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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 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 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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BIOSANTE PHARMACEUTICALS, INC.
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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

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

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

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	$ (23,730,408)	$ (44,959,682)	$ (21,229,274)	(47.2)%
Net loss per common share (basic and diluted)	$ (1.14)	$ (2.86)	$ 1.72	(60.1)%

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	Nine Months Ended September 30,			
	2012	2011	$ Change	% Change
Weighted average number of common shares and common equivalent shares outstanding	20,841,417	15,744,738	5,096,679	32.4%

The only revenue recognized during the nine 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 $333,163 during the nine months ended September 30, 2012 and $220,787 during the nine months ended September 30, 2011, is recorded within general and administrative expenses in our condensed statements of operations. In addition, during the nine 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 nine months ended September 30, 2012 decreased 61 percent compared to the nine months ended September 30, 2011 primarily as a result of the completion of our two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012.

General and administrative expenses for the nine months ended September 30, 2012 increased 1.3 percent compared to the nine months ended September 30, 2011 primarily as a result of an increase in professional fees and other administrative expenses.

The fair value adjustment on our convertible senior notes for the nine months ended September 30, 2012 was $4.0 million compared to $1.9 million for the nine months ended September 30, 2011. The increase in the expense for the nine months ended September 30, 2012 was primarily as a result of $3,157,151 non-cash fair value adjustment (expense) recorded upon cancellation of $12.5 million in aggregate principal amount of our convertible senior notes in February and July 2012. The convertible fair value adjustment for the nine months ended September 30, 2011 increased the recorded liability and corresponding expense by $1,929,000 and included the 2011 and 2013 Notes.

Interest expense was $283,348 and $516,000 for the nine 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 decreased $1,172 for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 as a result of lower cash balances and lower average interest rates during the nine months ended September 30, 2012.

We recognized an income tax benefit based on the receipt of an income tax credit for the nine months ended September 30, 2012 of $121,791 compared to the recognition of no income tax benefit for the 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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Liquidity and Capital Resources

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

Balance Sheet Data	September 30, 2012	December 31, 2011
Cash and cash equivalents	$ 38,049,095	$ 57,225,234
Total current assets	38,583,132	58,026,381
Investments	3,413,762	3,405,807
Total assets	43,211,746	62,379,755
Convertible senior notes due 2013	7,593,216	17,336,760
Total liabilities	10,922,066	24,564,463
Total stockholders' equity	32,289,680	37,815,292

Liquidity

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $241.0 million as of September 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 September 30, 2012, we had $38.0 million of cash and cash equivalents and $8,277,850 in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013 (2013 Notes) outstanding. 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 during the first quarter of 2013, we expect our cash and cash equivalents as of September 30, 2012 to meet our liquidity requirements through at least the anticipated closing of our merger with ANI, 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.

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

- the timing, cost and successful completion of our proposed merger with ANI;
- the progress, timing, cost and results of our clinical development programs, including in particular the conclusion of the LibiGel Phase III safety study, and if we have not completed our proposed merger with ANI, beginning in mid-2013, the two new LibiGel Phase III efficacy trials if we decide to commence such 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;

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- 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.
- 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, or sell certain assets or rights under our existing license agreements. 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 of $79,024, 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

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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 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 the success of our proposed merger with ANI, our LibiGel clinical development program, the future value of our company and/or economic and market conditions deteriorate. If we do not complete our proposed merger with ANI and 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 other business combination transactions 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 $22.1 million for the nine months ended September 30, 2012 compared to net cash used in operating activities of $36.9 million for the nine months ended September 30, 2011. Net cash used in operating activities for the nine months ended September 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 two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012. Net cash used in operating activities for the nine months ended September 30, 2011 was primarily the result of the net loss for that period.

Net cash used in investing activities was $536,697 for the nine months ended September 30, 2012 compared to net cash used in investing activities of $645,603 for the nine months ended September 30, 2011. Net cash used in investing activities for each of the nine months ended September 30, 2012 and 2011 was due primarily to the purchase of fixed assets.

Net cash provided by financing activities was $3.5 million for the nine months ended September 30, 2012 compared to net cash provided by financing activities of $69 million for the nine months ended September 30, 2011. Net cash provided by financing activities for the nine months ended September 30, 2012 was the result of our August 2012 registered direct offering, which resulted in net proceeds of $3.3 million, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities for the nine months ended September 30, 2011 was the result of our August 2011 underwritten public offering and March 2011 registered direct offering, which resulted in net proceeds of $45.1 million and $23.9 million, respectively, after deduction of underwriting discounts and commissions or placement agent fees and offering expenses.

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Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of September 30, 2012. We have a purchase obligation relating to a gel packaging machine of $40,608. This obligation is due upon the shipment, assembly and calibration of the machine at a location designated by us. In light of our pending merger with ANI, we are evaluating our future plans for this gel packaging machine. 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.

The following table summarizes the timing of these future contractual obligations and commitments as of September 30, 2012:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible senior notes	$ 8,277,850	$ 8,277,850	$ 0	$ 0	$ 0
Interest payment obligations related to convertible senior notes	150,898	150,898	0	0	0
Operating lease	350,413	246,119	104,295	0	0
Commitments under license agreements with Johns Hopkins University	320,000	45,000	135,000	90,000	50,000
Commitments under license agreement with Massachusetts Institute of Technology	100,000	50,000	50,000	0	0
Commitments under license agreement with University of California	300,000	20,000	60,000	40,000	180,000
Commitments under license agreement with Wake Forest	360,000	80,000	200,000	80,000	40,000
Total contractual cash obligations	$ 9,859,162	$ 8,869,867	$ 549,295	$ 210,000	$ 230,000

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 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 timing of our proposed merger with ANI;
- 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 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:

- risk relating to our proposed merger with ANI, as described in more detail later in this report under the heading “Part II — Item 1A. Risk Factors”;
- 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;
- 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 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;

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- 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;
- 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

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on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to interest rate sensitivity on our cash equivalents in money market funds and our outstanding fixed rate debt. The objective of our investment activities is to preserve principal, while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid U.S. Treasury money market funds. Our investments in U.S. Treasury money market funds are subject to interest rate risk. To

minimize the exposure due to an adverse shift in interest rates, we invest in short-term securities and our goal is to maintain an average maturity of less than one year. As of the date of this report, all of our cash equivalents are only invested in a U.S. Treasury money market fund and a certificate of deposit.

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

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

As of September 30, 2012	2012	2013	2014	Total	Fair Value September 30, 2012
Total Cash Equivalents	$ 36,957,469	—	—	—	$ 36,957,469
Average Interest Rate	0.04%	—	—	—	—
Fixed Interest Rate 2013 Convertible Senior Notes	—	$ 8,277,850	—	$ 8,277,850	$ 7,593,216
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,

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can provide only reasonable assurance of achieving the desired control objectives, and we are required to apply our judgment in evaluating the cost-benefit relationship of possible internal controls. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this quarterly report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that material information relating to our company is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the three months ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

We are affected by risks specific to us as well as factors that affect all businesses. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2012 under the heading "Part II — Item 1A. Risk Factors," which could materially adversely affect our business, financial condition or operating results. There has been no material change to those risk factors, except as described below:

The announcement and pendency of the merger could have an adverse effect on BioSante's stock price and/or the business, financial condition, results of operations or business prospects for BioSante.

The announcement and pendency of the merger could have an adverse effect on BioSante's stock price and/or the business, financial condition, results of operations or business prospects of BioSante. For example, third parties may seek to terminate and/or renegotiate their relationships with BioSante as a result of the merger, whether pursuant to the terms of their existing agreements with BioSante or otherwise. In addition, the attention of BioSante management may be directed toward the completion of the merger and related matters and may be diverted from the day-to-day business operations, including from other opportunities that otherwise might be beneficial to BioSante.

Failure to complete the merger could impact negatively BioSante's business, financial condition or results of operations or BioSante's stock price.

The completion of the merger is subject to a number of conditions and there can be no assurance that the conditions to the completion of the merger will be satisfied. If the merger is not completed, BioSante will be subject to several risks, including:

- the current trading price of BioSante common stock may reflect a market assumption that the merger will occur, meaning that a failure to complete the merger could result in a decline in the price of BioSante common stock;
- certain executive officers and/or directors of BioSante may seek other employment opportunities, and the departure of any of BioSante's executive officers and the possibility that the company would be unable to recruit and hire an executive could impact negatively BioSante's business and operating results;
- the BioSante board of directors will need to reevaluate BioSante's strategic alternatives, which alternatives may include a sale of the company, liquidation of the company or other strategic transaction;
- BioSante may be required to reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;

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- BioSante is expected to incur substantial transaction costs in connection with the merger whether or not the merger is completed;
- BioSante would not realize any of the anticipated benefits of having completed the merger; and
- under the merger agreement, BioSante is subject to certain restrictions on the conduct of its business prior to the completion of the merger, which restrictions could adversely affect its ability to realize its business strategies or take advantage of certain business opportunities.

If the merger is not completed, these risks may materialize and affect materially and adversely BioSante's business, financial condition, results of operations or stock price.

The issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will dilute substantially the voting power of current BioSante stockholders.

