 30, 2012	2012	2013	2014	Total	Fair Value June 30, 2012
Total Cash Equivalents	$ 41,468,496	—	—	—	$ 41,468,496
Average Interest Rate	0.02%	—	—	—	—
Fixed Interest Rate 2013 Convertible Senior Notes	—	—	$ 11,782,000	$ 11,782,000	$ 10,477,635
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	

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.

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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 June 30, 2012 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

The following are significant factors known to us that could materially adversely affect our business, financial condition, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report:

Risks Related to Our Possible Pursuit of a Strategic Alternative

In light of the risks involved in initiating two new LibiGel Phase III efficacy trials and recent investor and market reaction to our decision to initiate these two new efficacy trials, we may decide to pursue a strategic alternative which may include seeking others to fund continued LibiGel development and/or a transaction involving a merger or sale of our company.

Our lead product in development is LibiGel for the treatment of FSD. In December 2011, we announced top-line results from our two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. In June 2012, we announced a plan to initiate two new LibiGel Phase III efficacy trials and to continue the LibiGel Phase III safety study.

We expect that any new LibiGel Phase III efficacy trials would include the same FDA-required efficacy endpoints as our prior LibiGel Phase III efficacy trials. We estimate that the cost of the two new efficacy trials would be similar to the cost of the previous trials, a total of approximately $30-$36 million spread over 18 months. No assurance can be provided that these cost estimates will be correct or that we will be able to obtain the necessary working capital to fund the trials. In addition, no assurance can be provided that we will be able to design the two new efficacy trials to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. If we are not successful in this regard, our business may be harmed and we likely would disappoint our stockholders and may experience a decline in our stock price.

We have monitored, and continue to monitor, investor and analyst reaction to our corporate strategy and decision to pursue two new LibiGel Phase III efficacy trials and continue our ongoing LibiGel Phase III safety study. We also have continued to review our strategic alternatives. In light of recent investor and market reaction to our decision to initiate two new LibiGel Phase III efficacy trials, and in light of the risk involved in the initiation of the two new efficacy trials and the various strategic alternatives that may be available to us, we believe that there is a reasonable likelihood that we may decide not to initiate the two new LibiGel Phase III efficacy trials and to seek collaborations with others to help fund further development through license or sale of LibiGel. If our board of directors determines that a strategic alternative involving the merger or sale of our company is in the best interests of our company and stockholders, we may pursue such strategic alternative, even if the pursuit of such strategic alternative results in a change in our current strategic direction with respect to LibiGel and one or more of our other products in development.

Our possible pursuit of a strategic alternative involving the merger or sale of our company involves risks to our stockholders.

As a part of our corporate strategy, we continue to seek and 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. Therefore, as a matter of course, from time to time, 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, with the goal of maximizing stockholder value.

If our board of directors determines that a strategic alternative involving the merger or sale of our company is in the best interests of our company and stockholders, we may pursue such strategic alternative, even if the pursuit of such strategic alternative results in a change in our current strategic direction with respect to LibiGel and one or more of our other products in development.

There can be no assurance that any strategic alternative we pursue will be completed. Any strategic transaction we complete could subject us and our stockholders to a number of risks, including:

- the value of the stock received in the transaction being illiquid or not increasing over time;
- our stockholders owning less than a majority ownership interest in the surviving entity;
- changes in our board of directors and management;
- changes in our business strategy and focus;
- difficulties associated with assimilating and integrating the business and operations of the two companies; and
- the inability of the surviving company to develop successfully any products and generate revenue sufficient to meet our objectives in undertaking the transaction.

If a strategic transaction is pursued but not ultimately completed, our stockholders may be subjected to a number of other risks, including:

- the diversion of managerial, financial and other resources from the development of our own proposed products and technologies;

- the loss of key personnel and business relationships;
- the potential disruption of our ongoing business; and
- the incurrence of non-recurring or other charges, which could be significant.

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Risks Related to Our Financial Condition and Future Capital Requirements

We have not generated significant revenues and do not expect to in the near future. We have a history of operating losses, expect continuing losses and may never become profitable.

Substantially all of our revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. In order to generate new and significant revenues, we must develop and commercialize successfully our own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully, or acquire additional new products that generate or have the potential to generate revenues. Because of the numerous risks and uncertainties associated with our and our strategic partners' product development programs and our ability to acquire additional new products, we are unable to predict when we will be able to generate significant revenue or become profitable, if at all. We incurred a net loss of $51.6 million for the year ended December 31, 2011 and a net loss of $17.6 million for the six months ended June 30, 2012. As of June 30, 2012, our accumulated deficit was $234.8 million. We expect to continue to incur substantial and continuing losses for the foreseeable future. These losses likely will increase if we continue to spend money on the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials. Even if our approved products, products in development or any additional new products we may acquire or in-license are introduced commercially, they may never achieve market acceptance and we may never generate sufficient revenues or receive sufficient license fees or royalties on our licensed products and technologies in order to achieve or sustain future profitability.

Because we have no source of significant recurring revenue, we must depend on financing or partnering to sustain our operations. We likely will need to raise substantial additional capital or enter into strategic partnering agreements to fund our operations and we may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

Developing products requires substantial amounts of capital. We estimate that the cost of the two new LibiGel Phase III efficacy trials will be approximately $15-$18 million each, or a combined $30-$36 million spread over 18 months. No assurance can be provided, however, that our cost estimates will be correct. It is possible that the two new LibiGel Phase III efficacy trials will cost more than we anticipate. The cost of the two new LibiGel Phase III efficacy trials is in addition to the cost of the ongoing LibiGel Phase III safety study, which currently incurs approximately $1.7 million per month. If we continue with the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, we likely will need to raise substantial additional capital or enter into strategic partnering agreements to fund our operations and we may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

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

- the progress, timing, cost and results of our clinical development programs, including in particular the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, and if we in-license additional new products that require further development;
- the cost, timing and outcome of regulatory actions with respect to our products;
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, and our

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efforts to evaluate various strategic alternatives available with respect to our products and our company.

