BIOSANTE PHARMACEUTICALS INC
Form 10-Q
August 05, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2011

o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File Number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**58-2301143** (IRS Employer Identification Number)

111 Barclay Boulevard

Lincolnshire, Illinois 60069

(Address of principal executive offices)

(847) 478-0500

(Registrant s telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES 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 August 5, 2011 109,614,363 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

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As used in this report, references to BioSante, the company, we, our or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, LibiGel®, Elestrin , Bio-T-Gel , The Pill-Plus and BioLook . This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Balance Sheets

June 30, 2011 and December 31, 2010 (Unaudited)

	June 30, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 37,126,006**	**$ 38,155,251**
Prepaid expenses and other assets	**1,013,315**	**2,469,879**
	38,139,321	**40,625,130**
PROPERTY AND EQUIPMENT, NET	**1,132,519**	**635,776**
OTHER ASSETS		
Investments	**3,405,807**	**3,405,807**
Deposits	**86,203**	**99,937**
	$ 42,763,850	**$ 44,766,650**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 6,348,948**	**$ 4,864,217**
Accrued compensation	**1,072,972**	**526,022**
Other accrued expenses	**2,872,081**	**1,681,956**
Current portion of convertible senior notes	**1,187,497**	**1,111,132**
	11,481,498	**8,183,327**
Long-term convertible senior notes	**19,751,836**	**17,436,201**
TOTAL LIABILITIES	**31,233,334**	**25,619,528**
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2011 - 391,286; 2010 - 391,286 Class C special stock	**391**	**391**
2011 - 93,600,446; 2010 - 81,391,130 Common stock	**209,386,676**	**184,777,375**
	209,387,067	**184,777,766**
Accumulated deficit	**(197,856,551)**	**(165,630,644)**
	11,530,516	**19,147,122**
	$ 42,763,850	**$ 44,766,650**

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three and Six Months Ended June 30, 2011 and 2010 (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
REVENUE				
Grant revenue	$	$	$	$ 51,870
Royalty revenue	81,003		138,003	2,228,004
	81,003		138,003	2,279,874
EXPENSES				
Research and development	11,116,323	8,657,606	25,980,744	18,084,476
General and administration	1,989,103	1,540,200	3,582,659	3,307,202
Depreciation and amortization	40,519	42,546	82,463	87,967
	13,145,945	10,240,352	29,645,866	21,479,645
OTHER				
Convertible note fair value adjustment	(1,753,000)	(381,916)	(2,392,000)	(1,790,916)
Interest expense	(172,000)	(172,083)	(344,000)	(344,083)
Other income	13,000		13,000	
Interest income	1,711		4,956	
NET LOSS	$ (14,975,231)	$ (10,794,351)	$ (32,225,907)	$ (21,334,770)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.16)	$ (0.17)	$ (0.36)	$ (0.35)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	93,985,347	64,607,893	89,400,401	60,207,044

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Six Months Ended June 30, 2011 and 2010 (Unaudited)

	Six Months Ended June 30, 2011	2010
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (32,225,907)	$ (21,334,770)
Adjustments to reconcile net loss to net cash (used in) operations		
Depreciation and amortization	82,463	87,967
Loss on disposal of fixed assets	2,099	
Employee & director stock-based compensation	581,402	483,636
Stock warrant expense - noncash	152,554	57,195
Convertible note fair value adjustment	2,392,000	1,790,916
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses, deposits and other assets	1,470,298	1,113,203
Accounts payable and accrued liabilities	3,183,419	2,760,133
Net cash (used in) operating activities	(24,361,672)	(15,041,720)
CASH FLOWS (USED IN) INVESTING ACTIVITIES		
Purchase of fixed assets	(542,919)	(23,789)
Net cash (used in) investing activities	(542,919)	(23,789)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Proceeds from common stock option exercises	16,391	
Proceeds from issuance of common stock by registered direct offerings	23,858,955	31,589,156
Net cash provided by financing activities	23,875,346	31,589,156
NET (DECREASE) INCREASE CASH AND CASH EQUIVALENTS	(1,029,245)	16,523,647
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	38,155,251	29,858,465
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 37,126,006	$ 46,382,112
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION		
Interest paid	$ 344,000	$ 344,000
Noncash investing and financing activities		
Purchase of fixed assets on account, non-cash investing activity	$ 38,386	$

See accompanying notes to the condensed financial statements.

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

1. DESCRIPTION OF BUSINESS

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The Company s lead products include LibiGel (transdermal testosterone gel) for the treatment of female sexual dysfunction (FSD) which is in Phase III clinical development under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). The Company s first FDA-approved product is Elestrin (estradiol gel) indicated for the treatment of hot flashes associated with menopause, marketed in the U.S. by Azur Pharma International II Limited, BioSante s licensee. BioSante also is developing a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and are currently in several Phase II clinical trials at minimal cost to the Company. Other products are Bio-T-Gel, a testosterone gel for male hypogonadism, licensed to Teva Pharmaceuticals USA, Inc., for which a New Drug Application (NDA) is pending with the FDA, and an oral contraceptive in Phase II clinical development using the Company s patented technology.