Pursuant to the terms of the merger agreement, it is anticipated that BioSante will issue shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following the completion of the merger. After such issuance, the shares of BioSante common stock outstanding immediately prior to the completion of the merger will represent approximately 47 percent of the outstanding shares of common stock of the combined company as of immediately following the completion of the merger. These ownership percentages may change depending upon the amount of BioSante's net cash as of a determination date prior to the completion of the merger. Accordingly, the issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will reduce significantly the relative voting power of each share of BioSante common stock held by current BioSante stockholders. Consequently, the BioSante stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger.

The exchange ratios in the merger agreement are subject to adjustment based on BioSante's net cash as of a determination date prior to the completion of the merger, which could dilute further the ownership of the BioSante stockholders in the combined company.

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of capital stock of ANI issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive a number of shares of BioSante 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. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of "net cash" of BioSante, as defined in the merger agreement and generally consisting of BioSante's cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. If BioSante has more than $18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each $1 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than $18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each $1 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In no event, however, 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.

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The exchange ratios are not adjustable based on the market price of BioSante common stock and if the market price of BioSante common stock fluctuates, the market value of the shares of BioSante common stock to be received by the ANI stockholders in connection with the merger is subject to change prior to the completion of the merger.

The aggregate number of shares of BioSante common stock to be issued to ANI stockholders is expected to represent approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following the completion of the merger. The exchange ratios, as such ratios are calculated pursuant to the formulas set forth in the merger agreement, are based on the number of shares of BioSante common stock and ANI capital stock outstanding as of immediately prior to the completion of the merger, and in the case of BioSante, a certain percentage of the number of certain warrants to purchase shares of BioSante common stock outstanding as of such date, and will not be determined until that time. The exchange ratios will be adjusted upward or downward only as a result of changes to the outstanding capital stock of either or both of BioSante and ANI as of immediately prior to the completion of the merger and changes to BioSante's net cash as of a determination date prior to the completion of the merger. No adjustments to the exchange ratios will be made based on changes in the trading price of BioSante common stock or the value of ANI capital stock prior to the completion of the merger. Changes in the trading price of BioSante common stock or the value of ANI capital stock may result from a variety of factors, including, among others, general market and economic conditions, changes in BioSante's or ANI's respective businesses, operations and prospects, market assessment of the likelihood that the merger will be completed as anticipated or at all, and regulatory considerations. Many of these factors are beyond BioSante's or ANI's control. As a result, the value of the shares of BioSante common stock issued to ANI stockholders in connection with the merger could be substantially less or substantially more than the current market value of BioSante common stock.

The exchange ratios are not adjustable based on issuances by BioSante of additional shares of BioSante common stock either upon the exercise of options or warrants or the conversion of convertible securities or otherwise, which issuances would result in additional dilution to the BioSante stockholders.

As of November 1, 2012, BioSante had outstanding options to purchase an aggregate of approximately 1.2 million shares of BioSante common stock, warrants to purchase an aggregate of approximately 4.7 million shares of BioSante common stock, an aggregate of 65,211 shares of BioSante class C special stock that are convertible into 65,211 shares of BioSante common stock and an aggregate of $8.3 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 that are convertible into an aggregate of 370,871 shares of BioSante common stock. BioSante is not prohibited under the terms of the merger agreement from issuing additional equity securities under certain circumstances, including securities issued pursuant to the exercise of outstanding options or warrants or the conversion or exchange of outstanding convertible notes. It is possible that prior to the completion of the merger BioSante may issue additional equity securities. The exchange ratios in the merger agreement, which are designed to result in the issuance by BioSante of shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following the completion of the merger, are not adjustable based on issuances by BioSante of additional shares of BioSante common stock. Therefore, any such issuances by BioSante would result in additional dilution to the BioSante stockholders.

BioSante has incurred and will continue to incur significant transaction costs in connection with the merger, some of which will be required to be paid even if the merger is not completed.

BioSante has incurred and will continue to incur significant transaction costs in connection with the merger. These costs are primarily associated with the fees of attorneys and accountants and

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BioSante's financial advisor. Most of these costs will be paid even if the merger is not completed. In addition, if the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante may be required to pay ANI a termination fee of $1.0 million. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to $500,000 for its expenses in connection with the transaction.

The merger agreement and the voting agreements contain provisions that could discourage or make it difficult for a third party to acquire BioSante prior to the completion of the merger.

The merger agreement contains provisions that make it difficult for BioSante to entertain a third-party proposal for an acquisition of BioSante. These provisions include:

- the general prohibition on BioSante's soliciting or engaging in discussions or negotiations regarding any alternative acquisition proposal;
- the requirement that BioSante reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances; and
- the requirement that BioSante submit the merger-related proposals to a vote of the BioSante stockholders even if the BioSante board of directors changes its recommendation with respect to such proposals, as applicable.

Pursuant to the voting agreements entered into between ANI and the directors, executive officers and certain stockholders of BioSante, each such director, executive officer and applicable stockholder has agreed not to take any actions that BioSante is prohibited from taking pursuant to the no-solicitation restrictions contained in the merger agreement. In addition, holders of shares representing approximately two percent of the outstanding capital stock of BioSante as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of the shares of BioSante common stock, and the approval of the BioSante charter amendments, and BioSante is required under the terms of the merger agreement to convene and hold the BioSante special meeting regardless of any change in the recommendation of the BioSante board of directors.

These provisions might discourage an otherwise interested third party from considering or proposing an acquisition of BioSante, even one that may be deemed of greater value than the merger to BioSante stockholders. Furthermore, even if a third party elects to propose an acquisition, the concept of a termination fee or payment of the other party's expenses may result in that third party offering a lower value to BioSante stockholders than such third party might otherwise have offered.

Because the lack of a public market for ANI's outstanding shares makes it difficult to evaluate the fairness of the merger, ANI stockholders may receive consideration in the merger that is greater than the fair market value of the ANI shares.

ANI is privately held and its outstanding capital stock is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of ANI or its shares of capital stock. Since the percentage of BioSante's equity to be issued to the ANI stockholders was determined based on negotiations between the parties, it is possible that the value of the BioSante common stock to be issued in connection with the merger will be greater than the fair market value of ANI.

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BioSante may not issue CVRs and, even if issued, the CVRs will not be certificated or transferable and may not result in any cash payments to holders of CVRs.

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to BioSante stockholders, there is no assurance that the CVRs will be issued. BioSante currently has not entered into the contingent value rights agreement and the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the anticipated tax impact of the distribution and issuance of the CVRs to the BioSante stockholders. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as currently contemplated may be changed prior to BioSante entering into the contingent value rights agreement. Even if CVRs are issued, they will not be certificated or transferable and may not result in any cash payments to holders of CVRs. Under the contingent value rights agreement, the combined company will not have any obligation, other than an obligation to act in good faith to pursue, engage in, negotiate, enter into or consummate an actual or potential LibiGel transaction (as such term is defined in the contingent value rights agreement).

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 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, other than the issuance of an aggregate of 1,784,070 shares of our common stock to two of the holders of our convertible senior notes in exchange for cancellation of $3,504,150 in aggregate principal amount of such notes and accrued and unpaid interest of $20,686, which shares were issued in a transaction exempt from the registration requirements of the Securities Act by virtue of the exemption provided for in Section 3(a)(9) of the Securities Act for securities exchanged by the issuer with an existing security holder. No commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended September 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

On October 16, 2012, we entered into an amendment to our development and license agreement with Teva Pharmaceuticals USA, Inc. 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.

ITEM 6. EXHIBITS

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

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Exhibit No.	Description
1.1	Placement Agent Agreement dated August 16, 2012 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC (Incorporated

	by reference to Exhibit 1.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812))
4.1	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the investor in the August 2012 registered direct offering (Incorporated by reference to Exhibit 4.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812))
10.1	Form of Securities Purchase Agreement dated August 16, 2012 between BioSante Pharmaceuticals, Inc. and the investor in the August 2012 registered direct offering (Incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812))
10.2	Development and License Agreement dated December 27, 2002 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc. (Filed herewith)
10.3	First Amendment to Development and License Agreement dated March 13, 2003 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc. (Filed herewith)
10.4	Letter Amendment dated June 4, 2007 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc. (Filed herewith)
10.5	Third Amendment to Development and License Agreement dated as of October 16, 2012 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc. (Filed herewith)
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
101	The following materials from BioSante Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 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.

November 8, 2012

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer
(principal executive officer)

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

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EXHIBIT INDEX

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10.4	Letter Amendment dated June 4, 2007 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc.	Filed herewith
10.5	Third Amendment to Development and License Agreement dated as of October 16, 2012 between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc.	Filed herewith
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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

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Exhibit No.	Description	Method of Filing
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from BioSante Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

DEVELOPMENT AND LICENSE AGREEMENT

between

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road, North Wales, PA 19454
("Teva")

and

BIOSANTE PHARMACEUTICALS, INC.
111 Barclay Boulevard, Lincolnshire, IL 60069
("BioSante")

WHEREAS, BioSante is engaged in the development of pharmaceutical products and has in development the pharmaceutical product listed in **Annex A** hereto (the "Product" as defined further below);

WHEREAS, Teva, together with its Affiliates (as defined below), is engaged in the development, manufacture, sale, marketing and distribution of pharmaceutical products;

WHEREAS, BioSante desires to grant to Teva an exclusive license to the Product Know-How (as defined below) so that Teva may register, obtain Approval for, manufacture, market, sell and distribute the Product in the United States, all in accordance with and subject to the conditions set forth in this Agreement;

NOW THEREFORE, intending to be legally bound hereby and in consideration of the mutual representations, warranties and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, IT IS HEREBY AGREED BY THE PARTIES AS FOLLOWS:

1. INTERPRETATION AND DEFINITIONS

1.1 The preamble to this Agreement forms an integral part hereof.

1.2 Section headings in this Agreement are intended solely for convenience of reference and should be given no effect in the interpretation of this Agreement.

