BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 08, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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	(I.R.S. Employer

incorporation or organization) 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 November 7, 2012, 24,422,240 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.

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

Septbember 30, 2012 and December 31, 2011 (Unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 38,049,095	$ 57,225,234
Prepaid expenses and other assets	534,037	801,147
	38,583,132	58,026,381
PROPERTY AND EQUIPMENT, NET	1,184,764	861,364
OTHER ASSETS		
Investments	3,413,762	3,405,807
Deposits	30,088	86,203
	$ 43,211,746	$ 62,379,755
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,004,814	$ 3,150,677
Accrued compensation	463,942	1,597,329
Other accrued expenses	860,094	2,479,697
Current portion of convertible senior notes	7,593,216	
	10,922,066	7,227,703
Long-term convertible senior notes		17,336,760
TOTAL LIABILITIES	10,922,066	24,564,463
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2012 - 65,211; 2011 - 65,214 Class C special stock	65	65
2012 - 24,422,240; 2011 - 18,269,755 Common stock	273,259,171	255,054,375
	273,259,236	255,054,440
Accumulated deficit	(240,969,556)	(217,239,148)
TOTAL STOCKHOLDERS EQUITY	32,289,680	37,815,292
	$ 43,211,746	$ 62,379,755

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three and Nine Months Ended September 30, 2012 and 2011 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
REVENUE				
Licensing revenue	$	$ 100,000	$	$ 100,000
Royalty revenue	110,383	82,784	333,163	220,787
	110,383	182,784	333,163	320,787
EXPENSES				
Research and development	3,872,736	11,500,053	14,454,258	37,480,873
General and administration	1,546,864	1,675,268	5,327,711	5,257,853
Depreciation and amortization	25,749	35,670	87,548	118,132
	5,445,349	13,210,991	19,869,517	42,856,858
OTHER				
Convertible note fair value adjustment	(843,412)	463,000	(4,037,797)	(1,929,000)
Interest expense	(67,105)	(172,000)	(283,348)	(516,000)
Other income		2,000		15,000
Interest income	1,877	1,516	5,300	6,472
LOSS BEFORE INCOME TAX BENEFIT	(6,243,606)	(12,733,691)	(23,852,199)	(44,959,599)
Income tax benefit	121,791		121,791	
NET LOSS	$ (6,121,815)	$ (12,733,691)	$ (23,730,408)	$ (44,959,599)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.27)	$ (0.73)	$ (1.14)	$ (2.86)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	22,921,176	17,406,536	20,841,417	15,744,738

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Nine Months Ended September 30, 2012 and 2011 (Unaudited)

	Nine Months Ended September 30, 2012	2011
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (23,730,408)	$ (44,959,599)
Adjustments to reconcile net loss to net cash (used in) operations		
Depreciation and amortization	87,548	118,132
Loss on disposal of fixed assets	117,794	367,274
Employee & director stock-based compensation	852,468	886,564
Stock warrant expense - noncash		180,759
Convertible note fair value adjustment	4,037,797	1,929,000
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other assets	323,225	1,539,903
Accounts payable and accrued liabilities	(3,807,074)	2,993,059
Net cash (used in) operating activities	(22,118,650)	(36,944,908)
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Purchase of investment	(7,955)	
Purchase of fixed assets	(528,742)	(645,603)
Net cash (used in) investing activities	(536,697)	(645,603)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Fractional share payout	(658)	
Proceeds from common stock option exercises		32,442
Proceeds from warrants exercised	211,068	24,063
Proceeds from issuance of common stock by underwritten public offering		45,102,584
Proceeds from issuance of common stock by registered direct offerings	3,268,798	23,876,370
Net cash provided by financing activities	3,479,208	69,035,459
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(19,176,139)	31,444,948
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	57,225,234	38,155,251
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 38,049,095	$ 69,600,199
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Interest paid	$ 184,094	$ 344,000
Noncash investing and financing activities		
Shares issued for convertible senior notes and accrued interest	$ 13,881,052	$
Unpaid costs associated with registered direct offering	$ 7,933	$
Unpaid costs associated with underwritten public offering	$	$ 141,447
Purchase of fixed assets on account, non-cash investing activity	$	$ 59,016

See accompanying notes to the condensed financial statements.