2. BASIS OF PRESENTATION

In the opinion of management, the accompanying unaudited condensed financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of the Company as of June 30, 2011 and December 31, 2010, the results of operations for the three and six months ended June 30, 2011 and 2010, and the cash flows for the six months ended June 30, 2011 and 2010, in conformity with accounting principles generally accepted in the United States of America (GAAP). Operating results for the three and six month periods ended June 30, 2011 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2011.

To maintain consistency and comparability, certain amounts from previously reported condensed financial statements have been reclassified to conform to the current-year presentation. Specifically, in the condensed statement of operations, Licensing expense of $268,750 has been combined into General and administration expense for the six months ended June 30, 2010. Similarly, in the condensed statements of cash flows, Due to licensor Antares in the amount of $(18,033) has been combined into Accounts payable and accrued liabilities, and Accounts receivable in the amount of $11,489 has been combined into Prepaid expenses, deposits and other assets for the six months ended June 30, 2010.

These unaudited interim condensed financial statements should be read in conjunction with the financial statements and related notes contained in the Company s Annual Report on Form 10-K for the year ended December 31, 2010.

3. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). This pronouncement was issued to provide a consistent definition of fair value and ensure that the fair value measurement and disclosure requirements are similar between U.S. GAAP and IFRS. ASU 2011-04 changes certain fair value measurement principles and enhances the disclosure requirements particularly

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for Level 3 fair value measurements. This pronouncement is effective for reporting periods beginning on or after December 15, 2011, with early adoption prohibited. The new guidance will require prospective application. The Company will adopt this guidance at the beginning of its first quarter of 2012. Adoption of this guidance is not expected to have a material impact on the Company s financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, Presentation of Comprehensive Income which was issued to enhance comparability between entities that report under U.S. GAAP and IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity s equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. The Company will adopt this guidance at the beginning of its first quarter of 2012. Adoption of this guidance is not expected to have any impact on the Company s financial position, results of operations or cash flows.

4. LIQUIDITY AND CAPITAL RESOURCES

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

To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, Inc. (Cell Genesys) to fund its ongoing business operations and short-term liquidity needs. In March 2011, the Company completed an offering of an aggregate of approximately 12.2 million shares of the Company s common stock and warrants to purchase an aggregate of approximately 4.0 million shares of the Company s common stock, resulting in net proceeds of $23.9 million, after deducting placement agent fees and other offering expenses. See Note 9, Stockholders Equity, for additional discussion regarding the March 2011 registered direct offering. As of June 30, 2011, the Company had $37.1 million of cash and cash equivalents, including $34.9 million invested in a U.S. Treasury money market fund. On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 16.0 million shares of common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses. See Note 11, Subsequent Event.

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

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timing and costs of the Company s business development efforts to implement business collaborations, licenses and other business combinations or transactions, and its efforts to continue to evaluate various strategic alternatives available with respect to its products and the company, itself.

The Company expects its cash and cash equivalents as of June 30, 2011, together with the net proceeds from its August 2011 public offering, to meet the Company s liquidity requirements through at least the next 18 months. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

As of June 30, 2011, the Company did not have any existing credit facilities under which it could borrow funds. The Company does have a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited (Kingsbridge) in which Kingsbridge has committed to purchase, subject to certain conditions and at the Company s sole discretion, up to the lesser of $25.0 million or approximately 5.4 million shares of the Company s common stock. The CEFF term runs through December 2011. If the Company accessed capital under the CEFF, it would do so by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of the Company s common stock during the applicable pricing period. As of June 30, 2011, the Company had not sold any shares to Kingsbridge under the CEFF.

As an alternative to raising additional financing, the Company may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product (e.g. one or more of the Company s cancer vaccines) to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under its existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company.

5. BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net loss per share is intended to reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Because the Company has incurred net losses from operations in each of the periods presented, the Company s outstanding options, warrants and convertible debt are antidilutive; accordingly, there is no difference between the basic and diluted net loss per share amounts. The computation of diluted net loss per share for the three and six months ended June 30, 2011 does not include options to purchase an aggregate of approximately 5.5 million and 5.4 million shares of common stock with exercise prices ranging from $1.41 to $36.82 per share, warrants to purchase an aggregate of approximately 23.6 million and 23.7 million shares of common stock with exercise prices of $2.00 to $39.27 per share, or outstanding debt of $22.0 million that is convertible into an aggregate of approximately 5.6 million shares of common stock at conversion prices of either $3.72 or $49.78 per share, because of their antidilutive effect on net loss per share. The computation of diluted net loss per share for the three and six months ended June 30, 2010 does not include options to purchase an aggregate of approximately 3.6 million and 3.6 million shares of common stock with exercise prices ranging from $1.27 to $36.82 per share, and warrants to purchase an aggregate of approximately14.6 million and 12.7 million shares of common stock with exercise prices of $2.00 to $39.27 per share, or outstanding debt of $22.0 million that is convertible into an aggregate of approximately 5.6 million shares of common stock at conversion prices of either $3.72 or $49.78 per share, because of their antidilutive effect on net loss per share.