- 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-licenses;
- 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 (convertible senior notes) 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; 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.

Our future capital requirements and projected expenditures are based upon numerous assumptions and subject to many uncertainties, and actual requirements and expenditures may differ significantly from our projections. To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. We likely will need to raise additional capital to fund our operations. As of June 30, 2012, we had $42.4 million of cash and cash equivalents. We do not have any existing credit facilities under which we may borrow funds. 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 the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials. As of July 31, 2012, we had $8,277,850 in principal amount of convertible senior notes outstanding that mature on May 1, 2013. Assuming we continue the LibiGel Phase III safety study, and beginning in mid-2013, the two new LibiGel Phase III efficacy trials, we expect our cash and cash equivalents as of June 30, 2012 to meet our liquidity requirements until approximately the third quarter of 2013. This estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier in order to create a "cash cushion" and take advantage of favorable financing conditions.

The December 2011 announcement of the results of our prior completed LibiGel Phase III efficacy trials has significantly depressed the trading price of our common stock and harmed our ability to

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raise additional capital. 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 our LibiGel Phase III clinical development program, the future value of our company and/or if economic and market conditions deteriorate. We have on file effective shelf registration statements that allow us to raise up to an aggregate of $118.6 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, under applicable SEC rules, if we have a public float of less than $75.0 million, we can only offer to sell under the registration statement up to one-third of our public float during any 12 month period. We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, or at all. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to delay or terminate our Phase III clinical development program for LibiGel or otherwise make changes to our operations to reduce 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., our GVAX cancer vaccines, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights we have under our existing license agreements or decide or 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.

Raising additional funds by issuing additional equity securities may cause dilution to our existing stockholders, raising additional funds by issuing additional debt financing may restrict our operations and raising additional funds through licensing arrangements may require us to relinquish proprietary rights.

If we raise additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of our stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. In addition, the issuance of any equity securities could be at a discount to the market price.

If we incur additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on the ability of us to create liens, pay dividends, redeem our stock or make investments. There is no assurance that any equity or debt financing transaction will be available on terms acceptable to us, or at all.

As an alternative to raising additional financing by issuing additional equity or debt securities, 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 a possible sale or merger of our company. If we raise additional funds through licensing arrangements, we may be required to relinquish greater or all rights to our products at an earlier stage of development or on less favorable terms than we otherwise would choose.

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We have substantial indebtedness, in the form of convertible senior notes, which notes we may not be able to pay when they become due and payable on May 1, 2013, or earlier if we experience a "fundamental change" or an "event of default" under the indenture governing such notes.

As of July 31, 2012, we had $8,277,850 in aggregate principal amount of convertible senior notes outstanding. The annual interest payment on these notes is approximately $259,000. At maturity, on May 1, 2013, the entire then remaining aggregate outstanding principal amount of our convertible senior notes will become due and payable. In addition, upon the occurrence of a "fundamental change", holders of our convertible senior notes may require us to purchase their notes prior to the May 1, 2013 maturity date. A fundamental change includes a significant change in our ownership; the first day the majority of our board of directors does not consist of continuing directors; the consummation of certain recapitalizations, reclassifications, or changes of common stock, share exchanges or consolidations or mergers; or the termination of trading of our common stock (which will be deemed to have occurred if our common stock is neither listed for trading on a United States national securities exchange nor any United States system of automated dissemination of quotations of securities prices or traded in over-the-counter securities markets). Additionally, the aggregate principal amount of the outstanding convertible senior notes will become due and payable upon an uncured or unwaived event of default. We do not have any significant source of revenues; and thus, although we intend to seek additional financing to support our operations and pay the aggregate outstanding principal amount of our convertible senior notes,

it is possible that we may not have sufficient funds to pay the aggregate principal amount of our then outstanding convertible senior notes when they mature on May 1, 2013, or become due and payable earlier if we were to experience a "fundamental change" or an "event of default" under the indenture governing such notes.

The indentures governing our convertible senior notes contains covenants, which if not complied with, could result in an event of default and the acceleration of all amounts due under the notes.

The indenture governing our convertible senior notes contains covenants, such as the requirement to pay accrued interest on May 1 and November 1 of each year, the requirement to repurchase the notes upon a "fundamental change," as defined in the indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If we do not comply with the covenants in the indenture, an event of default could occur and all amounts due under the notes could become immediately due and payable. Upon the occurrence of an event of default under the indenture, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Although it is possible we could negotiate a waiver with the trustee and the holders of the notes, such a waiver likely would involve significant costs. It also is possible that we could refinance or restructure our obligations under the notes; however, such a refinancing or restructuring also likely would involve significant costs and likely would result in higher interest rates than the current 3.125% annual interest rate on the notes.

Future purchases, exchanges or restructurings of our outstanding convertible senior notes 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.

In February 2012, we entered into privately-negotiated securities exchange agreements with one of the holders of our convertible senior notes pursuant to which we issued an aggregate of 1,868,055 shares of our common stock, as adjusted to reflect our one-for-six reverse stock split effected on June 1, 2012, to the note holder in exchange for the cancellation of an aggregate of $9,000,000 principal amount of our convertible senior notes, including accrued and unpaid interest, and in July 2012, we entered into a privately-negotiated securities exchange agreement with two of the holders of our convertible senior notes

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pursuant to which we issued an aggregate of 1,784,070 shares of our common stock to the note holder in exchange for the cancellation of an aggregate of $3,504,150 principal amount of our convertible senior notes and accrued and unpaid interest of $20,686. As a result of these exchanges, an aggregate of $8,277,850 principal amount of the convertible senior notes remained outstanding as of July 31, 2012. From time-to-time, we again 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, the trading price and volume of our common stock, the willingness of the note holders to sell, exchange or restructure their notes, our available cash and cash equivalents, our liquidity requirements, regulatory limitations, 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.