1.3 All annexes to this Agreement, signed by both Parties, whether attached at the time of signature hereof or at any time thereafter, should be construed as an integral part of this Agreement.

1.4 For the purposes of this Agreement, the following words and phrases shall bear the respective meanings assigned to them below (and cognate expressions shall bear corresponding meanings):

1.4.1 "**Affiliates**" — shall mean with respect to either Party, any Person that is controlled by, controls, or is under common control with that Party. For this purpose, "control" of a corporation or other business entity shall mean direct or indirect beneficial ownership of more than fifty percent (50%) of the voting interest in, or more than fifty percent (50%) in the equity of, or the right to appoint more than fifty percent (50%) of the directors or management of such corporation or other business entity.

1.4.2 "**ANDA**" — shall mean an Abbreviated New Drug Application filed with the FDA pursuant to its rules and regulations.

1.4.3 "**Applicable Law**" — shall mean the applicable laws, rules, regulations, guidelines and requirements related to the development, registration, manufacture, importation and Marketing of the Product in the Territory.

1.4.4 "**Approval(s)**" — shall mean any and all approvals, licenses, registrations or authorizations of the applicable Regulatory Authority necessary for the Marketing of the Product and reimbursement, if applicable, in the Territory.

1.4.5 "**Calendar Quarter**" — shall mean a three (3) consecutive month period ending on March 31, June 30, September 30 or December 31.

1.4.6 "**Competing Product**" — shall mean any finished pharmaceutical product for sale in the prescription drug marketplace that contains the same active ingredient in the same dosage form and strength as the Product.

1.4.7 "**Confidential Information**" — shall mean all information, data and/or know-how disclosed by either Party and/or its Affiliates to the other Party and/or its Affiliates in writing (or if disclosed orally, visually and/or in another non-written form, identified as confidential at the time of disclosure, and summarized in reasonable detail in writing as to its general content within thirty (30) days after original disclosure) concerning the Product or concerning the technology, marketing strategies or business of the disclosing Party (whether disclosed prior to or subsequent to the Effective Date). Confidential Information shall not include information, data or know-how that the receiving Party can show:

(a) was in the public domain at the time of the disclosure by the disclosing Party, or thereafter becomes part of the public domain without any fault of the receiving Party;

(b) rightfully was in its possession prior to the disclosure by the disclosing Party;

(c) was lawfully obtained from a third party, who had the right to make such disclosures as evidenced by written records; or

(d) was developed by it independently of such disclosure as evidenced by written records.

1.4.8 "**Effective Date**" — shall mean the date on which this Agreement is signed by the latter of the Parties to sign this Agreement.

1.4.9 "**FDA**" — shall mean the United States Food and Drug Administration and all agencies under its direct control or any successor organization.

1.4.10 "**Force Majeure Events**" — shall have the meaning set forth in Section 16.

1.4.11 "**Launch Date**" — shall mean the date on which Teva makes its first commercial sale of the Product to an unrelated third party in an arms-length transaction in the Territory.

1.4.12 "**Market**" — shall mean to promote, distribute, market, advertise and/or sell.

1.4.13 "**Marketing Term**" — shall mean a period of ten (10) years from the Launch Date of the Product in the Territory, unless terminated prior to such date as expressly provided for in this Agreement.

1.4.14 "**Net Sales**" — shall mean the gross amount invoiced for the Product by Teva or Teva's Affiliates sold on an arms-length basis in the Territory, less the sum of: (a) trade, quantity and/or cash discounts, allowances, rebates, retroactive price adjustments, free goods, bad debts, cash incentive payments (e.g. slotting allowance), and chargebacks; (b) credits or refunds for rejected, outdated or returned Product; (c) any tax, duty or other government charge upon or related to the sale, delivery or use of that Product; (d) cost of short dated Product, which is destroyed by Teva or its Affiliates; and (e) other specifically identifiable amounts included in the Product's gross sales that will have been or ultimately will be credited and are substantially similar to those listed above; in each case determined in accordance with U.S. GAAP.

1.4.15 "**Party**", "**Parties**" — shall mean Teva and/or BioSante, as applicable.

1.4.16 "**Person**" — shall mean any individual, partnership, association, corporation, limited liability company, trust, or other legal person or entity.

1.4.17 "**Product**" — shall mean the finished pharmaceutical product listed in Annex A developed by BioSante.

1.4.18 "**Product Know-How**" — shall mean the Regulatory Documentation, Technical Package and any and all other proprietary methods, devices, technology, trade secrets, inventions, patent applications, patents,

compositions, designs, formulae, know-how, show-how, technical and training manuals and documentation and other information, including processes and analytical methodologies used in development, testing, analysis and manufacture, and medical, clinical testing as well as other scientific testing, related to or used in connection with the Product or any ingredient thereof, and/or the formulation, development, registration, manufacture, use or sale thereof, in BioSante's (or its Affiliates') possession or under its control whether now known or hereafter developed or otherwise acquired, directly or indirectly.

1.4.19 "**Regulatory Authority**" — shall mean any and all governmental bodies, organizations and agencies whose approval is necessary to develop, manufacture, import, use, and/or Market the Product in the Territory.

1.4.20 "**Regulatory Documentation**" — shall mean all submissions to Regulatory Authorities, including clinical studies, tests, and biostudies relating to the Product, including, without limitation, all ANDAs, 505(b)(2) applications, and DMFs, as well as all correspondence with Regulatory Authorities (registration and licenses, regulatory drug lists, advertising and promotion documents), adverse event files, complaint files, manufacturing records and inspection reports.

1.4.21 "**Regulatory Expenses**" — shall mean all reasonable out-of-pocket direct costs and expenses in connection with preparing, submitting, obtaining and maintaining Approvals of the Product.

1.4.22 "**Royalties**" — shall mean an amount equal to seven and one half percent (7.5%) of Net Sales; provided, however, that during the period of time that Teva is the sole marketer of a generic 1% testosterone gel AB-rated to AndroGel® in the Territory such amount shall be equal to ten percent (10%) of Net Sales.

1.4.23 "**Technical Package**" — shall have the meaning set forth in Section 2.4.

1.4.24 "**Term**" — shall mean the duration of this Agreement starting on the Effective Date and continuing until the end of the Marketing Term, unless terminated prior to such date pursuant to Section 12.

1.4.25 "**Territory**" — shall mean the U.S.

1.4.26 "**U.S.**" — shall mean the United States of America and its territories, districts and possessions.

1.4.27 "**U.S. GAAP**" — shall mean generally accepted accounting principles in the U.S., consistently applied.

2. GRANT OF RIGHTS

2.1 BioSante, for itself and its Affiliates, grants to Teva and its Affiliates in accordance with the terms and conditions of this Agreement, the exclusive right (even as to BioSante and its Affiliates), under all of the existing or future Product Know-How owned or controlled by BioSante or its Affiliates, to register, make or have made, develop, import/export or have imported/exported, use or have used, Market, offer for sale or have sold, and otherwise exploit the Product on a sole and exclusive basis (even as to BioSante and its Affiliates) in or for the Territory.

2.2 Neither BioSante nor its Affiliates shall, directly or indirectly, during the Term, Market the Product or cause or permit the Product to be Marketed in or for the Territory, except as otherwise may be specifically permitted by the terms of this Agreement.

2.3 BioSante and its Affiliates shall not, directly or indirectly, during the Term, disclose to any third party any Product Know-How, if such third party may or has the ability to use such Product Know-How to directly or indirectly Market a Competing Product in or for the Territory.

2.4 BioSante shall provide to Teva by no later than the Effective Date (a) all Regulatory Documentation in BioSante's (or its Affiliates') possession or under its control; and (b) all technical information, data and know-how in BioSante's (or its Affiliates') possession or under its control with respect to the Product, including, without limitation, any and all raw material, work in process and samples related to the Product, useful or necessary for Teva or its nominee to continue the development of the Product and to set up a facility for the commercial manufacture of the Product (the "**Technical Package**"). BioSante shall promptly forward to Teva any such Regulatory Documentation and/or Technical Package materials that should later become available to BioSante during the Term of this Agreement.

2.5 Teva shall have the right to subcontract, in whole or in part, the manufacturing of the Product to a third party.

3. REGULATORY APPROVAL

3.1 Teva shall prepare the necessary Approval applications for the Product to obtain Approval of the Product in the Territory from the applicable Regulatory Authorities.

3.2 Teva shall use its commercially reasonable efforts customarily employed by Teva with respect to other generic drug products to conduct all tests and studies reasonably required to enable Teva to apply for, obtain and maintain Approval for the Product in the Territory.