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NOTES TO THE CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1. DESCRIPTION OF BUSINESS

BioSante Pharmaceuticals, Inc. s (the Company) corporate strategy is to develop high value medically-needed pharmaceutical products and to implement strategic alternatives with respect to its products and the Company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies.

The Company s products, either approved or in 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 Meda Pharmaceuticals Inc. (Meda), the Company s 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 September 30, 2012 and December 31, 2011, the results of operations for the three and nine months ended September 30, 2012 and 2011, and the cash flows for the nine months ended September 30, 2012 and 2011, in conformity with accounting principles generally accepted in the United States of America (GAAP). Operating results for the three and nine month periods ended September 30, 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 nine month periods ended September 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

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operations to date have consisted mostly of licensing and research and development activities. The Company itself has not introduced commercially any products. 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 September 30, 2012, the Company had $38,049,095 of cash and cash equivalents. As of September 30, 2012, the Company had outstanding $8,277,850 in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. In August 2012, the Company completed an offering of an aggregate of 2,359,932 shares of the Company s common stock and warrants to purchase an aggregate of 1,179,966 shares of the Company s common stock, resulting in net proceeds of $3,268,798, after deducting placement agent fees and other offering expenses. See Note 7, Stockholders Equity, for additional discussion regarding the August 2012 registered direct offering.

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. Assuming the Company s pending merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI) is completed during the first quarter of 2013 (see Note 10, Subsequent Events), the Company expects its cash and cash equivalents as of September 30, 2012 to meet the Company s liquidity requirements through at least the Company s anticipated closing of the merger, including the requirement under our merger agreement to have at least $17 million of net cash (as defined in the merger agreement) available upon the closing of the merger. If the Company s pending merger with ANI is not completed, the Company will need to reevaluate its strategic alternatives, which may include a sale of the company, liquidation of the company or other strategic transaction. The Company s liquidity position will be dependent upon the strategic alternative selected; however, assuming the Company does not enter into another strategic transaction, and assuming the Company decides not to commence the two new efficacy trials for LibiGel, the Company expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet the Company s liquidity requirements for at least the next 3-5 years. Additional financing would be required should the Company decide to commence the two new efficacy trials for LibiGel. 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 attempt 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. 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

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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 complete its proposed merger with ANI, execute other strategic alternatives or leave the Company without sufficient cash remaining for operations.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the Company s business and future prospects, the future value of the Company and/or economic and market conditions deteriorate. In addition, the Company s ability to raise additional financing is limited by the terms of its agreement and plan of merger with ANI. See Note 10, Subsequent Events. 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 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 September 30, 2012 and December 31, 2011 was $8,277,850 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 of $79,024. 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. Non-cash fair value adjustments of $(2,545,530) and $(611,621) were recorded during the first and third quarters of 2012 as a result of the cancellation of such notes. The fair value adjustment recorded upon the cancellation of the 2013 Notes is primarily attributable to the time value effect of settling these obligations at a date prior to the stated maturity of the 2013 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 September 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

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in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

As described in Note 3, 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 September 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 $7,593,216 as of September 30, 2012 differs from their total stated aggregate principal amount of $8,277,850 as of such date by $684,634. 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 nine months ended September 30, 2012, the Company recorded a fair value adjustment of $(843,412) and $(4,037,797) related to the 2013 Notes that were converted to common stock during 2012 or that remained outstanding as of September 30, 2012, that for the three months and nine months ended September 30, 2012 increased the recorded liability and corresponding expense. For the three and nine months ended September 30, 2011, the Company recorded a fair value adjustment of $463,000 and $(1,929,000) that decreased and increased the recorded liability and corresponding expense, respectively.

For the nine months ended September 30, 2012 and 2011, approximately $(41,000) and $230,000, 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 nine months ended September 30, 2012 was estimated by calculating the difference between the September 30, 2012 fair value of the 2013 Notes as recorded and what the fair value of the 2013 Notes would have been on September 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 September 30, 2012 were:

Average risk-free rate	0.14%
Volatility of BioSante common stock	90.0%
Discount rate for principal payments in cash	19.6%

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

The Company typically grants options to purchase shares of the Company s common stock to existing employees and non-employee directors on an annual basis during the first quarter of each year and to new employees and non-employee directors throughout the year on or around the date their employment or service with the Company commences. All options are granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the 2008 Plan). As of September 30, 2012, approximately 981,272 shares of the Company s common stock remain available for issuance under the 2008 Plan.