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6. INVESTMENTS

The Company s investments balance of $3.4 million as of June 30, 2011 and December 31, 2010 consists of the Company s investments that are recorded using the cost method, and substantially represents the Company s investment in Ceregene, Inc. (Ceregene), a privately held biotechnology company (Ceregene). The Company has recorded its investment in Ceregene using the cost method, as no active market exists for this investment, and the Company does not possess significant influence over operating and financial policies of Ceregene, although the Company by virtue of its stock ownership of Ceregene has the right to designate one member on the Ceregene board of directors.

The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest the investment may not be recoverable. The fair value of the cost method investments are not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investments and it is not practicable to estimate the fair value of the investments.

7. CONVERTIBLE SENIOR NOTES

The Company has two series of convertible senior notes outstanding. The terms of the convertible senior notes are as follows:

- $20,782,000 principal amount of 3.125% Convertible Senior Notes due May 1, 2013 (the 2013 Notes), convertible at the option of the holder into an aggregate of 5,586,559 shares of the Company s common stock at a conversion price of $3.72 per share. Under certain circumstances, the Company has the right to redeem the 2013 Notes for cash as a whole or in part after May 1, 2011. The Company may be obligated to repurchase the 2013 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.

- $1,234,000 principal amount of 3.125% Convertible Senior Notes due November 1, 2011 (the 2011 Notes and collectively with the 2013 Notes, the Notes), convertible at the option of the holder into an aggregate of 24,789 shares of the Company s common stock at a conversion price of $49.78 per share. Under certain circumstances, the Company has the right to redeem the 2011 Notes for cash as a whole or in part. The Company may be obligated to repurchase the 2011 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.

Interest on both series of Notes is payable on May 1 and November 1 each year through maturity. Under certain circumstances, the Company may redeem some or all of the Notes on or after specified dates at a redemption price equal to 100 percent of the principal amount of the Notes plus accrued and unpaid interest. Holders of the Notes may require the Company to purchase some or all of their Notes at a repurchase price equal to 100 percent of the principal amount of the Notes plus accrued and unpaid interest if certain changes in control occur or upon termination of trading of the Company s common stock.

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation and recognition. Accordingly, the Company

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has adjusted the carrying value of the Notes to their fair value as of June 30, 2011, with changes in the fair value of the Notes occurring since December 31, 2010 reflected in convertible note fair value adjustment in the unaudited condensed statements of operations. The fair value of the Notes is based on Level 2 inputs. The aggregate recorded fair value of the Notes of $20.9 million as of June 30, 2011 differs from their total stated principal amount of $22.0 million by $1.1 million. The aggregate recorded fair value of the Notes of $18.5 million as of December 31, 2010 differs from their total stated principal amount of $22.0 million by $3.5 million. The Company recorded a fair value adjustment of $1.8 million and $2.4 million related to the Notes for the three and six months ended June 30, 2011 to increase its recorded liability and corresponding expense.

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

The assumptions as of December 31, 2010 were:

	2013 Notes	2011 Notes
Average risk-free rate	0.82%	0.29%
Volatility of BioSante common stock	78.7%	61.0%
Discount rate for principal payments in cash	17.0%	17.0%

The assumptions as of June 30, 2011 were:

	2013 Notes	2011 Notes
Average risk-free rate	0.45%	0.19%
Volatility of BioSante common stock	58.3%	51.8%
Discount rate for principal payments in cash	15.4%	15.4%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a C and Ca rating for long-term corporate obligations as assigned by Moody s Investors Service. Volatility is based on the historical fluctuations in the Company s stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate is based on observed yields as of the measurement date of one-year, two-year and three-year U.S. Treasury Bonds.

8. STOCK-BASED COMPENSATION

At the annual meeting of the Company s stockholders held on May 26, 2011, the Company s stockholders approved a second amended and restated BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (the 2008 Plan), which, among other things, increased the number of shares of the Company s common stock authorized for issuance under the plan from 4.0 million to 6.0 million plus the number of shares subject to stock options outstanding under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of May 26, 2011 but only to the extent that such outstanding awards are forfeited, expire or otherwise terminate without the issuance of such shares. As of June 30, 2011, approximately 2.5 million shares of the Company s common stock remain available for issuance under the 2008 Plan.