We are subject to pending purported securities class action and shareholder derivative litigation, which 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 and execute certain strategic alternatives.

As described in more detail elsewhere in this report, we are subject to pending purported securities class action and shareholder derivative 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 BioSante and our President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of our 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 our 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 plaintiff seeks to represent a class of persons who purchased our 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. We believe the action is without merit and intend to defend the action vigorously.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of our 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 our directors as defendants and our company as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits are generally related to the same events that are the subject of the class action litigation described above. The complaints allege 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 complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in our corporate governance and internal control procedures. Additional lawsuits may be filed by other purported stockholders of our company.

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These lawsuits are in their early stages; and, therefore, we are 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 our operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on our operations, including our financial condition, results of operations, or cash flows. In additions, these

lawsuits 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 or execute certain strategic alternatives.

If we fail to meet continued listing standards of The NASDAQ Global Market, our common stock may be delisted which could have a material adverse effect on the liquidity of our common stock.

In order for our securities to be eligible for continued listing on The NASDAQ Global Market, we must remain in compliance with certain listing standards, including a $1.00 minimum closing bid price per share requirement, a $50 million market capitalization and a $15 million public float requirement or a $12 million minimum stockholders' equity requirement, and certain corporate governance standards. If our common stock were to be delisted from The NASDAQ Global Market, we could apply to list our common stock on The NASDAQ Capital Market or our common stock could be traded in the over-the-counter market on an electronic bulletin board established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board.

While we intend to maintain our listing on The NASDAQ Global Market, there can be no assurance that we will be able to keep our listing on The NASDAQ Global Market or transfer our listing to The NASDAQ Capital Market. Stocks trading on The NASDAQ Capital Market rather than The NASDAQ Global Market tend to be more volatile and less liquid as trading volumes are generally significantly lower on The NASDAQ Capital Market than The NASDAQ Global Market. Furthermore, if we fail to meet all applicable NASDAQ Stock Market requirements and NASDAQ determines to delist our common stock, the delisting could decrease substantially trading in our common stock, affect adversely the market liquidity of our common stock, decrease the trading price of our common stock, increase the volatility of our stock price, decrease analyst coverage of our common stock, decrease investor demand and information available concerning trading prices and volume of our common stock, make it more difficult for investors to buy or sell shares of our common stock and harm our ability to obtain additional financing for the continuation of our operations and could result in the loss of confidence by investors.

In addition, if our common stock were to be delisted from The NASDAQ Stock Market, and our trading price remained below $5.00 per share, trading in our common stock also might become subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange that has a market price of less than $5.00 per share, subject to certain exceptions). Many brokerage firms are reluctant to recommend low-priced stocks to their clients. Moreover, various regulations and policies restrict the ability of stockholders to borrow against or "margin" low-priced stocks, and declines in the stock price below certain levels may trigger unexpected margin calls. Additionally, because brokers' commissions on low-priced stocks generally represent a higher percentage of the stock price than commissions on higher priced stocks, the current price of our common stock can result in an individual stockholder paying transaction costs that represent a higher percentage of total share value than would be the case if the price of our common stock were higher. This factor also may limit the willingness of institutions to purchase our common stock. Finally, the additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from facilitating trades in our common stock, which could severely limit the market liquidity of the stock and the ability of investors to trade our common stock.

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Risks Related to Our Business

Our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that the two new LibiGel Phase III efficacy trials, which we announced in June 2012, will not meet the co-primary and secondary endpoints, which could harm our business and further disappoint our stockholders and cause our stock price to decrease.

Our lead near term product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved product. In June 2012, we announced a plan to initiate two new LibiGel Phase III efficacy trials. This decision was based on an extensive analysis of previous efficacy data, consultation with key opinion leaders (KOLs) in FSD, testosterone therapy and placebo effects, as well as a meeting with the FDA. The protocol for the two new efficacy trials is in development. We intend to apply for an FDA Special Protocol Assessment (SPA) agreement prior to initiating the two new efficacy trials. Currently, it is expected that the efficacy trials will include the same FDA-required efficacy endpoints as prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire.

The initiation of the two new LibiGel Phase III efficacy trials involves risk, especially since our prior LibiGel Phase III efficacy trials failed to meet the co-primary or secondary endpoints. Although the results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD, the placebo response in the two efficacy trials was greater than expected; and therefore, LibiGel's results were not shown to be statistically different from placebo. No assurance can be provided that we will be able to design the two new LibiGel Phase III efficacy trials to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. In addition, we can provide no assurance that we will be able to obtain an FDA SPA agreement for such trials or that we will initiate or complete the trials on a timely basis, or ever. Any of these possible results could harm our business and further disappoint our stockholders and cause our stock price to decrease.

Although our male testosterone gel is approved by the FDA, we are uncertain as to when Teva will begin to market and sell our male testosterone gel and thus when or if we would begin to receive royalties from such sales in light of Teva's settlement agreement with a subsidiary of Abbott Laboratories.

Our male testosterone gel initially was developed by us, and then licensed by us to Teva for late stage clinical development. Teva submitted a New Drug Application, which NDA 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. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. In light of the settlement agreement, we are uncertain as to when or if Teva will begin to market and sell our male testosterone gel and thus when or if we would begin to receive royalties from such sales.

Several of our products are in the human clinical development stages and, depending on the product, likely will not be approved by regulatory authorities or introduced commercially for at least several years and likely more, if at all.