3.3 Teva shall be responsible for all communications with the Regulatory Authorities relating to the Approval for the Product in the Territory. Teva shall provide to

BioSante copies of all Regulatory Documentation submitted to the Regulatory Authorities with respect to obtaining Approval for the Product.

3.4 Upon the request of BioSante, Teva shall provide BioSante with periodic updates (no more often than once per Calendar Quarter) concerning the development of the Product.

3.5 The Approval applications shall be filed in Teva's name and Teva shall be the sole and exclusive owner of such Approval applications and all Regulatory Documentation in connection therewith.

3.6 BioSante shall grant Teva reasonable and unrestricted access, without any charges, costs or expense, to any and all relevant documentation, data, information, tests, studies or know-how related to the Product, in its possession or under its control, and provide free of charge any and all assistance that Teva may reasonably request in order for Teva to obtain Approval for the Product in the Territory, and as necessary in connection with the manufacture and Marketing of the Product in or for the Territory.

3.7 Teva or its Affiliates shall be responsible for filing the Product, and thereafter processing such filing, with appropriate federal, state or private formularies in the Territory.

3.8 Each Party shall perform, or cause to be performed, its activities in furtherance of the provisions of this Section 3 in a good scientific manner, in compliance in all material respects with all requirements of Applicable Law, and in an efficient and expeditious manner.

3.9 Teva agrees that it will use its commercially reasonable efforts customarily used by Teva with respect to other generic drug products to Market the Product in the Territory.

3.10 Teva has the sole and exclusive right to determine all terms and conditions for the sale of the Product in the Territory, including the determination of timing of launch of the Product in the Territory, which timing of launch shall be consistent with that customarily used by Teva for other generic products.

3.11 Subject to pre-approval by Teva, Teva shall bear all Regulatory Expenses incurred by BioSante after July 1, 2002. Payments with respect to Regulatory Expenses shall be made by Teva within thirty (30) days following the end of each month and upon receipt of an invoice and all supporting documentation from BioSante.

3.12 Upon the request of BioSante, the Parties will discuss in good faith how Teva may provide assistance to BioSante in manufacturing the Product for sale outside the Territory.

4. TRADE MARK(S)

Teva and its Affiliates shall have the right, in their respective sole discretion and at their expense, to select and to register any of their trademarks, as they wish to employ in connection with the Marketing of the Product in the Territory and to Market Product using such trademarks. Teva or its Affiliates shall own all right, title and interest in and to all such trademarks, and BioSante hereby agrees it shall have no right, title or interest in same.

5. ROYALTIES

5.1 Commencing on the Launch Date for the Product in the Territory, Teva shall pay to BioSante the Royalties as set forth in Section 5.2 below.

5.2 No later than thirty (30) days after the end of each Calendar Quarter, Teva shall report to BioSante the Net Sales for the Product sold by Teva and/or its Affiliates in the Territory and the Royalties due to BioSante for such period. The payment of Royalties by Teva to BioSante shall be made within thirty (30) days after the end of each Calendar Quarter.

6. AUDITS

6.1 Teva and its Affiliates shall permit an independent certified public accounting firm selected by BioSante, and reasonably acceptable to Teva, to have access, during normal business hours and upon reasonable prior notice (not more often than once in any calendar year), to those books and records maintained by Teva necessary for BioSante to verify the accuracy of Teva's calculation of any Net Sales and Royalties hereunder for any period ending not more than two (2) years prior to the date of such request. All such information shall be retained on a confidential basis by the accounting firm, and such accounting firm's use of such information shall be limited to the aforementioned verification.

6.2 BioSante and its Affiliates shall permit an independent certified public accounting firm selected by Teva, and reasonably acceptable to BioSante, to have access, during normal business hours and upon reasonable prior notice (not more often than once in any calendar year), to those books and records maintained by BioSante necessary for Teva to verify the accuracy of BioSante's calculation of any Regulatory Expenses hereunder for any period ending not more than two (2) years prior to the date of such request. All such information shall be retained on a confidential basis by the accounting firm, and such accounting firm's use of such information shall be limited to the aforementioned verification.

6.3 Teva shall calculate and record Net Sales and Royalties in accordance with U.S. GAAP, and shall maintain all books and records related thereto in accordance with standard cost accounting policies and practices, in accordance with U.S. GAAP for the Term plus an additional three (3) years thereafter.

6.4 Each Party shall promptly supply the other Party with a copy of any notices or reports received from any Regulatory Authority related to an audit or other

investigation by the Regulatory Authority with respect to the Product. Each Party shall use its commercially reasonable best efforts to provide such Regulatory Authority with a prompt, accurate and complete response to any deficiencies noted, and to promptly address, and if necessary correct, any and all such deficiencies to the satisfaction of the Regulatory Authority.

7. MILESTONE PAYMENTS

In partial consideration of the rights granted herein and subject to the terms and conditions set forth in this Agreement, Teva shall be obligated to BioSante for the following milestone payments:

(a) One Million Five Hundred Thousand U.S. Dollars (U.S. $1,500,000) upon the Effective Date;

(b) One Million U.S. Dollars (U.S. $1,000,000) within thirty (30) days following acceptance by the FDA of the ANDA for the Product;

(c) One Million U.S. Dollars (U.S. $1,000,000) within thirty (30) days following final Approval by the FDA for the Product; and

(d) provided that Teva is the sole marketer in the Territory of a generic 1% testosterone gel AB-rated to AndroGel® for at least one hundred and eighty (180) days immediately following the Launch Date in the Territory, then, in such event, Teva shall pay to BioSante, within thirty (30) days following such one hundred and eighty (180) day period, an amount equal to Four Million U.S. Dollars (U.S. $4,000,000).

8. ADDITIONAL REPRESENTATIONS, WARRANTIES AND COVENANTS OF BIOSANTE

8.1 BioSante hereby represents and/or warrants and/or undertakes to Teva that:

8.1.1 it has the corporate authority to enter into this Agreement and to perform its obligations hereunder;

8.1.2 neither the execution and delivery of this Agreement by BioSante nor its performance hereunder conflicts with or results in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, bond, mortgage, indenture, license, agreement or other instrument or obligation to which it or any of its

Affiliates is a party or by which it or any of its Affiliates or any of their respective properties or assets may be bound, or to its best knowledge, violate any statute, law, rule, regulation, writ, injunction, judgment, order or decree of any court, administrative agency or governmental authority binding on it or any of its Affiliates or any of their respective properties or assets, excluding any such breaches or defaults that, individually and in the aggregate, would not have a material adverse effect on its business or financial condition;

8.1.3 this Agreement is a legal, valid and binding agreement of BioSante enforceable in accordance with its terms;

8.1.4 neither it nor any of its Affiliates have or will, directly or indirectly, enter into any contract or any other transaction with any third party or Affiliate that conflicts or derogates from its undertakings hereunder;

8.1.5 neither the Product nor the process for making the Product violates, infringes, or otherwise conflicts or interferes with the intellectual property rights of any third party in the Territory;

8.1.6 BioSante has furnished Teva with a complete copy of the Regulatory Documentation and Technical Package for the Product, and BioSante is and was, at all times prior to the Effective Date, the lawful holder of all rights under the Product Know-How; and

8.1.7 BioSante has the right, power and authority to grant the rights to Teva hereunder.

9. ADDITIONAL REPRESENTATIONS, WARRANTIES AND COVENANTS OF TEVA

9.1 Teva hereby represents and/or warrants and/or undertakes to BioSante that:

9.1.1 it has the corporate authority to enter into this Agreement and to perform its obligations hereunder;

9.1.2 neither the execution and delivery of this Agreement by Teva nor its performance hereunder conflicts with or results in any violation or breach of, or constitutes (with or without due notice or lapse of time or both) a default under any of the terms or conditions of any note, bond, mortgage, indenture, license, agreement or other instrument or obligation to which it is a party or by which it or any of its properties or assets may be bound, or to its best knowledge, violate any statute, law, rule, regulation, writ, injunction, judgment, order or decree of any court, administrative agency or governmental authority binding on it or any of its properties or assets, excluding any such breaches or defaults that, individually and in the aggregate, would not have a material adverse effect on its business or financial condition;

9.1.3 this Agreement is a legal, valid and binding agreement of Teva, enforceable in accordance with its terms; and

9.1.4 it has not and will not, directly or indirectly, enter into any contract or any other transaction with any third party or Affiliate that conflicts or derogates from its undertakings hereunder.

10. INDEMNIFICATIONS AND LIABILITY

10.1 BioSante shall indemnify, defend and hold Teva, its Affiliates, and their respective officers, directors, employees, and representatives harmless from and against any and all losses, liabilities, damages, costs and expenses, including reasonable attorney's fees and disbursements, (collectively, "**Damages**") in connection with any and all suits, investigations, claims or demands by third parties resulting from or arising out of: (a) any breach or alleged breach by BioSante (or its Affiliates) of any representation, warranty, undertaking or covenant in this Agreement ; or (b) any negligence or willful misconduct by BioSante (or its Affiliates).