During the six months ended June 30, 2011, the Company granted options under the 2008 Plan to purchase an aggregate of 1,941,750 shares of the Company s common stock to certain employees of the Company and the Company s non-employee directors with a weighted average exercise price of $1.80 per share. Options to purchase an aggregate of 197,371 shares of the Company s common stock expired and were cancelled during the six months ended June 30, 2011. Options to purchase an aggregate of 9,834 shares of the Company s common stock at a weighted average exercise price of $1.67 per share

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were exercised during the six months ended June 30, 2011. Options are granted at an exercise price equal to the closing price of the Company s common stock on the date of the grant.

No warrants were granted during the six months ended June 30, 2011, other than the warrants issued in conjunction with the Company s March 8, 2011 offering described in Note 9, Stockholders Equity. No warrants were exercised during the six months ended June 30, 2011 and warrants to purchase an aggregate of 66,667 shares of the Company s common stock at an exercise price of $4.78 per share expired on May 14, 2011.

9. STOCKHOLDERS EQUITY

On March 8, 2011, the Company completed an offering of approximately 12.2 million shares of its common stock and warrants to purchase an aggregate of approximately 4.0 million shares of its common stock at a purchase price of $2.0613 per share to institutional investors for gross proceeds of $25.1 million. The offering resulted in net proceeds to the Company of $23.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of $2.25 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 243,990 shares of the Company s common stock at an exercise price of $2.58, which warrants are exercisable immediately and will expire on June 9, 2014. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities.

On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 16.0 million shares of common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses. See Note 11, Subsequent Event.

10. 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.

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Financial assets and liabilities recorded at fair value on a recurring basis as of June 30, 2011 and December 31, 2010 are classified in the tables below in one of the three categories described above:

Description	June 30, 2011 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 34,894,518		$ 34,894,518	
Total assets	$ 34,894,518		$ 34,894,518	
Liabilities:				
2011 Notes	$ 1,187,497		$ 1,187,497	
2013 Notes	19,751,836		19,751,836	
Total liabilities	$ 20,939,333		$ 20,939,333	

Description	December 31, 2010 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 21,729,230		$ 21,729,230	
Total assets	$ 21,729,230		$ 21,729,230	
Liabilities:				
2011 Notes	$ 1,111,132		$ 1,111,132	
2013 Notes	17,436,201		17,436,201	
Total liabilities	$ 18,547,333		$ 18,547,333	

The Company made an election to record the values of the 2011 Notes and 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 2011 Notes and 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company s common stock, and the current borrowing rates for similar companies. See Note 7, Convertible Senior Notes for more information and disclosures regarding key assumptions used in this fair value determination.

11. SUBSEQUENT EVENT

On August 2, 2011, subsequent to the end of the Company s second quarter 2011, the Company completed an underwritten public offering issuing 16.0 million shares of common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses. The Company expects to use the net proceeds for general corporate purposes, including, without limitation, to fund its Phase III clinical study program for LibiGel, and for working capital.

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

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

Business Overview

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

Our products, either approved, awaiting approval or in human clinical development, include:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Azur Pharma International II Limited (Azur).

- Bio-T-Gel once daily transdermal testosterone gel for the treatment of hypogonadism, or testosterone deficiency in men, for which a New Drug Application (NDA) is pending and which is licensed to Teva Pharmaceuticals USA, Inc.

- The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development for the treatment of FSD in contraception.

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

We believe LibiGel remains the most clinically advanced pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder in menopausal women, and that it has the potential to be the first product approved by the FDA for this

common and unmet medical need. We believe based on discussions with the FDA, including an SPA relating to the design of our two LibiGel Phase III safety and efficacy trials, that these trials and a minimum average exposure to LibiGel per subject of 12 months in our Phase III cardiovascular and breast cancer safety study are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, these three LibiGel Phase III studies are underway. We completed enrollment in the two LibiGel safety and efficacy trials in the first quarter 2011, and in May 2011 we announced the completion of enrollment in the LibiGel Phase III cardiovascular and breast cancer safety study. According to the protocol, the cardiovascular and breast cancer safety study will continue for 12 months of therapy from the date the last subject is enrolled before the primary analysis will be conducted, which will provide data for our NDA submission. In total, subjects will be in the safety study for five years each. Therefore, the study will continue until June 2, 2016.

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3,656 subjects were enrolled in the safety study resulting in over 4,000 subject-years of exposure as of June 30, 2011. We anticipate submitting our NDA for LibiGel by the end of 2012.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), our licensee, is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received $3.15 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur s sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, we believe our receipt of such payments unlikely in the near term, if at all.