During the nine months ended September 30, 2012, the Company granted options under the 2008 Plan to purchase an aggregate of 358,582 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 $4.08 per share. Options to purchase an aggregate of 105,781 shares of the Company s common stock expired and were cancelled during the nine months ended September 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 nine months ended September 30, 2012.

No warrants were granted during the nine months ended September 30, 2012, other than the warrants issued in conjunction with the Company s August 2012 offering described in Note 7, Stockholders Equity .

7. STOCKHOLDERS EQUITY

During the nine months ended September 30, 2012, the Company issued an aggregate of 3,652,125 shares of its common stock to holders of the 2013 Notes in exchange for the cancellation of $12,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $99,710. See Note 5, Convertible Senior Notes for information regarding the 2013 Notes.

In August 2012, the Company completed an offering of 2,359,932 shares of its common stock and warrants to purchase an aggregate of 1,179,966 shares of its common stock at a purchase price of $1.4725 per share to one institutional investor for gross proceeds of $3,475,000. The offering resulted in net proceeds to the Company of $3,268,798, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continue for a period of 5 years, at an exercise price of $1.50 per share. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities. On September 20, 2012, warrants from the August 2012 offering to purchase an aggregate of 140,712 shares of common stock were exercised resulting in proceeds of $211,068 to the Company.

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 one-for-two and not more than one-for-ten. On June 1, 2012, the Board of

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Directors of the Company effected a one-for-six reverse split of the Company s outstanding shares of common stock and class C special stock. No fractional shares were issued as a result of the reverse stock split, and stockholders who otherwise would have been entitled to a fractional share received, in lieu thereof, a cash payment based on the closing sale price of BioSante s common stock on June 1, 2012. The total cash payment for fractional shares was $658. 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 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.

8. COMMITMENTS AND CONTINGENCIES

Aptar Pharma Gel Packaging Machine

The Company has a commitment with Aptar Pharma to purchase a gel packaging machine for $844,740. As of September 30, 2012, the Company had paid Aptar $804,132. The remaining obligation of $40,608 is due upon the shipment, assembly and calibration of the machine at a location designated by the Company. In light of the Company s pending merger with ANI (see Note 10, Subsequent Events), the Company is evaluating the future plans for this gel packaging machine.

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 10, 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 October 10, 2012, the District Court entered an order setting the dates on which the plaintiff s consolidated amended complaint is due and establishing a briefing schedule on the defendants anticipated motion to dismiss. On November 6, 2012, plaintiff filed a consolidated amended complaint; the Company and Mr. Simes intend to file motions to dismiss the consolidated amended complaint on or before December 21, 2012.

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 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. On September 24, 2012, the District Court

consolidated the two cases before it and entered a stipulation and order setting the dates on which the plaintiff s consolidated amended complaint is due and establishing a

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briefing schedule on defendants anticipated motions to dismiss. The Company expects a similar scheduling order to be entered in the action pending in Illinois state court.

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 reasonable assurance and that may not be known for extended periods of time.

9. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

Description		September 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	$	36,957,469		$ 36,957,469	
Total assets	$	36,957,469		$ 36,957,469	
Liabilities:					
2013 Notes		7,593,216		7,593,216	
Total liabilities	$	7,593,216		$ 7,593,216	

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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	

The Company made an election to record the values of the 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately. The fair values of the 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company s stock, and the current borrowing rates for similar companies. See Note 6, Convertible Senior Notes for more information and disclosures regarding key assumptions used in this fair value determination.