10.2 Teva shall indemnify, defend and hold BioSante, its Affiliates, and their respective officers, directors, employees, and representatives harmless from and against any and all Damages as defined above in connection with any and all suits, investigations, claims or demands by third parties resulting from or arising out of: (a) any breach or alleged breach by Teva (or its Affiliates) of any representation, warranty, undertaking or covenant in this Agreement; (b) any negligence or willful misconduct by Teva (or its Affiliates); or (c) any claims of strict product liability, whether based on allegations of design defect or unreasonable dangerousness, if allegedly arising out of Teva's or its designees' actions related to the Product, including but not limited to the manufacturing or Marketing of the Product.

10.3 In the event that in determining the respective obligation of indemnification under this Section 10, it is found that the fault of BioSante, Teva or their respective Affiliates, contributes to any Damages relating to the Product supplied and/or distributed or sold hereunder, then each of BioSante and Teva shall be responsible for that portion of the Damages to which its fault contributed.

10.4 As soon as a Party becomes aware of the possibility of a claim involving indemnification under this Section 10, the indemnified Party shall give the indemnifying Party prompt written notice in writing and shall permit the indemnifying Party to have control over the defense of such claim or suit. The indemnified Party agrees to provide all reasonable information and assistance to the indemnifying Party in such defense. No such claims shall be settled other than by the Party defending the same, and then only with the consent of the other Party, which shall not be unreasonably withheld or delayed; provided, however, that the indemnified Party shall have no obligation to consent to any settlement of any such claim which imposes on the indemnified Party any liability or obligation which cannot be assumed and performed in full by the indemnifying Party.

10.5 Except in the event of and to the extent of Damages awarded to a third party in connection with the indemnification provisions set forth in Sections 10.1 and 10.2, above, neither Teva nor BioSante shall be liable to the other for special, indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise.

11. CONFIDENTIALITY

11.1 Each of the Parties agrees that: (a) it will not disclose any Confidential Information of the other to any third party at any time during the Term without the prior written consent of the disclosing Party; (b) it will not make use of any Confidential Information of the other Party for any purpose other than for the purposes set forth in, or in furtherance of the transactions contemplated by this Agreement; and/or (c) it will use all reasonable efforts to prevent unauthorized publication or disclosure by any person of such Confidential Information including requiring its employees, consultants or agents to enter into confidentiality agreements that require them to maintain Confidential Information in confidence to the same degree as its own confidential information.

11.2 Notwithstanding the foregoing, either Party may upon reasonable prior written notice to the other Party disclose Confidential Information as required by law or court order, except that upon receipt of any such request or requirement of law or court order, each Party agrees to promptly notify the other in order to give the other a reasonable opportunity to seek a protective order in the appropriate forum.

11.3 All Confidential Information in any form must be returned to the Party who disclosed the Confidential Information within thirty (30) days of the termination or expiration of this Agreement, save for the retention of one (1) copy of the Confidential Information by the receiving Party as a record of the receiving Party's ongoing confidentiality obligations under this Agreement.

11.4 Each of the Parties agrees that all Confidential Information that it receives from the other Party and/or its Affiliates in connection with the Product is the sole property of the disclosing Party and shall be used by it only in accordance with the terms and provisions of this Agreement.

11.5 This Section 11 shall be in effect during the Term and for a period of five (5) years following the termination or expiration thereof.

11.6 The Parties acknowledge that it is their intention to limit the disclosure of Confidential Information hereunder to the Product and matters directly related thereto.

12. TERM AND TERMINATION

12.1 Upon expiration of the Term, BioSante shall grant to Teva and its Affiliates a perpetual, fully paid, royalty free, exclusive license to manufacture and Market the Product in or for the Territory and to use any Product Know-How existing as of the date of such expiration necessary to enable Teva and/or its Affiliates to manufacture and/or Market the Product in or for the Territory.

12.2 This Agreement may be terminated by either Party by written notice provided to the other Party at any time during the Term if the other Party (the "**Breaching Party**") is in material breach or default of any of its obligations hereunder

(including, without limitation, any payment obligations) or any of its representations or warranties hereunder were untrue in a material respect when made, as follows: (i) the terminating Party shall send written notice of the material breach or material default to the Breaching Party, and (ii) the termination shall become effective sixty (60) days after written notice thereof was provided to the Breaching Party, unless the Breaching Party has cured any such material breach or default prior to the expiration of the sixty (60) day period or if such material breach or material default is not capable of being cured within such sixty (60) day period, and the Breaching Party has commenced activities reasonably expected to cure such material breach or material default within such sixty (60) day period and thereafter uses diligent efforts to complete the cure as soon as practicable, but in no event shall such period exceed ninety (90) days.

12.3 Subject to the provisions of Section 13.3 hereof, BioSante may terminate this Agreement effective upon issuance of written notice if, at any time, Teva files a petition in bankruptcy, or enters into an arrangement with its creditors, or applies for or consents to the appointment of a receiver or trustee, or makes an assignment for the benefit of creditors, or suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent.

13. CONSEQUENCES OF TERMINATION

13.1 Termination of this Agreement for whatever reason shall not affect the liabilities or obligations of the Parties hereunder in respect of matters accrued at the time of such termination, and shall be without prejudice to any other right or remedies available at law or in equity.

13.2 In the event of early termination of this Agreement by BioSante pursuant to Section 12.2 and without derogating from any other rights or remedies available to BioSante, all rights, Approvals and data shall be promptly returned to BioSante without charge, and Teva agrees to execute without delay all documentation necessary to effectuate this purpose.

13.3 All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of 11 U.S.C. §101 et seq. (the "**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that Teva, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights (including, without limitation, any right to enforce any exclusivity provision of this Agreement (including any embodiment of such "intellectual property")), remedies and elections under the Bankruptcy Code. To the fullest extent permitted by Applicable Law, the Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against BioSante under the Bankruptcy Code, Teva shall be entitled to all applicable rights under Section 365 of the Bankruptcy Code, including but not limited to, a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all

embodiments of such intellectual property upon written request therefore by Teva, and such, if not already in its possession, shall be promptly delivered to Teva.

14. INDEPENDENT CONTRACTORS

The status of the Parties under this Agreement shall be that of independent contractors. Nothing is this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties hereto. No Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any person that it has any such right or authority. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15. SUCCESSORS AND ASSIGNS

The terms and provisions hereof shall inure to the benefit of, and be binding upon, Teva, BioSante and their respective successors and permitted assigns. Neither Party shall assign this Agreement or any part of it to any third party without the prior written consent of the other Party, such consent not to be unreasonably withheld; provided, however, that either party may, without obtaining the consent of the other Party but upon written notice to the other Party, assign this Agreement or delegate any of its rights or obligations hereunder to any of its Affiliates.

16. FORCE MAJEURE

16.1 Neither Party shall be liable for non-performance or delay in the fulfillment of its obligations when any such non-performance or delay shall be occasioned by any unforeseeable cause beyond the reasonable control of Teva or BioSante, as the case may be, including without limitation, acts of God, fire, flood, earthquakes, explosions, sabotage, strikes, or labor disturbances (regardless of the reasonableness of the demands of the labor force), civil commotion, riots, military invasions, wars, failure of utilities, failure of carriers, or any acts, restraints, requisitions, regulations, or directives issued by a competent government authority not engendered by any act or omission of the Party ("**Force Majeure Events**").

16.2 In the event that either Party is prevented from discharging its obligations under this Agreement on account of a Force Majeure Event, such Party shall notify the other forthwith, and shall nevertheless make every endeavor, in the utmost good faith, to discharge its said obligations, even if in a partial or compromised manner.

17. CURRENCY

All payments under this Agreement shall be made in U.S. Dollars and, as applicable, the calculation of exchange rates shall be based upon the average over a twenty (20) business day period preceding the date that payment is due of the applicable rate of exchange as published in the Wall Street Journal.

18. PUBLICITY AND DISCLOSURE OF AGREEMENT

Concurrently with the execution of this Agreement, the Parties shall agree in good faith on a form of press release that BioSante may release. The Parties agree that no future press releases or other public announcements concerning the transactions contemplated hereby shall be issued without the advance written consent of the other Party, which consent shall not be unreasonably withheld, to the extent such release or announcement includes statements concerning terms of this Agreement and/or explicitly includes the Product or either Parties' name(s), except to the extent such release or announcement may be required by Applicable Law. For releases or announcements required by law, the Party making the release or announcement shall, before making any such release or announcement, afford the other Party a reasonable opportunity to review and comment. Any copy of this Agreement to be filed with the Securities and Exchange Commission or any other Regulatory Authority shall be redacted to the fullest extent permitted by Applicable Law and to the reasonable satisfaction of both Parties; provided, however, in the event that the Securities and Exchange Commission or Regulatory Authority, as applicable, objects to the redaction of any portion of the Agreement after the initial submission, the filing Party shall inform the other Party of the objections and shall in good faith respond to the objections in an effort to limit the disclosure required by the Securities and Exchange Commission or Regulatory Authority, as applicable.

19. SEVERABILITY

Should any part or provision of this Agreement be held unenforceable or in conflict with Applicable Law, the invalid or unenforceable part or provision shall, provided that it does not go to the essence of this Agreement, be replaced with a revision which accomplishes, to the extent possible, the original commercial purpose of such part or provision in a valid and enforceable manner, and the balance of this Agreement shall remain in full force and effect and binding upon the Parties hereto.