Several of our products are in the human clinical development stages and will require further development, preclinical and clinical testing and investment prior to obtaining required regulatory approvals and commercialization in the United States and abroad. Other than Elestrin and our male

testosterone gel, none of our products has been approved by the FDA or other regulatory authorities; and

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accordingly, none of our products have been introduced commercially and most are not expected to be for several years and likely more, if at all. Some of our products are not in active development. We cannot assure you that any of our products in human clinical development will:

- be developed successfully;
- prove to be safe and effective in clinical studies;
- meet applicable regulatory standards or obtain required regulatory approvals;
- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs;
- obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or
- be marketed successfully or achieve market acceptance by physicians and patients.

If we fail to obtain regulatory approval to manufacture commercially or sell any of our future products, or if approval is delayed or withdrawn, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each product or drug that we intend to commercialize. The FDA approval process typically is very lengthy and expensive, and approval never is certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development eventually are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, the credibility of our management, the value of our company and our operating results and liquidity would be affected adversely. Even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review and we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or our manufacture of the product subsequently are discovered. The FDA also may require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition.

To obtain regulatory approval to market many of our products, costly and lengthy human clinical trials are required, and the results of the studies and trials are highly uncertain. As part of the FDA approval process, we must conduct, at our own expense or the expense of current or potential licensees or other entities, clinical trials in human subjects on each of our products. We expect the number of human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. Depending on the stage of development, may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

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After we have conducted pre-clinical studies in animals, if required, we must demonstrate that our products are safe and effective for use in the target human population in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. As an example, our prior two pivotal LibiGel Phase III efficacy trials did not meet the co-primary endpoints of an increase in satisfying sexual events and an increase in desire and the secondary endpoint of a decrease in distress compared to placebo even though treatment with LibiGel in our Phase II clinical trial significantly increased satisfying sexual events compared to placebo. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent us from submitting for regulatory approval of our products.

Additional factors that can cause delay or termination of our human clinical trials include:

- slow subject enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- new or additional trials or studies that are designed differently in order to increase the chances of demonstrating efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and

· lack of funding.

Delays in our clinical trials could allow our competitors additional time to develop or market competing products and thus can be extremely costly in terms of lost sales opportunities and increased clinical trial costs.

The process for obtaining FDA approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

Our products in development will require the submission and approval of an NDA in order to obtain required approval by the FDA to commercially market the product. The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

· the information submitted may be insufficient to demonstrate that a product is safe and effective;

· the FDA might not approve the processes or facilities of a company, or those of its vendors, that will be used for the commercial manufacture of a product; or

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· the FDA's interpretation of the nonclinical, clinical or manufacturing data provided in an NDA may differ from a company's interpretation of such data.

If the FDA determines that the clinical studies submitted for a product candidate in support of an NDA are not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the FDA does not agree with a company's interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical studies required to support an NDA could affect negatively a company's ability to obtain marketing authorization for a product and would have a material adverse effect on a company's business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during development or the review period.

We may not achieve projected goals and objectives in the time periods that we anticipate or announce publicly, which could have an adverse effect on our business and could cause the price of our common stock to decline.

We set goals and objectives for, and make public statements regarding, the timing of certain accomplishments and milestones regarding our business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the submission of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our current clinical studies, the amount of time, effort and resources committed to our programs by us and our current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving our products in development will advance or be completed in the time periods that we or our strategic partners announce or expect, that we or our current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future strategic partners will be able to adhere to our current schedule for the achievement of key milestones under any of our development programs. If we or any of our strategic partners fail to achieve one or more of these milestones as planned, our business could be affected adversely and materially and the price of our common stock could decline. As an example, prior to our receipt of the results from our prior two pivotal LibiGel Phase III efficacy trials in December 2011, our objective with respect to LibiGel was to submit an NDA in 2012. This is no longer a realistic objective of ours in light of the fact that unexpectedly our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints.

We also disclose from time-to-time projected financial information, including our cash position and anticipated cash burn rate and other expenditures, for future periods. These financial projections are based on management's current expectations and may not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

If the market opportunities for our products are smaller than we anticipate, then our future revenues and business may be affected adversely.

From time-to-time, we disclose estimated market opportunity data for our products and products in development. Although we believe we have a reasonable basis for our market opportunity estimates, our estimates may prove to be incorrect. If the market opportunities for our products are smaller than we anticipate, our anticipated revenues from the sales or licensure of such products will be lower than we anticipate.

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Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could affect adversely the market for our hormone therapy products and the trading price of our common stock.

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal

women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. Our products differ from the products used in the WHI study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of our products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies, although the market now seems to have stabilized. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to our products, also could affect adversely our business and likely decrease our stock price.

If clinical studies for our products are terminated, prolonged or delayed, it may be difficult for us to find a strategic partner to assist us in the development and commercialization of our non-partnered products or commercialize such products on a timely basis, which would require us to incur additional costs and delay or prevent our receipt of any revenue from potential product sales or licenses.

We may encounter problems with our completed, ongoing or planned clinical studies for our products that may cause us or the FDA to delay, suspend or terminate those studies or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or cause us to suspend or terminate our ongoing and planned clinical studies for our products and negatively impact our ability to obtain regulatory approval or enter into strategic partnerships for, or market or sell, a particular product:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical studies;

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- delay in developing, or our inability to obtain, a clinical dosage form, insufficient supply or deficient quality of our products or other materials necessary to conduct our clinical studies;
- negative or inconclusive results from clinical studies, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;
- serious and/or unexpected product-related side effects experienced by subjects in our clinical studies; or
- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which our clinical studies are conducted all have the power to stop or recommend stopping our clinical studies prior to completion. Our clinical studies for our products in development may not begin as planned, may need to be amended, suspended or terminated and may not be completed on schedule, if at all. This is particularly true if we no longer believe we can obtain regulatory approval for a particular product or if we no longer have the financial resources to dedicate to a clinical development program for a particular product.

We rely on a few third parties to assist us in certain aspects of our clinical studies. If these third parties do not perform as required contractually or expected, our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.