10. SUBSEQUENT EVENTS

Agreement and Plan of Merger

On October 3, 2012, the Company entered into an agreement and plan of merger (the Merger Agreement) with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Merger Agreement, ANI will merge with and into the Company, with the Company continuing as the surviving company (the Merger). At the effective time of the Merger, each outstanding share of capital stock of ANI will be converted into the right to receive a number of shares of the Company s common stock, if any, as determined pursuant to the exchange ratios described in the Merger Agreement and the provisions of ANI s certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the Merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the Merger. No fractional shares of the Company s common stock will be issued in connection with the Merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following the consummation of the transactions contemplated by the Merger Agreement, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of the Company are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the Merger Agreement depending upon the amount of the Company s net cash , as defined in the Merger Agreement and generally consisting of the Company s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current Company stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The Merger Agreement provides that, immediately following the effective time of the Merger, the board of directors of the combined company will consist of five former directors of ANI and two former directors of the Company, and ANI s current executive officers are expected to serve as executive officers

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of the combined company. In connection with the Merger, the Company will seek to amend its certificate of incorporation to: (i) effect a reverse split of its common stock at a ratio between the range of one-for-two and one-for-five, as determined by the Company and ANI, which is intended to ensure that the listing requirements of The NASDAQ Global Market or The NASDAQ Capital Market are satisfied; and (ii) change the name of the Company to ANI Pharmaceuticals, Inc. or another name as designated by ANI (together, the Charter Amendments). No fractional shares of the Company s common stock will be issued in connection with the reverse split and holders of the Company s common stock will be entitled to receive cash in lieu thereof.

Consummation of the Merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the Merger Agreement and the transactions contemplated thereby by both the Company s and ANI s stockholders and the approval of the Charter Amendments by the Company s stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by the Company with the Securities and Exchange Commission to register the shares of the Company s common stock to be issued in connection with the Merger, which will contain a joint proxy statement/prospectus; (iii) approval for the listing of shares of the Company s common stock to be issued in the Merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iv) written opinions of counsel that the Merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (v) other customary closing conditions. In addition, the obligation of ANI to effect the Merger is subject to a condition that the Company s net cash, as calculated pursuant to the terms of the Merger Agreement, be no less than $17.0 million immediately prior to the effective time of the Merger.

Each of the Company and ANI have made customary representations, warranties and covenants in the Merger Agreement, including among others, covenants that (i) each party will conduct its business in the ordinary course consistent with past practice during the interim period between the execution of the Merger Agreement and the consummation of the Merger; (ii) each party will not engage in certain kinds of transactions or take certain actions during such period; (iii) ANI will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the Merger Agreement and the transactions contemplated thereby and the board of directors of ANI will recommend that its stockholders adopt and approve the Merger Agreement, subject to certain exceptions; and (iv) the Company will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the Merger Agreement and the transactions contemplated thereby and the approval of the Charter Amendments and the Company s board of directors will recommend that the Company s stockholders adopt and approve the Merger Agreement and approve the charter amendments, subject to certain exceptions. Each of the Company and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for the Company in the event of the Company s receipt of a superior proposal.

The Merger Agreement contains certain termination rights in favor of each of ANI and the Company in certain circumstances. If the Merger Agreement is terminated due to certain triggering events specified in the Merger Agreement, the Company will be required to pay ANI a termination fee of up to $1.0 million or ANI will be required to pay the Company a termination fee of up to $750,000. The Merger Agreement also provides that under specified circumstances, the Company may be required to reimburse ANI up to $500,000 for ANI s expenses in connection with the transaction. Any expenses paid by the Company will be credited against the $1.0 million termination fee if the termination fee subsequently becomes payable by the Company.

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Voting Agreements

Concurrently and in connection with the execution of the Merger Agreement, certain of ANI s stockholders, who collectively hold approximately 90 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into voting agreements with the Company, pursuant to which each stockholder agreed to vote its shares of ANI capital stock in favor of the Merger, the Merger Agreement and the transactions contemplated by the Merger Agreement and against certain transactions or certain actions that would delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement. In addition, one of the stockholders of ANI, who holds approximately 57 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, has agreed to vote in favor of the election of the two directors designated by the Company at the first annual meeting of stockholders following the completion of the Merger.