20. ENTIRE AGREEMENT

This Agreement (including its Annexes) constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all prior agreements, arrangements, dealings or writings between the Parties. This Agreement may not be amended or modified except in writing executed by the duly authorized representatives of both Parties.

21. WAIVER

No waiver of a breach or default hereunder shall be considered valid unless in writing and signed by the Party giving such waiver, and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature.

22. GOVERNING LAW

This Agreement shall be governed, interpreted and construed in accordance with the laws of the Commonwealth of Pennsylvania, without regard to principles of conflicts of law. To the extent that it may otherwise be applicable, the Parties hereby expressly agree to exclude from the operation of this Agreement the United Nations Convention on Contracts for the International

Sale of Goods, concluded at Vienna, on 11 April 1980, as amended and as may be amended further from time to time.

23. NOTICES

Notices provided for under this Agreement shall be given in writing, in English, by facsimile; by first-class mail, federal express or similar service to the mailing address or facsimile numbers set out below:

If to Teva

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, PA 19454
Attention: President
Telephone: 215-591-3000
Facsimile: 215-591-8846

With a copy to:

TEVA NORTH AMERICA
1090 Horsham Road
North Wales, Pennsylvania 19454
Attention: Vice President and General Counsel
Teva North America
Telephone: (215) 591-3000
Facsimile: (215) 591-8813

If to BioSante

BIOSANTE PHARMACEUTICALS, INC.
Stephen Simes
111 Barclay Boulevard
Lincolnshire, IL 60069
Telephone: 847 478-0500, ext 100
Facsimile: 847 478-9260

With a copy to:

GARY I. LEVENSTEIN
Ungaretti & Harris
3500 Three First National Plaza
Chicago, Illinois 60602-4283
Telephone: 312 977-4400
Facsimile: 312 977-4405

or to such other addresses or facsimile numbers as a Party shall designate by notice, similarly given, to the other Party. Notices shall be deemed to have been sufficiently given and served the day transmitted by facsimile (with confirmed transmission) or a date five (5) business days after the date of express mail or by mail courier.

24. RESOLUTION OF DISAGREEMENTS

If disagreements should arise under this Agreement, both BioSante and Teva agree to make good faith efforts to resolve the disagreements by discussion and negotiation. Any disagreements in

connection with this Agreement or a Party's alleged breach of this Agreement that either Party believes has not been satisfactorily resolved through discussion and negotiation shall be resolved upon the written notice of either Party to the other requesting final and binding arbitration. If initially requested by Teva, the arbitration shall be held in Chicago, Illinois. If initially requested by BioSante, the arbitration shall be held in a location of Teva's selection within the Commonwealth of Pennsylvania. Such arbitration shall be before three (3) arbitrators, where each Party shall select one (1) arbitrator and the two (2) selected shall choose the third, and conducted under the Commercial Arbitration Rules of the American Arbitration Association. The prevailing Party in any such arbitration shall be entitled to recover only reasonable out-of-pocket costs of the arbitration (not attorney's fees) in addition to any award determined by the arbitrators. Any award rendered in such arbitration may be entered and enforced by either Party in any court having jurisdiction.

25. STEERING COMMITTEE

The Parties agree that a Steering Committee, comprised of two (2) representatives of each Party, shall be formed within thirty (30) days of the Effective Date and shall work cooperatively, and meet from time to time as it shall deem desirable, with the goals of effectuating smooth and prompt implementation of the Parties' obligations under this Agreement and avoidance and resolution of disagreements between the Parties; and to provide updates of information as provided for in this Agreement.

IN WITNESS WHEREOF, each of the Parties has executed this Agreement and Annexes as of the date below.

TEVA PHARMACEUTICALS USA, INC. BIOSANTE PHARMACEUTICALS, INC.

Signature:	/s/ George S. Barrett	Signature:	/s/ Stephen M. Simes
Name:	George S. Barrett	Name:	Stephen M. Simes
Title:	President & CEO	Title:	President & CEO
Date:	December 23, 2002	Date:	12/27/02

ANNEX A

The Product

1% testosterone gel AB-rated to AndroGel®

FIRST AMENDMENT TO DEVELOPMENT AND LICENSE AGREEMENT
("First Amendment")

between

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road, North Wales, PA 19454
("Teva")

and

BIOSANTE PHARMACEUTICALS, INC.
111 Barclay Boulevard, Lincolnshire, IL 60069
("BioSante")

WHEREAS, Teva and BioSante entered into a Development and License Agreement with an effective date of December 27, 2002 ("**the Agreement**");

WHEREAS, subsequent to signature of the Agreement, the Parties have concluded that additional regulatory and legal work may be required;

WHEREAS, Teva and BioSante desire to amend the Agreement as their sole remedy for the changed circumstances of which they are both now aware, and in order to continue working together;

WHEREAS, in consideration of the mutual covenants set forth herein and for other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, BioSante and Teva agree to amend certain provisions of the Agreement pursuant to this First Amendment;

WHEREAS, any defined terms used in this First Amendment shall have the same meaning as set out in the Agreement;

NOW THEREFORE, Teva and BioSante agree to amend the Agreement as set forth below.

1. The definition of "**Product**" in Section 1.4.17 of the Agreement shall be deleted in its entirety and replaced with the following:

   "**Product**" — shall mean the finished pharmaceutical product listed in **Annex A** developed in whole or in part by BioSante.

2. The definition of "**Royalties**" in Section 1.4.22 of the Agreement shall be deleted in its entirety and replaced with the following:

   "**Royalties**" — shall mean the following:

   (a) In the event that Teva launches the Product using a formulation developed solely by BioSante, an amount equal to seven and one half percent (7.5%) of Net Sales; provided, however, that during the period of time that Teva Markets such formulation and is the sole marketer of a generic 1% testosterone gel AB-rated to AndroGel® in the Territory such amount shall be equal to ten percent (10%) of Net Sales.

   (b) In the event that Teva launches the Product using a formulation that was not developed solely by BioSante, an amount equal to five percent (5%) of Net Sales; provided, however, that during the period of time that Teva Markets such formulation and is the sole marketer of a generic 1% testosterone gel AB-rated to AndroGel® in the Territory such amount shall be equal to seven and one half percent (7.5%) of Net Sales.

3. The following shall be added as Section 2.6:

   2.6 All data, information and know-how developed by Teva and/or its Affiliates with or without the assistance of BioSante in connection with the Product shall be owned solely and exclusively by Teva.

4. Section 3.11 shall be deleted in its entirety and replaced with the following:

   3.11 Subject to pre-approval by Teva, Teva shall reimburse BioSante for all Regulatory Expenses incurred by BioSante after July 1, 2002; provided, however, that Teva shall have no obligation to reimburse BioSante for any Regulatory Expenses related to a formulation for the Product based in whole or in part on information, data or expertise not contained in the Technical Package provided to Teva by BioSante on or before the Effective Date. Payment with respect to Regulatory Expenses recoverable by BioSante under this Section 3.11 shall be made by Teva within thirty (30) days following receipt of an invoice and all supporting documentation from BioSante.

5. Section 3.12 shall be renumbered to Section 3.13 and the following shall be added as Section 3.12:

   3.12 Teva shall bear its own Regulatory Expenses; provided, however, that following launch of the Product in the Territory, Teva shall reduce the Royalties payable to BioSante hereunder by an amount equal to any and all Regulatory Expenses incurred by Teva and/or its Affiliates related to developing a formulation for the Product based in whole or in part on information, data or expertise not contained in the Technical Package provided to Teva by BioSante on or before the Effective Date. For the sake of clarification, the foregoing reduction shall apply only in the event that such formulation is used for the Product.

6. Section 5.2 shall be renumbered to Section 5.3 and the following shall be added as Section 5.2:

5.2 If a third party institutes a patent infringement suit or similar proceeding against Teva, its Affiliates and/or its subcontractors during the Term of this Agreement, which suit alleges that the filing of the ANDA for the Product and/or the manufacturing, Marketing, use, sale or offers for sale of the Product in the Territory infringes one or more patents owned by or licensed to such third party ("**Patent Suit**"), then Teva shall assume direction, control and disposition of the defense of claims arising therefrom. BioSante shall provide, at its sole cost and expense, any and all assistance that Teva may reasonably request relating to such Patent Suit. Teva shall advance all legal fees, expenses and reasonable settlement payments incurred by Teva and/or its Affiliates in connection with such Patent Suit ("**Legal Expenses**"). Following launch of the Product in the Territory, Teva shall be entitled prior to any payment to BioSante either under Section 5 (Royalties) or Section 7(d) (Milestone Payments), to recoup all reasonable Legal Expenses and shall reduce any such payments due until it is fully reimbursed such Legal Expenses. Nothing contained in this Section 5.2 is meant to derogate from BioSante's representations and warranties and covenants as contained in Section 8 or its indemnification obligations as contained in Section 10.

7. Subsections. (b) and (c) of Section 7 relating to milestone payments shall be deleted in their entirety and replaced with the following:

(b) provided that a Patent Suit has not been instituted against Teva and/or its Affiliates and/or its subcontractors, One Million U.S. Dollars (U.S. $1,000,000) within thirty (30) days following the Launch Date;

(c) provided that a Patent Suit has not been instituted against Teva and/or its Affiliates and/or its subcontractors, One Million U.S. Dollars (U.S. $1,000,000) one hundred and twenty (120) days following the Launch Date; and

8. The following shall be added to the end of Section 7:

; provided, however, that in the event that a Patent Suit is instituted against Teva and/or its Affiliates and/or its subcontractors following payment by Teva of the milestone payments set forth in subsections (b) or (c), above, BioSante shall reimburse to Teva the applicable milestone payment within thirty (30) days following written request by Teva.