We rely on a few third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist us in certain aspect of our clinical studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on these few third parties does not relieve us of these responsibilities. If the third parties assisting us with certain aspects of our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, our ability to collect damages may be limited contractually.

Our products will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals, and the sale of any future products could be suspended.

Even if we receive regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of our approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy, or REMS. If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the

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drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with any future products, suppliers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

We may enter into additional strategic relationships with third parties to help develop and commercialize our products in development. If we do not enter into such relationships, we will need to undertake development and commercialization efforts on our own, which would be costly and could delay our ability to obtain required approvals for and commercialize our future products.

A key element of our business strategy is our intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have a strategic relationship with Jazz Pharmaceuticals with respect to Elestrin, with Teva with respect to our male testosterone gel, with Pantarhei Science with respect to The Pill Plus and with several third parties with respect to our GVAX cancer vaccines. We currently do not have a strategic partner for LibiGel.

We may enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, our products in development, including in particular LibiGel, and any additional new products we may acquire or in-license. We face significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic relationships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such

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relationships. If we are unable to negotiate additional strategic relationships for our products, we may be forced to curtail the development of a particular product, reduce, delay or terminate its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we would then bear all the risk related to the development and commercialization of that product. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our products in development and any additional new products we may acquire or in-license if they receive regulatory approvals to market and generate product revenue.

If we are unable to partner with a third party and obtain assistance for the potential commercialization of our products, if approved for commercial sale, we would need to establish our own sales and marketing capabilities, which involves risk.

We do not have an internal sales and marketing organization and we have limited experience in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, revenues from sales of the product or the profitability of these product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

Although our preferred alternative would be to engage a pharmaceutical or other healthcare company with an existing sales and marketing organization and distribution systems to sell, market and distribute our products, if approved for commercial sale, if we are unable to engage such a sales and marketing partner, we may need to establish our own specialty sales force. Factors that may inhibit our efforts to commercialize any future products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales and marketing capabilities depends on the progress towards commercialization of our products and because of the numerous risks and uncertainties involved with establishing our own sales and marketing capabilities, we are unable to predict when, if ever, we will establish our own sales and marketing capabilities. If we are not able to partner with additional third parties and are unsuccessful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would harm our business and financial condition.

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Our current strategic relationships and any future additional strategic relationships we may enter into involve risks with respect to the development and commercialization of our products.

A key element of our business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have strategic relationships with Jazz Pharmaceuticals with respect to Elestrin, with Teva with respect to our male testosterone gel and with Pantarhei Science with respect to The Pill Plus and several third parties with respect to our GVAX cancer vaccines.

Our current strategic relationships and any future additional strategic relationships we may enter into involve a number of risks, including:

- business combinations or significant changes in a strategic partner's business strategy may affect adversely a strategic partner's willingness or ability to complete its obligations under any arrangement;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our partnered products;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;
- strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to delay research and development programs or commercialization of a partnered product;
- strategic partners may not commit adequate resources to the marketing and distribution of our partnered products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our partnered products or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not maintain properly or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate or delay the arrangement or allow it to expire, which would delay the development or commercialization of the partnered product and may increase the cost of developing or commercializing the partnered product.

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Although we maintain the right to receive sales-based milestones of up to $140 million, our ability to receive these milestones is dependent upon Jazz Pharmaceuticals' ability to market and sell Elestrin, and based on Elestrin sales to date, we believe it is unlikely that we will receive any sales-based milestone payments from Jazz Pharmaceuticals in the foreseeable future, or at all.

Jazz Pharmaceuticals, Inc. (which acquired Azur) 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 continue to recognize certain royalty revenue from sales of Elestrin; however, such revenue is offset by our corresponding obligation to pay royalties to Antares, from whom we licensed the technology underlying our Elestrin product. 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. We cannot assure you that Jazz Pharmaceuticals will be successful in marketing Elestrin, Elestrin will be accepted widely in the marketplace or that Jazz Pharmaceuticals will remain focused on the commercialization of Elestrin, especially if Jazz Pharmaceuticals does not experience significant Elestrin sales. Based on current sales of Elestrin, we believe it is unlikely that we will receive any sales-based milestone payments from Jazz Pharmaceuticals in the near term, if at all.

If our products in development receive FDA approval and are introduced commercially, they may not achieve expected levels of market acceptance, which could harm our business, financial position and operating results and could cause the market value of our common stock to decline.

The commercial success of our products in development, if they receive the required FDA or other regulatory approvals, and the commercial success of our male testosterone gel, which is FDA approved, are dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products, if approved for commercial sale with respect to our products in development, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials with respect to our products in development;
- the existence, prevalence and severity of any side effects;
- the availability of competitive or alternative treatments and potential or perceived advantages or disadvantages compared to competitive or alternative treatments;
- the timing of market entry relative to competitive treatments;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our products by third-party payors and governmental and other payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Some of these factors are not within our control, especially if we have transferred all of the marketing rights associated with the product, as we have with the U.S. marketing rights to Elestrin to Jazz

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Pharmaceuticals, and the U.S. development and marketing rights to our male testosterone gel to Teva. Our products may not achieve expected levels of market acceptance.

Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by our industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the use, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and in the future may result, in the discontinuance of product marketing. These situations, should they occur, could harm our business, financial position and results of operations, and the market value of our common stock could decline.

Even if we or our strategic partners successfully develop, obtain required regulatory approvals and commercialize any of our products under development, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could affect adversely the commercial success of our products.

Our ability to collect significant revenues from sales of our products, if approved and commercialized, may depend on our ability, and the ability of any current or potential future strategic partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies;
- government health administration authorities; and
- other healthcare-related organizations.

Third party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any of our strategic partners may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our products, which could affect adversely our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA. This legislation may have far reaching consequences for life science companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who

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currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for our products, if approved, is substantially less that we expect in the future, our business could be affected materially and adversely.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

We and our licensees depend on third-party manufacturers to produce our products and if these third parties do not manufacture successfully these products our business would be harmed.