We license the technology underlying certain of our gel products, including LibiGel and Elestrin, from Antares Pharma, Inc. (Antares). Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by us or a licensee.

Bio-T-Gel was initially developed by BioSante, and then it was licensed to Teva for late stage clinical development. Teva has filed a Bio-T-Gel NDA and the PDUFA date is November 14, 2011. In April 2011, Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement with respect to Bio-T-Gel. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent listed in the FDA Orange Book related to Abbott s testosterone gel for men. Although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

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

Our cancer vaccine technology is designed to stimulate the patient s immune system to fight effectively the patient s own cancer. Multiple Phase II trials of our vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia and breast cancer. Four of these vaccines have been granted FDA orphan drug designation. We license our cancer vaccine technology from Johns Hopkins University and The Whitehead Institute for Biomedical Research. Under various agreements, we are required to pay Johns Hopkins University certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the in-licensed technology.

In March 2011, we licensed our Pancreas Cancer Vaccine and Prostate Cancer Vaccine to Aduro BioTech, a clinical-stage immunotherapy company, solely for use in combination with Aduro s proprietary vaccine platform based on *Listeria monocytogenes* (Lm). Under the agreement, we are entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using our cancer vaccine technology. In June 2011, we announced that the FDA s clinical hold on the GVAX Prostate Cancer Vaccine (GVAX Prostate) for the treatment of prostate cancer was lifted by the FDA. Manufacturing of new GVAX Prostate is complete, and planning for a Phase II clinical trial, funded by others, at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center is underway.

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In July 2011, we announced an exclusive worldwide license of our Melanoma Vaccine to The John P. Hussman Foundation, in exchange for our receipt of an upfront license fee, milestone payments, royalties on any sales and a percentage of any sublicense fees. Additionally, the Hussman Foundation has committed up to approximately $11 million in Melanoma Vaccine clinical development funding.

One of our strategic goals is to continue to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, we may engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger or sale of our company.

Financial Overview

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our 2009 merger with Cell Genesys, Inc., to fund our ongoing business operations and short-term liquidity needs. On August 2, 2011, subsequent to the end of our second quarter 2011, we completed an underwritten public offering issuing 16.0 million shares of our common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses.

Our business operations to date have primarily consisted of licensing and research and development activities and we expect this to continue for the immediate future. If and when our products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves. As of June 30, 2011, we had $37.1 million of cash and cash equivalents. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. We expect our cash and cash equivalents as of June 30, 2011, together with the net proceeds from our August 2011 public offering, to meet our liquidity requirements through at least the next 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of $26.0 million on research and development activities during the six months ended June 30, 2011, which is a 44 percent increase compared to the same period in 2010, primarily as a result of the conduct of the three LibiGel Phase III clinical studies, including in particular increased amounts spent to conduct the studies and the increased number of subjects in the studies during the most recent period. We anticipate spending on research and development activities of $3.0 million to $4.0 million per month for our LibiGel Phase III clinical development program through the completion of the two efficacy trials, which we expect to occur during fourth quarter 2011, after which time we expect our research and development spending to decrease to $2.0 million to $3.0 million per month. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash available; (2) our development schedule, including the timing and scope of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our products; and (5) competitive developments.

Our general and administrative expenses for the six months ended June 30, 2011 increased 8 percent compared to the same period in 2010 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and administrative expenses may

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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 fees and expenses incurred.

We recognized a net loss for the three and six months ended June 30, 2011 of $15.0 million and $32.2 million, respectively, compared to a net loss of $10.8 million and $21.3 million for the three and six months ended June 30, 2010, respectively. These increases were due primarily to the increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for the three and six months ended June 30, 2011 of $0.16 and $0.36, respectively, compared to a net loss per share of $0.17 and $0.35 for the three and six months ended June 30, 2010, respectively. These slight changes in net loss per share were the result of the higher net loss described above, partially offset by a significantly higher weighted average number of shares outstanding during the three and six months ended June 30, 2011. We expect to continue to incur substantial and continuing losses for at least the next 18 to 24 months.

Results of Operations

Three Months Ended June 30, 2011 Compared to Three Months Ended June 30, 2010

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

	Three Months Ended June 30,			
	2011	**2010**	**$ Change**	**% Change**
Revenue	$ 81,003	$	$ 81,003	N/A
Expenses				
Research and development	11,116,323	8,657,606	2,458,717	28.4%
General and administrative	1,989,103	1,540,200	448,903	29.1%
Other expense Convertible note fair value adjustment	(1,753,000)	(381,916)	1,371,084	359.0%
Other expense Interest expense	(172,000)	(172,083)	(83)	(0.0)%
Other income	13,000		13,000	N/A
Other income - Interest income	1,711		1,711	N/A
Net loss	$ (14,975,231)	$ (10,794,351)	$ 4,180,880	38.7%
Net loss per common share (basic and diluted)	$ (0.16)	$ (0.17)	$ 0.01	5.9%
Weighted average number of common shares and common equivalent shares outstanding	93,985,347	64,607,893	29,377,454	45.5%

Revenue increased $81,003 as a result of increased net sales of Elestrin. The only revenue recognized during the three months ended June 30, 2011 consisted of the royalty revenue from Azur for Elestrin sales, which royalty revenue is offset by our corresponding obligation to pay Antares royalties representing the same amount. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $81,003 during the three months ended June 30, 2011 and $0 during the three months ended June 30, 2010, is recorded within general and administrative expenses in our statements of operations.