9. The Parties agree that the following shall be added as Section 26 of the Agreement:

26. **PERIODIC REPORTS/RIGHT TO AUDIT**

Teva shall provide quarterly reports to BioSante of any Regulatory Expenses and/or Legal Expenses incurred by Teva, which BioSante must reimburse to Teva pursuant to Sections 3.12 and/or 5.2 herein. Teva shall permit an independent certified auditor selected by BioSante and reasonably acceptable to Teva to have access, during normal business hours and upon reasonable prior notice, to those books and records maintained by Teva reasonably necessary for BioSante to verify the accuracy of any such Regulatory Expenses and/or Legal Expenses; provided, however, that BioSante agrees to preserve the confidentiality of all

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privileged or confidential information. Any such independent audit shall be performed at BioSante's sole cost and expense.

10. The Parties agree that save as expressly provided for herein all terms and conditions of the Agreement shall remain in full force and effect and that this First Amendment shall form an integral part of the Agreement.

IN WITNESS WHEREOF, each of the Parties has executed this First Amendment as of the date below.

the date below.

TEVA PHARMACEUTICALS USA, INC.		BIOSANTE PHARMACEUTICALS, INC.	
Signature:	/s/ Richard Egosi	Signature:	/s/ Stephen M. Simes
Name:	Richard Egosi	Name:	Stephen M. Simes
Title:	V.P. General Counsel	Title:	President & CEO
Date:	March 11, 2003	Date:	3/13/03

TEVA

Administrative Offices;
TEVA PHARMACEUTICALS USA
1090 Horsham Road, PO Box 1090
North Wales, PA 19454-1090

Phone: (215) 591-3000
Toll Free: 888 TEVA USA

Mr. Stephen Simes
President & CEO
BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, IL 60069

Re: Development and License Agreement between Teva Pharmaceuticals USA, Inc. ("Teva") and BioSante Pharmaceuticals, Inc. ("BioSante") effective December 27, 2002, as amended (the "Agreement").

Dear Mr. Simes:

This letter will confirm that effective as of the date of your countersignature below ("**Reactivation Date**"), Teva and BioSante have mutually agreed that they will reactivate the Agreement and reactivate the development of a generic 1% testosterone gel product under the terms and conditions of the Agreement, as further amended as follows:

(1) The following shall be added as a new definition to Section 1.4:

"**Commercially Reasonable Efforts**" — shall mean with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, reasonable, diligent, good-faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances exercising reasonable business judgment, it being understood and agreed that, with respect to the development, manufacture and commercialization of the Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential as the Product, taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Product, the likelihood of regulatory approval given the regulatory structure involved, the profitability, and other relevant factors commonly considered in similar circumstances. It is anticipated that the level of effort may change over time, reflecting changes in the status of the Product.

(2) The term "commercially reasonable efforts" as used throughout the Agreement shall be deleted in its entirety and replaced with "Commercially Reasonable Efforts."

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(3) Section 3.9 of the Agreement shall be deleted in its entirety and replaced with the following:

Teva shall use Commercially Reasonable Efforts to file an ANDA for the Product. Following the Launch Date, Teva shall use Commercially Reasonable Efforts to Market the Product in the Territory.

(4) Section 3.11 shall be deleted in its entirety and replaced with "[intentionally left blank]."

(5) Section 3.12 of the Agreement shall be deleted in its entirety and replaced with the following:

Each Party shall bear its own Regulatory Expenses.

(6) Section 5.2 of the Agreement shall be deleted in its entirety and replaced with the following:

If a third party institutes a patent infringement suit or similar proceeding against Teva, its Affiliates and/or its subcontractors during the Term of this Agreement, which suit alleges that the filing of the ANDA for the Product and/or the manufacturing, Marketing, importation, use, sale or offers for sale of the Product in the Territory infringes one or more patents owned by or licensed to such third party ("**Patent Suit**"), then Teva shall assume direction, control and disposition of the defense of claims arising therefrom. BioSante shall provide, at its sole cost and expense, any and all assistance that Teva may reasonably request relating to such Patent Suit. Teva shall initially bear all legal fees, expenses and reasonable settlement payments incurred by Teva and/or its Affiliates in connection with such Patent Suit ("**Legal Expenses**"); provided, however, that following the launch of the Product in the Territory, Teva shall be entitled prior to any payment to BioSante under Section 5 (Royalties) to deduct the amount of any and all such Legal Expenses from Net Sales. Teva shall permit an independent certified auditor selected by BioSante and reasonably acceptable to Teva to have access, during normal business hours and upon reasonable prior notice, to those books and records maintained by Teva reasonably necessary for BioSante to verify, on a one time basis, the accuracy of any such Legal Expenses; provided, however, that BioSante agrees to preserve the confidentiality of all privileged or confidential information. Any such independent audit shall be performed at BioSante's sole cost and expense. Nothing contained in this Section 5.2 is meant to derogate from BioSante's representations and warranties and covenants as contained in Section 8 or its indemnification obligations as contained in Section 10.

(7) The following sentence shall be added to the end of Section 7 of the Agreement:

Notwithstanding the foregoing, following the launch of the Product in the Territory, and provided BioSante has not previously reimbursed Teva for the milestone payments as a result of a Patent Suit, Teva shall be entitled prior to any payment to BioSante under Section 5 (Royalties) to deduct the amount of any and all milestone payments paid by Teva to BioSante under subsections (b) and (c), above, from Net Sales.

(8) The following Sections 12.4, 12.5 and 12.6 shall be added to the Agreement:

12.4 Teva shall have the right, at its sole option, to terminate this Agreement immediately upon written notice to BioSante in the event that any pilot or pivotal bioequivalence study for the Product, completed subsequent to the Reactivation Date, fails to demonstrate bioequivalence of the Product to the branded product AndroGel® to the reasonable satisfaction of Teva consistent with FDA bioequivalence standards and prevailing standards of statistical methods. In such event, subject to the provisions of Section 12.6, Teva shall grant to BioSante a perpetual, worldwide, semi-exclusive license to all data, information and know-how developed by Teva, as referenced in Section 2.6, including but not limited to biostudy reports and other clinical data related to the Product (the "**Teva License**") to be used by BioSante to Market the Product. For purposes of the definition of "Teva License", "semi-exclusive" shall mean that Teva and/or its Affiliates (or a third party on their behalf) shall have the right to use such Teva data, information and know-how for any purpose whatsoever. For the avoidance of doubt, Teva acknowledges and agrees that following the termination of this Agreement for any reason, except as expressly set forth in this Agreement, Teva shall not be permitted to use for any purpose BioSante's Confidential Information contained in the Technical Package provided to Teva by BioSante on or before the Effective Date.

12.5 Teva shall have the right to terminate this Agreement, upon ninety (90) days prior written notice to BioSante, in the event that Teva determines, in its sole discretion, that the continued development and/or Marketing of the Product is no longer commercially viable. In the event that Teva exercises such termination right, subject to the provisions of Section 12.6, Teva shall grant to BioSante the Teva License to Market the Product.

12.6 In the event that Teva grants to BioSante the Teva License under Sections 12.4 or 12.5, then if BioSante, its Affiliate or a third party pursuant to an arrangement with BioSante subsequently launches or sells a generic 1% testosterone gel product AB Rated to AndroGel® in the Territory, BioSante shall pay to Teva, on a quarterly basis, five percent (5%) of all consideration received by BioSante or its Affiliates as a result of the commercial sale of such product until such time that

Teva has been paid either (a) Three Million Five Hundred Thousand U.S. Dollars (U.S. $3,500,000) if (i) Teva did not file an ANDA for the Product, or (ii) Teva filed an ANDA for the Product and a Patent Suit was not instituted against Teva and/or its Affiliates and/or its subcontractors, or (b) Five Million U.S. Dollars (U.S. $5,000,000) if Teva filed an ANDA for the Product and a Patent Suit was instituted against Teva and/or its Affiliates and/or its subcontractors. For purposes of this Section 12.6, "consideration" shall mean, by way of example and not limitation, net sales (calculated in the same manner as Net Sales hereunder), and all royalties, milestone payments, and other payments, but shall not include reimbursement of costs and expenses or payments for the costs of goods and/or services.

(9) Section 26 of the Agreement shall be deleted in its entirety.

(10) Upon the Reactivation Date, both the notice of termination provided by Teva by letter of February 9, 2005 to BioSante and Section 4 of the letter of July 27, 2005 provided by Teva to BioSante shall be considered null and void. However, BioSante and Teva each fully and forever releases, acquits and discharges the other Party and its predecessors, successors, assigns, Affiliates, officers and directors from any and all claims, demands, obligations, losses, damages, promises, costs, expenses, liabilities and causes of action of any nature whatsoever, whether in law or in equity, whether direct or indirect, whether known or unknown, whether fixed or contingent, whether suspected or unsuspected, relating to or arising out of (a) the contents and the disclosure to BioSante of the Teva Data (as defined in the July 27, 2005 letter) and (b) the performance or non-performance by either party under the Agreement prior to the Reactivation Date. Notwithstanding the foregoing, BioSante shall continue to be bound by its obligations of confidentiality with respect to the Teva Data and shall be responsible for the breach of any such obligations by itself or any third party to whom BioSante provided the Teva Data under Section 2 of the July 27, 2005 letter.