We have no manufacturing experience or manufacturing capabilities for the production of our products for our clinical studies or, if approved, commercial sale. In order to continue to develop products, apply for regulatory approvals and commercialize our products following approval, if obtained, we or our licensees must be able to manufacture or contract with third parties to manufacture our products in clinical and commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our products may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing our products may make them prohibitively expensive. If supplies of any of our products become unavailable on a timely basis or at all or are contaminated or otherwise lost, our clinical studies could be seriously delayed or compromised, and with respect to our approved products, our future revenue from royalties and milestone payments could be affected adversely.

To the extent that we or our licensees enter into manufacturing arrangements with third parties, we and such licensees will depend upon these third parties to perform our obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

Our existing and future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. If a natural disaster, business failure, strike or other difficulty occurs, we may be unable to replace these contract manufacturers in a timely or cost-effective manner and the production of our products would be interrupted, resulting in delays and additional costs. Switching manufacturers or manufacturing sites would be difficult and time-consuming because the number of potential manufacturers is limited. In addition, before a product from any replacement manufacturer or manufacturing site can be commercialized, the FDA must approve that site. This approval would require regulatory testing and compliance inspections. A new manufacturer or manufacturing site also would have to be educated in, or develop substantially equivalent processes for, production of our products. It may be difficult or impossible to transfer certain elements of a manufacturing process to a new

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manufacturer or for us to find a replacement manufacturer on acceptable terms quickly, or at all, either of which would delay or prevent our ability to develop and commercialize our products.

If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be affected adversely in a number of ways, including:

- we and our strategic partners may be unable to initiate or continue clinical studies of our products that are under development;
- we and our strategic partners may be delayed in submitting applications for regulatory approvals for our products that are under development; and
- we and our strategic partners may be unable to meet commercial demands for any approved products.

In addition, if a third-party manufacturer fails to perform as agreed, our ability to collect damages may be contractually limited.

If we choose to acquire or invest in new businesses, products or technologies by way of a license, purchase or merger transaction, these transactions could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

We actively continue to seek to acquire, invest in or merge with other businesses, products or technologies. Such acquisitions, investments or mergers may take the form of a license, purchase or merger transaction. Acquisitions, investments and such transactions involve numerous risks, including:

- the inability to complete the transaction;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired or merged entities, products or technologies;
- difficulties in operating the acquired or merged business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;

- potential loss of key employees;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any such transactions may result in one or more of the following:

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;

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- the incurrence of additional debt;
- the assumption of significant liabilities;
- increased operating costs and losses;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges.

Any of these factors could materially harm our business, operating results, financial condition and stock price.

If we reallocate our resources to other products and technologies in our current product portfolio or any additional new products and technologies that we may acquire or in-license, we may not be successful in developing such products and technologies and we will be subject to all the risks and uncertainties associated with research and development of products and technologies.

We continue to explore the possibility of reallocating our resources towards other products and technologies in our current product portfolio or any additional new products and technologies that we may acquire or in-license. We cannot guarantee that any such allocation would result in the identification and successful development of one or more approved and commercially viable products. The development of products and technologies is subject to a number of risks and uncertainties, including:

- the time, costs and uncertainty associated with the clinical testing required to demonstrate the safety and effectiveness of our products and obtain regulatory approvals;
- the ability to raise sufficient funds to fund the research and development of our products;
- the ability to find third party strategic partners to assist or share in the costs of product development, and potential dependence on such strategic partners, to the extent we rely on them for future sales, marketing or distribution;
- the ability to protect the intellectual property rights associated with our products;
- litigation;
- competition;
- ability to comply with ongoing regulatory requirements;
- government restrictions on the pricing and profitability of products in the United States and elsewhere; and
- the extent to which third-party payers, including government agencies, private health care insurers and other health care payers, such as health maintenance organizations, and self-insured employee plans, will cover and pay for newly approved therapies.

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We have very limited staffing and are dependent upon key employees and the limited use of independent contractors, the loss of some of which could affect adversely our operations.

Our success is dependent upon the efforts of a relatively small management team and staff. We also engage independent contractors from time-to-time on an as needed, project by project, basis. In January 2012, in order to reduce our operating expenses, we terminated several of our independent contractor arrangements and reduced our total employee headcount. Such reductions in force, combined with our future business prospects and financial condition, put us at risk of losing key personnel who we will need going forward to implement our business strategies. We have no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. We have employment arrangements in place with our executive and

other officers, but none of these executive and other officers is bound legally to remain employed with us for any specific term. We do not have key man life insurance policies covering our executive and other officers or any of our other employees. If key individuals leave our company, our business could be affected adversely if suitable replacement personnel are not recruited quickly. There is competition for qualified personnel in the biotechnology and biopharmaceutical industry in the suburban Chicago, Illinois area in all functional areas, which makes it difficult to retain and attract the qualified personnel necessary for the development and growth of our business. Our financial condition and recent reduction in force and expense reductions may make it difficult for us to retain current personnel and attract qualified employees and independent contractors in the future.

If plaintiffs bring product liability lawsuits against us, we may incur substantial liabilities and may be required to delay development or limit commercialization of any of our products approved for commercial sale.

We face an inherent risk of product liability as a result of the clinical testing of our products in development and the commercial sale of our products that have been or will be approved for commercial sale. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for our products, injury to our reputation, withdrawal of clinical studies, costs to defend litigation, substantial monetary awards to clinical study participants or patients, loss of revenue and the inability to commercialize any products that we develop.