In addition, certain of the Company s stockholders, directors and officers, who collectively hold approximately two percent of the outstanding shares of the Company s capital stock as of the close of business on October 3, 2012, entered into voting agreements with ANI, pursuant to which each stockholder agreed to vote its shares of the Company s capital stock in favor of the Merger, the Merger Agreement and the transactions contemplated by the Merger Agreement and the charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the Merger or the transaction contemplated by the Merger Agreement.

Lock-Up Agreements

Concurrently and in connection with the execution of the Merger Agreement, ANI s chief executive officer and chief financial officer and certain stockholders of ANI, who collectively hold approximately 85 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into lock-up agreements with the Company, pursuant to which each stockholder will be subject to a six-month lock-up on the sale of shares of the Company s common stock received in the Merger.

Contingent Value Rights Agreement

The Company has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to its existing stockholders immediately prior to the completion of the Merger. The Company expects that one CVR will be issued for each share of the Company s common stock outstanding as of the record date to be set at a date prior to the completion of the Merger. However, the CVRs will not be certificated and will not be attached to the shares of the Company s common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event the Company receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to the Company s LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between the Company and an as of yet unidentified third party, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to the Company s LibiGel program, as determined pursuant to the CVR agreement, and will not exceed $40 million in the aggregate.

Employee Reduction Implications

As a result of the conclusion of the Company s LibiGel Phase III cardiovascular events and breast cancer safety study, as announced by the Company in September 2012, and considering the Company s

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October 4, 2012 announcement of its potential merger with ANI, the Company plans to reduce its workforce during the fourth quarter of 2012. In connection with the announced reduction, the Company will pay approximately $300,000 in aggregate severance costs during the remainder of 2012. The termination of employment of these employees will result in the cessation of any further vesting in certain stock options held by these employees and a reversal of previously recognized non-cash stock-based compensation expense related to such options in a similar amount, thereby offsetting the employee reduction severance costs.

Third Amendment To License Agreement with Teva

In October 2012, the Company entered into an amendment to its development and license agreement with Teva pursuant to which Teva made a $1.0 million payment to the Company upon the signing of the amendment and agreed to make the following milestone-based payments to the Company: (1) $500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an AB-rated equivalent to AndroGel®; (2) $750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva s submission to the FDA of a final report regarding a washing clinical study required by the FDA; and (3) $500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva s commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay the Company $4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to the Company under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

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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 clinical development, include:

- LibiGel once daily transdermal testosterone gel in Phase III 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 Meda Pharmaceuticals, Inc. (Meda), our licensee.

Our corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of our corporate strategy, we seek 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.

Recent Development

Agreement and Plan of Merger

On October 3, 2012, we entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI). The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. At the effective time of the merger, each outstanding

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share of capital stock of ANI will be converted into the right to receive a number of shares of our common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI s certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of our common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following the consummation of the transactions contemplated by the merger agreement, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of BioSante are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of our net cash, as defined in the merger agreement and generally consisting of our cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The merger agreement provides that, immediately following the effective time of the merger, the board of directors of the combined company will consist of five former directors of ANI and two former directors of BioSante, and ANI s current executive officers are expected to serve as executive officers of the combined company. In connection with the merger, we will seek to amend our certificate of incorporation to: (i) effect a reverse split of our common stock at a ratio between the range of one-for-two and one-for-five, as determined by us and ANI, which is intended to ensure that the listing requirements of The NASDAQ Global Market or The NASDAQ Capital Market are satisfied; and (ii) change the name of our company to ANI Pharmaceuticals, Inc. or another name as designated by ANI (together, the charter amendments).

Consummation of the merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the merger agreement and the transactions contemplated thereby by both our and ANI s stockholders and the approval of the charter amendments by our stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by us with the Securities and Exchange Commission to register the shares of our common stock to be issued in connection with the merger, which will contain a joint proxy statement/prospectus; (iii) approval for the listing of shares of our common stock to be issued in the merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iv) written opinions of counsel that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (v) other customary closing conditions. In addition, the obligation of ANI to effect the merger is subject to a condition that our net cash, after deducting all remaining liabilities, as calculated pursuant to the terms of the merger agreement, be no less than $17.0 million immediately prior to the effective time of the merger. No fractional shares of our common stock will be issued in connection with the reverse split and holders of our common stock will be entitled to receive cash in lieu thereof.