Research and development expenses for the three months ended June 30, 2011 increased 28.4 percent compared to the three months ended June 30, 2010 primarily as a result of the conduct of the

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three LibiGel Phase III clinical studies, including in particular increased amounts spent to conduct the studies and the increased number of subjects in the studies during the most recent period.

General and administrative expenses for the three months ended June 30, 2011 increased 29.1 percent compared to the three months ended June 30, 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses, partially offset by a decrease in licensing expense during the three months ended June 30, 2011 compared to the prior year period. We did not incur any licensing expense during the three months ended June 30, 2011.

The convertible note fair value adjustment to increase the recorded liability and corresponding expense was $1.8 million for the three months ended June 30, 2011 compared to a fair value adjustment to increase the recorded liability and corresponding expense of $381,916 for the three months ended June 30, 2010. The larger increase in the liability for the three months ended June 30, 2011 was primarily a result of the increase in our common stock price increasing the fair value of the conversion feature in the debt and, to a lesser extent, a decline in the discount rate during the current year period.

Interest expense, as a result of our convertible senior notes, was $172,000 and $172,083 for each of the three months ended June 30, 2011 and 2010, respectively.

Six Months Ended June 30, 2011 Compared to Six Months Ended June 30, 2010

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

	Six Months Ended June 30,			
	2011	**2010**	**$ Change**	**% Change**
Revenue	$ 138,003	$ 2,279,874	$ (2,141,871)	(93.9)%
Expenses				
Research and development	25,980,744	18,084,476	7,896,268	43.7%
General and administrative	3,582,659	3,307,202	275,457	8.3%
Other expense Convertible note fair value adjustment	(2,392,000)	(1,790,916)	601,084	33.6%
Other expense Interest expense	(344,000)	(344,083)	(83)	(0.0)%
Other income	13,000		13,000	N/A
Other income - Interest income	4,956		4,956	N/A
Net loss	$ (32,225,907)	$ (21,334,770)	$ 10,891,137	51.0%
Net loss per common share (basic and diluted)	$ (0.36)	$ (0.35)	$ (0.01)	(2.9)%
Weighted average number of common shares and common equivalent shares outstanding	89,400,401	60,207,044	29,193,357	48.5%

Revenue decreased $2.1 million, or 94 percent, as a result of the recognition of royalty revenue during the six months ended June 30, 2010 resulting primarily from the receipt of non-refundable upfront payments from Azur in exchange for the elimination of all remaining future royalty payments that we are not required to pay Antares under a separate agreement and certain future milestone payments due us under the

terms of the original license, as permitted by the amendment to our license agreement signed in December. The only revenue recognized during the six months ended June 30, 2011 consisted of royalty

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revenue from Azur for Elestrin sales, which royalty revenue is offset by our corresponding obligation to pay Antares royalties representing the same amount.

Research and development expenses for the six months ended June 30, 2011 increased 44 percent compared to the six months ended June 30, 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

General and administrative expenses for the six months ended June 30, 2011 increased 8 percent compared to the six months ended June 30, 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during the six months ended June 30, 2011 compared to the prior year period.

The fair value adjustment on our convertible senior notes for the six months ended June 30, 2011 was $2.4 million compared to $1.8 million for the six months ended June 30, 2010. The larger increase in the liability for the six months ended June 30, 2011 was a result of the increase in our common stock price increasing the fair value of the conversion feature in the debt.

Interest expense for the six months ended June 30, 2011 was $344,000 compared to $344,083 for the six months ended June 30, 2010.

Liquidity and Capital Resources

The following table highlights several items from our balance sheets:

Balance Sheet Data	June 30, 2011	December 31, 2010
Cash and cash equivalents	$ 37,126,006	$ 38,155,251
Total current assets	38,139,321	40,625,130
Investments	3,405,807	3,405,807
Total assets	42,763,850	44,766,650
Total current liabilities	11,481,498	8,183,327
Convertible senior notes due 2013	19,751,836	17,436,201
Total liabilities	31,233,334	25,619,528
Total stockholders equity	11,530,516	19,147,122

Liquidity

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $197.9 million as of June 30, 2011. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our 2009 merger with Cell Genesys, to fund our ongoing business operations and short-term liquidity needs.