We currently maintain limited product liability insurance. We may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, our insurance coverage. Our insurance does not cover third parties' negligence or malpractice, and our clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct our clinical studies or otherwise carry out our business, we may have to assume liabilities contractually for which we may not be insured. If we are unable to look to our own or a third party's insurance to pay claims against us, we may have to pay any arising costs and damages ourselves, which may be substantial. Even if we ultimately are successful in product liability litigation, the litigation likely would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which likely would impair our ability to generate sales of the affected product and our other products. Moreover, product recalls may be issued at our discretion or at the direction of the FDA, other governmental agencies or other companies having regulatory control for our product sales. Product recalls generally are expensive and often have an adverse effect on the reputation of the products being recalled and of the product's developer or manufacturer.

We may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify us against damages

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and other liabilities arising from their activities do not fulfill their obligations, then we may be held responsible for those damages and other liabilities.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to assess the effectiveness of our internal control over financial reporting and to provide a report by our registered independent public accounting firm addressing the effectiveness of our internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If we are unable to assert that our internal control over financial reporting is effective (or if our registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or they issue an adverse opinion on our internal control over financial reporting), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal control over financial reporting could have an adverse effect on our stock price.

Our business is subject to increasingly complex corporate governance, public disclosure and accounting requirements that could affect adversely our business and financial results.

We are subject to changing rules and regulations of federal and state governments as well as the stock exchange on which our common stock is listed. These entities, including the SEC and The NASDAQ Stock Market, continue to issue new requirements and regulations in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC and NASDAQ to adopt additional rules and regulations in these areas. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from our other business activities.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our principal executive office and our only business location is in Lincolnshire, Illinois, which is a suburb of Chicago. Natural disasters or other catastrophic events could disrupt our operations or those of our strategic partners, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors' insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results, and could delay our efforts to identify and execute any strategic opportunities.

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Risks Related to Our Industry

Because our industry is very competitive, we may not succeed in bringing certain of our products to market and any products we or our strategic partners introduce commercially may not be successful.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our potential competitors, some of whom are our strategic partners, will not succeed in developing similar technologies and products more rapidly than we do, commercially introducing such technologies and products to the marketplace prior to us, or that these competing technologies and products will not be more effective or successful than any of those that we currently are developing or will develop.

Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply, we could experience material adverse effects on our business, operating results and financial position, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration (DEA), and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act (FDCA), the Controlled Substances Act of 1970 (CSA) and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals.

In addition to compliance with "current good manufacturing practice" regulations, commonly referred to as "cGMP" regulations and requirements, drug manufacturers must register each manufacturing facility with the FDA. Manufacturers and distributors of prescription drug products are also required to be registered in the states where they are located and in certain states that require registration by out-of-state manufacturers and distributors. Manufacturers also must be registered with the DEA and similar applicable state and local regulatory authorities if they handle controlled substances, and also must comply with other applicable DEA requirements.

Despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

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The trend towards consolidation in the pharmaceutical and biotechnology industries may affect us adversely.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend also may result in fewer potential strategic partners or licensees for our products and technology. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or strategic partners as a result of such consolidation. This trend may affect adversely our ability to enter into strategic arrangements for the development and commercialization of our products, and as a result may harm our business.

Risks Related to Our Intellectual Property

We license rights to the technology underlying LibiGel and many of our other products and technologies from third parties. The loss of these rights, including in particular, our rights underlying LibiGel, could have an adverse effect on our business and future prospects and could cause the market value of our common stock to decline.

We license rights to certain of the technology underlying certain of our gel products, including LibiGel, but not our male testosterone gel, from Antares Pharma, Inc., our GVAX cancer vaccines from Johns Hopkins University and The Whitehead Institute for Biomedical Research, and The Pill Plus from Wake Forest University Health Sciences. We may lose our rights to these technologies if we breach our obligations under the license agreements. Although we intend to use commercially reasonable efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements, the other party to these agreements under certain circumstances may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owed at the time of termination.

We have licensed some of our products to third parties and any breach by these parties of their obligations under these license agreements or a termination of these license agreements by these parties could affect adversely the development and marketing of our licensed products. In addition, these third parties also may compete with us with respect to some of our products.

We have licensed some of our products to third parties, including Jazz Pharmaceuticals, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and Valeant Pharmaceuticals. All of these parties, except for Jazz Pharmaceuticals, have agreed to be responsible for continued development, regulatory filings and all have agreed to manufacturing and marketing associated with the products. In addition, in the future we may enter into additional similar license agreements. Our products that we have licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. Our current and future licensees may have different and, sometimes, competing priorities. We cannot assure you that our strategic partners or any future third party to whom we may license our products will remain focused on the development and commercialization of our partnered products or will not otherwise breach the terms of our agreements with them, especially since these third parties also may compete with us with respect to some of our products. Any breach of our agreements by our strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the

partnered products in these agreements if we are unable to license the products to another party on substantially the same or better terms or continue the development and future

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commercialization of the products ourselves. As an example, our male testosterone gel initially was developed by us, and then licensed to Teva for late stage clinical development and commercialization. Teva submitted an NDA for our male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva's NDA submission, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. In light of the settlement agreement, we are uncertain as to when or if Teva will begin to market and sell our male testosterone gel and thus when or if we would begin to receive royalties from such sales.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. We rely on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our proprietary technology. These legal means, however, afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Where appropriate, we seek patent protection for certain aspects of our technology. Our owned and licensed patents and patent applications, however, may not ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our licensor's patent applications will result in issued patents.
- Competitors may interfere with our patents and patent process in a variety of ways. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Competitors also may have our patents reexamined by demonstrating to the patent examiner that the invention was not original or novel or was obvious.
- We are engaged in the process of developing products. Even if we receive a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around our patents. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Though patent term extension may be possible for particular products, any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our products.
- Litigation also may be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may affect adversely our operating results. Such litigation also may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose protection on products covered by those patents.