Each of BioSante and ANI have made customary representations, warranties and covenants in the merger agreement, including among others, covenants that (i) each party will conduct its business in the ordinary course consistent with past practice during the interim period between the execution of the merger agreement and the consummation of the merger; (ii) each party will not engage in certain kinds of transactions or take certain actions during such period; (iii) ANI will convene and hold a meeting of its stockholders for the purpose of considering the adoption and approval of the merger agreement and the transactions contemplated thereby and the board of directors of ANI will recommend that its stockholders

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adopt and approve the merger agreement, subject to certain exceptions; and (iv) we will convene and hold a meeting of our stockholders for the purpose of considering the adoption and approval of the merger agreement and the transactions contemplated thereby and the approval of the charter amendments and our board of directors will recommend that our stockholders adopt and approve the merger agreement and approve the charter amendments, subject to certain exceptions. Each of BioSante and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for us in the event of our receipt of a superior proposal.

The merger agreement contains certain termination rights in favor of each of ANI and us in certain circumstances. If the merger agreement is terminated due to certain triggering events specified in the merger agreement, we will be required to pay ANI a termination fee of up to $1.0 million or ANI will be required to pay us a termination fee of up to $750,000. The merger agreement also provides that under specified circumstances, we may be required to reimburse ANI up to $500,000 for ANI s expenses in connection with the transaction. Any expenses paid by us will be credited against the $1.0 million termination fee if the termination fee subsequently becomes payable by us.

Voting Agreements

Concurrently and in connection with the execution of the merger agreement, certain of ANI s stockholders, who collectively hold approximately 90 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into voting agreements with us, pursuant to which each stockholder agreed to vote its shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. In addition, one of the stockholders of ANI, who holds approximately 57 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, has agreed to vote in favor of the election of the two directors designated by us at the first annual meeting of stockholders following the completion of the merger.

In addition, certain of our stockholders, directors and officers, who collectively hold approximately two percent of the outstanding shares of our capital stock as of the close of business on October 3, 2012, entered into voting agreements with ANI, pursuant to which each stockholder agreed to vote its shares of our capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and the charter amendments, and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement.

Lock-Up Agreements

Concurrently and in connection with the execution of the merger agreement, ANI s chief executive officer and chief financial officer and certain stockholders of ANI, who collectively hold approximately 85 percent of the outstanding shares of ANI capital stock as of the close of business on October 3, 2012, entered into lock-up agreements with us, pursuant to which each stockholder will be subject to a six-month lock-up on the sale of shares of our common stock received in the merger.

Contingent Value Rights Agreement

We have the right in our sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to our existing stockholders immediately prior to the completion of the merger. We expect that one CVR will be issued for each share of our common stock outstanding as of the record

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date to be set at a date prior to the completion of the merger. However, the CVRs will not be certificated and will not be attached to the shares of our common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event we receive net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to our LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between us and an as of yet unidentified third party, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to our LibiGel program, as determined pursuant to the CVR agreement, and will not exceed $40 million in the aggregate.

Additional Business Developments

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 focused our efforts on two Phase III LibiGel efficacy trials and our 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 two efficacy trials was greater than expected, and LibiGel s results were not shown to be statistically different from the placebo.

Beginning in December 2011, we analyzed the data from our Phase III LibiGel efficacy trials, consulted with key opinion leaders 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.

In September 2012, we announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, we also announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA advised us that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.5 months; more than 3,200 subjects had been in the study for more than one year and over 1,700 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, we believe that adequate safety data of LibiGel use in menopausal women has been obtained.

We are continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA SPA agreement covering aspects of the two new efficacy trials.

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Elestrin was our first FDA approved product and now is one of our two FDA approved products. Meda Pharmaceuticals, Inc. (which acquired Jazz Pharmaceuticals, Inc. s women s health business and which in turn had 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 Meda 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.

Our male testosterone gel is our second FDA approved product. This product initially was developed by us, and then licensed by us to Teva for late stage clinical development. Teva submitted an 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 disclosed publicly. No launch date for this product has been announced by Teva.