In March 2011, we completed an offering of an aggregate of approximately 12.2 million shares of our common stock and warrants to purchase an aggregate of approximately 4.0 million shares of our common stock, resulting in net proceeds of $23.9 million, after deducting placement agent fees and other offering expenses.

As of June 30, 2011, we had $37.1 million of cash and cash equivalents. On August 2, 2011, subsequent to the end of our second quarter 2011, we completed an underwritten public offering issuing 16.0 million shares of our common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses. We expect to use the net proceeds for

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general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital.

Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our LibiGel Phase III clinical development program;

- the cost, timing and outcome of regulatory reviews of our products;

- our ability to license LibiGel or our other products for development and commercialization;

- the rate of technological advances;

- the commercial success of our products;

- our general and administrative expenses; and

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

We expect the ongoing LibiGel Phase III clinical development program to continue to require significant resources. If and when LibiGel or our other products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing and other expenses if we choose to market the products ourselves. We expect our cash and cash equivalents as of June 30, 2011, together with the net proceeds from our August 2011 public offering, to meet our liquidity requirements through at least the next 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

As of June 30, 2011, we did not have any existing credit facilities under which we could borrow funds. We have a committed equity financing facility described below. If we are unable to raise additional financing when needed or secure another funding source for our LibiGel Phase III clinical development program, we may need to temporarily slow or delay the program or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product (e.g. one or more of our cancer vaccines) to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

Committed Equity Financing Facility with Kingsbridge Capital Limited

We have a committed equity financing facility with Kingsbridge Capital Limited (Kingsbridge), under which Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or approximately 5.4 million shares of our common stock through the end of December 2011. If we choose to access capital under the facility, we can do so by

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providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include, among other conditions, a minimum price for our common stock of $1.15 per share, and is permitted to terminate the facility under certain limited circumstances, such as if a material and adverse event has occurred affecting our business, operations, properties or financial condition. As of June 30, 2011, we had not sold any shares to Kingsbridge under the committed equity financing facility.

Convertible Senior Notes Due November 2011 and May 2013

As a result of our merger with Cell Genesys, we assumed $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the notes is approximately $0.7 million, which will decrease slightly after November 1, 2011 when the $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 reach maturity. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between us and the trustees thereunder, the November 2011 convertible notes are convertible into an aggregate of 24,789 shares of our common stock at a conversion price of $49.78 per share and the May 2013 convertible notes are convertible into an aggregate of approximately 5.6 million shares of our common stock at a conversion price of $3.72 per share, in each case subject to adjustments for stock dividends, stock splits and other similar events. The convertible notes are our general, unsecured obligations, ranking equally with all of our existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of our subsidiaries. The convertible notes are subject to repurchase by us at each holder s option, if a fundamental change (as defined in the indentures) occurs, at a repurchase price equal to 100 percent of the principal amount of the convertible notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by us, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of our common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of June 30, 2011, the notes were not eligible for redemption. The indentures governing the convertible notes, as supplemented by the supplemental indentures, do not contain any financial covenants and do not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indentures.

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

We have elected to record our convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, we have adjusted the carrying value of the convertible senior notes to their fair value as of June 30, 2011,

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with changes in the fair value of the notes occurring since December 31, 2010 reflected in convertible note fair value adjustment in our 2011 unaudited condensed statements of operations. The recorded fair value of the convertible senior notes of an aggregate of $20.9 million as of June 30, 2011 differs from their total stated principal amount of $22.0 million by $1.1 million. The recorded fair value of the convertible senior notes of an aggregate of $18.5 million as of December 31, 2010 differs from their total stated principal amount of $22.0 million by $3.5 million.

Uses of Cash and Cash Flow

Net cash used in operating activities was $24.4 million for the six months ended June 30, 2011 compared to net cash used in operating activities of $15.0 million for the six months ended June 30, 2010. Net cash used in operating activities for the six months ended June 30, 2011 was primarily the result of the net loss for that period which was higher compared to the prior year period due to higher clinical trial related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities. Net cash used in operating activities of $15.0 million for the six months ended June 30, 2010 was primarily the result of the net loss for that period, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets.

Net cash used in investing activities was $542,919 for the six months ended June 30, 2011 compared to net cash used in investing activities of $23,789 for the six months ended June 30, 2010. Net cash used in investing activities for each of the six months ended June 30, 2011 and 2010 was due to the purchase of fixed assets. The increase in the purchase of fixed assets was primarily due to the purchase of machinery and more computers and furniture during the most recent period.