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- We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

We also rely on unpatented proprietary technology. It is unclear whether efforts to secure our trade secrets will provide useful protection. We rely on the use of registered trademarks with respect to the brand names of some of our products. We also rely on common law trademark protection for some brand names, which are not protected to the same extent as our rights in the use of our registered trademarks. We cannot assure you that we will be able to meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop and obtain patent protection substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with our employees and consultants. Such agreements, however, may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to increased competition, inhibit our ability to find strategic partners and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which we license from Antares Pharma are scheduled to expire in June 2022 and the new U.S. patent covering the "method of use" of LibiGel for treating FSD and HSDD will expire in December 2028. Although we have filed additional U.S. patent applications covering LibiGel, we can provide no assurance that such applications will be granted and that the patents will issue. In addition to patents, we may receive three years of marketing

exclusivity for LibiGel under the Hatch-Waxman Act and an additional six months of pediatric exclusivity, if we decide to pursue regulatory approval for LibiGel. Depending upon if and when we receive regulatory approval for LibiGel and our other products in development and the then expiration dates of the patents underlying LibiGel and such other products, we may not have sufficient time to recover our development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

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

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

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- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development delays;
- require us to develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our potential gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results. With respect to products which we have licensed to others, our licensees may be responsible for the defense of any patent infringement claims, which would result in our dependence upon them to defend our intellectual property rights.

Risks Related to Our Common Stock

The price of our common stock has been volatile, and your investment in our common stock or convertible senior notes could decline in value.

The price of our common stock has fluctuated in the past and it is likely that the price of our common stock will continue to fluctuate in the future. Since January 1, 2011 through June 30, 2012, the sale price of our common stock ranged from $2.01 per share to $24.12 per share. These prices reflect the one-for-six reverse stock split of our common stock that was effective at the close of business on June 1, 2012. The securities of small capitalization, biopharmaceutical companies, including our company, from time to time experience significant price fluctuations, often unrelated to the operating performance of these companies. In addition, as our convertible senior notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of the notes. Interest rate fluctuations also can affect the price of our convertible senior notes. In particular, the market price of our common stock and our convertible senior notes may fluctuate significantly due to a variety of factors, including:

- general stock market and general economic conditions in the United States and abroad, not directly related to our company or our business;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products in development or our competitors' products;
- actual or anticipated results of our clinical studies or those of our competitors;
- changes in anticipated or actual timing of our development programs, including delays or cancellations of clinical studies for our products;
- announcements of technological innovations or new products by us or our competitors;

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- announcements by licensors or licensees of our technology;
- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- developments concerning our efforts to identify and implement strategic opportunities and the terms and timing of any resulting transactions;
- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- our cash and cash equivalents and our need and ability to obtain additional financing;
- equity sales by us to fund our operations or restructure our outstanding convertible senior notes;

- changes in laws or regulations applicable to our products;
- the resolution of our pending purported class action and shareholder derivative litigation;
- developments or disputes concerning patents or other proprietary rights;
- period-to-period fluctuations in our financial results, including our cash and cash equivalents, operating expenses, cash burn rate or revenues;
- loss of key management;
- common stock sales and purchases in the public market by one or more of our larger stockholders, officers or directors;
- reports issued by securities analysts regarding our common stock and articles published regarding our business and/or products;
- changes in the market valuations of other life science or biotechnology companies; and
- other financial announcements, including delisting of our common stock from The NASDAQ Global Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in our filings with the SEC or our failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this report or in subsequent reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. We currently are subject to such litigation as described elsewhere in this report. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

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Future exercises by holders of warrants and options and conversions or securities exchanges by holders of our convertible senior notes and other issuances of additional securities could substantially dilute our common stock.

As of July 31, 2012, we had warrants to purchase an aggregate of 3,698,839 shares of our common stock outstanding that are exercisable at prices ranging from $12.00 per share to $24.00 per share and options to purchase an aggregate of 1,202,968 shares of our common stock outstanding that are exercisable at prices ranging from $2.02 per share to $220.92 per share. In addition, as of July 31, 2012, we had an aggregate of $8,277,850 in principal amount of convertible senior notes that are convertible into an aggregate of 370,871 shares of our common stock at a conversion price of $22.32 per share. Our stockholders, therefore, could experience substantial dilution of their investment upon exercise of these warrants and options and conversion or exchange of these notes. A substantial majority of these shares of common stock issuable upon exercise of the warrants and options and conversion or exchange of the notes currently are either registered or otherwise available for immediate resale, and thus once issued, will be available for immediate resale in the public market. In addition, we have the ability to offer and sell common stock, preferred stock and warrants under currently effective universal shelf registration statements. Any issuance of additional equity securities would dilute your share ownership. In addition, these sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

- authorizing the issuance of "blank check" preferred shares that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and
- advance notice provisions in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

We do not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in our common stock must come from increases in the fair market value and trading price of our common stock.

We do not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in our common stock must come from increases in the fair market value and trading price of our common stock.

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

Recent Sales of Unregistered Equity Securities

During the three months ended June 30, 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 (the Securities Act).

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 June 30, 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.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
3.1	Certificate of Amendment of the BioSante Pharmaceuticals, Inc. Restated Certificate of Incorporation (Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812))
10.1	BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812))
10.2	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812))
10.3	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the Securities

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Exhibit No.	Description
	and Exchange Commission on June 1, 2012 (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 June 30, 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.*

* 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.

August 1, 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)

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

Exhibit No.	Description	Method of Filing
3.1	Certificate of Amendment of the BioSante Pharmaceuticals, Inc. Restated Certificate of Incorporation	Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.1	BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.2	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.3	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (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 June 30, 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.

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: August 1, 2012

/s/ Stephen M. Simes

Stephen M. Simes
Vice Chairman, President and Chief Executive Officer
(principal 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: August 1, 2012

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary
(principal financial officer)

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 June 30, 2012 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
August 1, 2012

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 June 30, 2012 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
August 1, 2012