Under our development and license agreement with Teva, Teva has agreed to market our male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, which was paid to us in December 2002, and an obligation by Teva to pay us certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more detail below. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. We may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

In October 2012, we entered into an amendment to our agreement with Teva pursuant to which Teva made a $1.0 million payment to us upon the signing of the amendment and agreed to make the following milestone based payments to us: (1) $500,000 if the FDA authorizes marketing of the licensed male testosterone gel as an AB-rated equivalent to AndroGel®; (2) $750,000 upon the earlier to occur of (a) December 31, 2012 and (b) five business days after Teva s submission to the FDA of a final report regarding a washing clinical study required by the FDA; and (3) $500,000 upon the earlier to occur of (a) December 31, 2013 and (b) five business days after Teva s commencement of commercial manufacture of the licensed product for sale in the United States. In addition, Teva has agreed to pay us $4.0 million in the event Teva is the sole marketer in the United States of a generic 1% testosterone gel AB-rated to AndroGel® for at least 180 days immediately following the launch date of the licensed product in the United States. The royalty rate to be paid by Teva to us under the agreement is five percent of net sales; provided, however, that during the period of time that Teva markets the licensed product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the United States, the royalty rate will be seven and one half percent of net sales. Additionally, pursuant to the terms of the October 2012 amendment, the parties agreed to release each other from certain liabilities.

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We license the technology underlying certain of our gel products, including LibiGel and Elestrin, but not our male testosterone gel, from Antares Pharma, Inc. The patents covering the formulations used in the gel products covered under the license agreement are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the method of use of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. 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. Since entering into the agreement and through September 30, 2012, we have paid Antares an upfront payment of $1.0 million, an aggregate of $5.1 million in milestone payments and an aggregate of $100,000 in royalties. Aggregate potential milestone payments to be paid by us to Antares under the agreement include 25 percent of the potential $140 million in sales-based milestone payments, or $35 million from Meda 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.

The term of our license agreement with Antares will expire on a country-by-country and product-by-product basis when the royalties expire (at patent expiration), at which time we will have a fully paid-up exclusive license regarding the applicable product in such country. We and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if we do not continue development, seeking regulatory approval or marketing of such products in the covered territories. We may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if we determine that it is not economically viable to continue development or marketing of a product in a territory.

We license the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

Our 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. The studies are being funded by various sources, including certain foundations and our licensees. Our objective with respect to our GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes monetizing the entire portfolio or seeking additional licensees to fund, develop and eventually commercialize the cancer vaccines.

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 if we

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do not complete our proposed merger with ANI, we would expect this to continue for the immediate future. 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 September 30, 2012, we had $38.0 million of cash and cash equivalents and had outstanding $8.3 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations. Assuming our pending merger with ANI is completed, we expect our cash and cash equivalents as of September 30, 2012 to meet our liquidity requirements through at least our anticipated closing of the merger, including the requirement under our merger agreement to have at least $17 million of net cash (as defined in the merger agreement) available upon the closing of the merger. If the Company s pending merger with ANI is not completed, the Company will need to reevaluate its strategic alternatives, which may include a sale of the company, liquidation of the company or other strategic transaction. The Company s liquidity position will be dependent upon the strategic alternative selected; however, assuming the Company does not enter into another strategic transaction, and assuming the Company decides not to commence the two new efficacy trials for LibiGel, the Company expects its cash and cash equivalents as of September 30, 2012 will be sufficient to meet the Company s liquidity requirements for at least the next 3-5 years. Additional financing would be required should the Company decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of $14.5 million on research and development activities during the nine months ended September 30, 2012, which is a 61 percent decrease compared to the same period in 2011, primarily as a result of the conclusion of our two LibiGel Phase III efficacy trials at the end of 2011. We anticipate that our research and development expenses for the remainder of 2012 will consist primarily of expenses associated with the conclusion of the safety study and continuing to develop a protocol for the two new LibiGel Phase III efficacy trials. We currently expect to spend approximately $1.1 million per month on research and development activities during the remainder of 2012, which is based on the assumption that we do not in-license additional products and technologies requiring additional development.