Please sign below as your confirmation of the foregoing, and return a signed copy of this letter to me via facsimile at (215) 591-8811.

Best regards,

/s/ John C. James

John C. James
Vice President, Alliance Management

By: /s/ not legible
Its: _____

Acknowledged and Agreed
this 4th day of June, 2007

BioSante Pharmaceuticals, Inc.

By:	/s/ Stephen M. Simes	/s/ Phillip B Donenberg	
Its:	President & CEO	CFO	6/4/07

THIRD AMENDMENT TO DEVELOPMENT AND LICENSE AGREEMENT

THIS AMENDMENT TO DEVELOPMENT AND LICENSE AGREEMENT ("Third Amendment"), is entered into as of the Third Amendment Effective Date (as defined below), by and between Teva Pharmaceuticals USA, Inc. ("Teva") and BioSante Pharmaceuticals, Inc. ("BioSante"), and amends certain terms of the Agreement (as defined below).

BACKGROUND

WHEREAS, Teva and BioSante entered into a Development and License Agreement on December 27, 2002 (as amended by the First Amendment and the 2007 Letter Agreement (each as defined below), the "Agreement");

WHEREAS, Teva and BioSante amended certain terms of the Agreement pursuant to the First Amendment to Development and License Agreement (dated March 13, 2003) (the "First Amendment"), and further amended certain terms of the Agreement pursuant to the letter agreement dated June 4, 2007 (the "2007 Letter Agreement"); and

WHEREAS, Teva and BioSante desire to amend certain terms of the Agreement as set forth in this Third Amendment.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby mutually acknowledged, Teva and BioSante agree as follows:

1. Definitions. All terms used and not otherwise defined in this Third Amendment shall have the same meanings ascribed to them in the Agreement.

2. Payment**.** In full and complete consideration for the agreements set forth in this Third Amendment, within five (5) business days following the date the later of the two parties signs and delivers to the other party this Third Amendment (the "Third Amendment Effective Date"), Teva shall make a one-time payment to BioSante of One Million Dollars (US$1,000,000).

3. Amendment. The Agreement is hereby amended as follows:

A. Sections 7(b) and (c) (as amended by the First Amendment) are hereby deleted in their entirety, Section 7(d) is hereby re-lettered as Section 7(e), and the following new Sections 7(b), (c) and (d) shall be added to the Agreement:

"(b) Five Hundred Thousand U.S. Dollars (US$500,000) if the FDA authorizes marketing of the Product as an "AB-rated" equivalent to AndroGel®;

(c) Seven Hundred Fifty Thousand U.S. Dollars (US$750,000) upon the earlier to occur of (i) December 31, 2012 and (ii) five (5) business days after Teva's submission to the FDA of a final report regarding the clinical study required by the FDA and titled "A Clinical Study to Evaluate the Effects of Washing the Application Site on Residual Concentrations of Testosterone Following Single Topical Applications of 5 grams of 1% Testosterone Gel (Teva) in Healthy Male Subjects"; and

(d) Five Hundred Thousand U.S. Dollars (US$500,000) upon the earlier to occur of (i) December 31, 2013 and (ii) five (5) business days after Teva's

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Commencement of Commercial Manufacture of Product for sale in the Territory. For purposes hereof, "**Commencement of Commercial Manufacture**" shall mean commencement of the manufacturing of the first batch of Product after successful completion of the validation process.

B. The final sentence of Section 7 of the Agreement (as added by Paragraph (7) of the 2007 Letter Agreement) is hereby deleted in its entirety.

C. The definition of "Royalties" in Section 1.4.22 (as amended by the First Amendment) is hereby deleted in its entirety and is replaced with the following:

""Royalties" - shall mean an amount equal to five percent (5%) of Net Sales; provided, however, that during the period of time that Teva Markets Product and is the sole marketer of a generic 1% testosterone gel that is AB-rated to AndroGel® in the Territory, such amount shall be equal to seven and one half percent (7.5%) of Net Sales."

4. Acknowledgement. Notwithstanding anything contained in this Third Amendment or the Agreement to the contrary, BioSante hereby acknowledges and agrees that the success of the development and/or commercialization of the Product is not guaranteed and that Teva has not yet secured a source for commercial manufacture of the Product. Accordingly, BioSante further acknowledges and agrees, subject to Teva's obligations under Sections 3.2 and 3.9 to use commercially reasonable efforts to (i) apply for, obtain and maintain Approval for the Product and (ii) Market the Product, in each case in the Territory, that the milestone payments contained in Section 7(b) and 7(e) of the Agreement and the royalty contained in the Agreement are contingent in nature, due solely upon the occurrence of the certain events that are expressly set forth herein.

5. Release of Teva by BioSante. In consideration of its execution of this Third Amendment and its agreement to be legally bound by the terms hereof, including, without limitation, its rights to receive the milestone payments in accordance with this Third Amendment, and subject to the remainder of this Paragraph 5 and Paragraph 7, BioSante, with the intention of binding itself and its Affiliates, and its and their respective predecessors, successors, heirs and assigns, directors, officers, employees and representatives, hereby fully, finally and irrevocably releases and discharges Teva and its Affiliates, and its and their respective predecessors, successors, heirs and assigns, directors, officers, employees and representatives, from any and all actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, liabilities, controversies, agreements, promises, variances, trespasses, damages, judgments, extents, executions, claims, counterclaims, demands, costs, expenses, losses, liens and obligations (collectively, "Liabilities"), whatsoever, in law or equity, whether known or unknown, and waive any and all defenses, occurring before or as of the Third Amendment Effective Date related to the performance or non-performance by Teva under the

Agreement prior to the Third Amendment Effective Date. In connection with this Agreement, BioSante, on behalf of itself and its Affiliates, expressly waives and relinquishes all rights and benefits afforded in any jurisdiction similar to those afforded in Section 1542 of the California Civil Code, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR

HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

6. Release of BioSante by Teva. In consideration of its execution of this Third Amendment and its agreement to be legally bound by the terms hereof, and subject to the remainder of this Paragraph 6 and Paragraph 7, Teva, with the intention of binding itself and its Affiliates, and its and their respective predecessors, successors, heirs and assigns, directors, officers, employees and representatives, hereby fully, finally and irrevocably releases and discharges BioSante and its Affiliates, and its and their respective predecessors, successors, heirs and assigns, directors, officers, employees and representatives, from any and all Liabilities whatsoever, in law or equity, whether known or unknown, and waive any and all defenses, occurring before or as of the Third Amendment Effective Date related to the performance or non-performance by BioSante under the Agreement prior to the Third Amendment Effective Date. In connection with this Agreement, Teva, on behalf of itself and its Affiliates, expressly waives and relinquishes all rights and benefits afforded in any jurisdiction similar to those afforded in Section 1542 of the California Civil Code, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN TO HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

7. Unreleased Liabilities. Notwithstanding anything in Paragraphs 5 and 6 to the contrary, nothing herein shall release or discharge either Party from, or prevent or impair the right of either Party to bring a claim or action regarding, any Unreleased Liabilities. For the purposes of this Third Amendment, "Unreleased Liabilities" means any liabilities arising out of (i) a breach by a Party of its obligations of confidentiality set forth in in Sections 11 or 18 of the Agreement, (ii) a breach by BioSante of the warranties and representations in Sections 8.1.1, 8.1.3, 8.1.5 or 8.1.6 of the Agreement, (iii) a breach by Teva of the warranties and representations in Sections 9.1.1 or 9.1.3 of the Agreement or (iv) a Party's indemnification obligations under Section 10 of the Agreement, but only with respect to suits, investigations, claims or demands brought or asserted by Third Parties after the Third Amendment Effective Date.

8. General Terms. This Third Amendment will act to amend the Agreement strictly as stated in Paragraph 2 above. All other terms and conditions of the Agreement shall remain in full force and effect, without modification. For the avoidance of doubt, the Parties acknowledge and agree that the terms of this Third Amendment and the negotiations of the Parties pertaining to them, shall be maintained in confidence by the Parties in accordance with Sections 11 or 18 of the Agreement.

9. Counterparts. This Third Amendment may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Third Amendment.

10. Governing Law. This Third Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania without regard to any conflict of laws provisions thereof.

[***Remainder of page intentionally left blank***]

IN WITNESS WHEREOF, BioSante and Teva each has caused this Third Amendment to be executed by its duly authorized representative.

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Jamie Bertansko

Name: Jamie Bertansko

Title: VP of Finance and Controller

Date: 10/12/2012

By: /s/ Timothy C. Crew

Name: Timothy C. Crew

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes

Name: Stephen M. Simes

Title: President and CEO

Date: 10/9/2012

Title: SVP, Teva Pharmaceuticals

Date: 10/12/2012

Exhibit 31.1

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

I, Stephen M. Simes, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 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: November 8, 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 September 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
November 8, 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 September 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
November 8, 2012