Our general and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the same period in 2011 due primarily to an increase in professional fees and other administrative expenses. Our general and administrative expenses generally 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 an income tax benefit based on the receipt of an income tax credit for the three and nine months ended September 30, 2012 of $121,791 compared to the recognition of no income tax benefit for the three and nine months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Sec. 168(k)(4) of the Internal Revenue Code of 1986, as amended.

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We recognized a net loss for the three and nine months ended September 30, 2012 of $6.1 million and $23.7 million, respectively, compared to a net loss of $12.7 million and $45.0 million for the three and nine months ended September 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 in September 2012 the conclusion of the LibiGel Phase III safety study, and were offset, in part, by an increase in the non-cash fair value adjustment relating to the cancellation of $12.5 million in aggregate principal amount of our convertible senior notes. We recognized a net loss per share for the three and nine months ended September 30, 2012 of $0.27 and $1.14, respectively, compared to a net loss per share of $0.73 and $2.86 for the three and nine months ended September 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.

Results of Operations

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

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

	Three Months Ended September 30,			
	2012	2011	$ Change	% Change
Revenue	$ 110,383	$ 182,784	$ (72,401)	(39.6)%
Expenses				
Research and development	3,872,736	11,500,053	(7,627,317)	(66.3)%
General and administrative	1,546,864	1,675,268	(128,404)	(7.7)%
Other expense Convertible note fair value adjustment	(843,412)	463,000	1,306,412	282.2%
Other expense Interest expense	(67,105)	(172,000)	(104,895)	(61.0)%
Other income - Interest income	1,877	1,516	361	23.8%
Income tax benefit	121,791		121,791	100.0%
Net loss	$ (6,121,815)	$ (12,733,691)	$ (6,611,876)	(51.9)%
Net loss per common share (basic and diluted)	$ (0.27)	$ (0.73)	$ (0.46)	(63.0)%
Weighted average number of common shares and common equivalent shares outstanding	22,921,176	17,406,536	5,514,640	31.7%

The only revenue recognized during the three months ended September 30, 2012 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 $110,383 during the three months ended September 30, 2012 and $82,784 during the three months ended September 30, 2011, is recorded within general and administrative expenses in our condensed statements of operations. In addition, during the three months ended September 30, 2011, we recognized an additional $100,000 in revenue from our receipt of an upfront non-refundable licensing fee from The John P. Hussman Foundation.

Research and development expenses for the three months ended September 30, 2012 decreased 66 percent compared to the three months ended September 30, 2011 primarily as a result of the

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completion of our two LibiGel Phase III efficacy trials at the end of 2011, and the conclusion of the LibiGel Phase III safety study as announced in September 2012.

General and administrative expenses for the three months ended September 30, 2012 decreased 8 percent compared to the three months ended September 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 increase the recorded liability and corresponding expense was $843,412 for the three months ended September 30, 2012 compared to a fair value adjustment to decrease the recorded liability and corresponding expense of $463,000 for the three months ended September 30, 2011.

Interest expense was $67,105 and $172,000 for the three months ended September 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 $12.5 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first and third quarter of 2012 in exchange for the issuance of 3,652,125 shares of our common stock.

Interest income increased $361 for the three months ended September 30, 2012 compared to the three months ended September 30, 2011 as a result of higher average cash balances during the three months ended September 30, 2012.

We recognized an income tax benefit based on the receipt of an income tax credit for the three months ended September 30, 2012 of $121,791 compared to the recognition of no income tax benefit for the three months ended September 30, 2011. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Sec. 168(k)(4) of the Internal Revenue Code of 1986, as amended.

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011

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

	Nine Months Ended September 30,			
	2012	**2011**	**$ Change**	**% Change**
Revenue	$ 333,163	$ 320,787	$ 12,376	3.9%
Expenses				
Research and development	14,454,258	37,480,873	(23,026,615)	(61.4)%
General and administrative	5,327,711	5,257,853	69,858	1.3%
Other expense Convertible note fair value adjustment	(4,037,797)	(1,929,000)	2,108,797	109.3%

Other expense	Interest expense	(283,348)	(516,000)	(232,652)	(45.1)%
Other income -	Interest income	5,300	6,472	(1,172)	(18.1)%
Income tax benefit		121,791		121,791	100.0%
Net loss					