Net cash provided by financing activities was $23.9 million for the six months ended June 30, 2011 compared to net cash provided by financing activities of $31.6 million for the six months ended June 30, 2010. Net cash provided by financing activities for the six months ended June 30, 2011 was the result of our March 2011 registered direct offering, which resulted in net proceeds of $23.9 million, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities for the six months ended June 30, 2010 was the result of our March 2010 and June 2010 registered direct offerings, which resulted in net proceeds of $17.5 million and $14.1 million, respectively, after deduction of placement agent fees and offering expenses.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of June 30, 2011. We have, however, several financial commitments, including our convertible senior notes, product development milestone payments to the licensors of certain of our products, payments under our license agreements with Johns Hopkins University and Wake Forest University Health Sciences, as well as minimum annual lease payments.

We refer you to the description of our contractual obligations and commitments as of December 31, 2010 as set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. There were no material changes to such information since that date through June 30, 2011.

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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, 2010. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

Recently Issued Accounting Pronouncements

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

In June 2011, the FASB issued ASU No. 2011-05, Presentation of Comprehensive Income which was issued to enhance comparability between entities that report under U.S. GAAP and IFRS, and to provide a more consistent method of presenting non-owner transactions that affect an entity s equity. ASU 2011-05 eliminates the option to report other comprehensive income and its components in the statement of changes in stockholders equity and requires an entity to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement or in two separate but consecutive statements. This pronouncement is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. Early adoption of the new guidance is permitted and full retrospective application is required. We will adopt this guidance at the beginning of our first quarter of 2012. Adoption of this guidance is not expected to have a material impact on our financial position, results of operations or cash flows.

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Forward-Looking Statements

This quarterly report on Form 10-Q contains not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, would, might, possible, potential, project, expect, intend, plan, predict, anticipate, estimate, hope, approximate, contemplate or continue, the negative of these words, ot terms of similar meaning or the use of future dates. These forward-looking statements may be contained in the notes to our condensed financial statements and elsewhere in this report, including under the heading Part I. Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations. Our forward-looking statements generally relate to:

- the timing of the completion of our LibiGel Phase III clinical studies, the submission of an NDA for LibiGel and other clinical and regulatory status of our products in development;

- approval by the FDA of our products that are currently in clinical development and other regulatory decisions and actions;

- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes and licensure or acquisition of new products;

- our spending on general and administrative expenses;

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

- the future market size and market acceptance of our products;

- the effect of new accounting pronouncements and future health care, tax and other legislation;

- whether and how long our existing cash will be sufficient to fund our operations;

- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and

- our substantial and continuing losses.

Forward-looking statements are based on current expectations about future events affecting us and are subject to uncertainties and factors that affect all businesses operating in a global market as well as matters specific to us. These uncertainties and factors are difficult to predict and many of them are beyond our control. The following are some of the uncertainties and factors known to us that could cause

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our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results:

- the results of our clinical studies and the actions of the independent DMC or certain regulatory bodies, including the FDA;
- our failure to submit applications for and obtain and maintain required regulatory approvals on a timely basis or at all;
- the failure of certain of our products to be introduced commercially for several years or at all;
- the size of the market and the level of market acceptance of our products if and when they are commercialized;
- our dependence upon the maintenance of our license with Antares Pharma IPL AG and, to a lesser extent, other licensors;
- our dependence upon our licensees for the development, marketing and sale of certain of our products;
- our dependence upon certain third parties who assist us in certain aspects of our clinical studies and certain manufacturers who produce our products;
- our ability to obtain additional capital when needed or on acceptable terms;
- our ability to implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;
- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;

- our ability to compete in a competitive industry;
- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;
- adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
- changes in generally accepted accounting principles and the effect of new accounting pronouncements; or
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

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For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see the information under the heading Part II Item 1A. Risk Factors later in this report.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above and 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 under the heading Part II Item 1A. Risk Factors are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update, amend or clarify forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

Interest Rate Sensitivity

Principal Amount by Expected Maturity and Average Interest Rate

As of June 30, 2011	2011	2012	2013	Total	Fair Value June 30, 2011
Total Cash Equivalents	$ 34,894,518				$ 34,894,518
Average Interest Rate	0.03%				
Fixed Interest Rate 2011 Convertible Senior Notes	$ 1,234,000			$ 1,234,000	$ 1,187,497

Average Interest Rate	3.125%	3.125%	3.125%	3.125%	
Fixed Interest Rate 2013 Convertible Senior Notes			20,782,000	20,782,000	$ 19,751,836
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	

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As of December 31, 2010	2011	2012	2013	Total	Fair Value December 31, 2010
Total Cash Equivalents	$ 21,729,230				$ 21,729,230
Average Interest Rate	0.04%				
Fixed Interest Rate 2011 Convertible Senior Notes	$ 1,234,000			$ 1,234,000	$ 1,111,132
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	
Fixed Interest Rate 2013 Convertible Senior Notes			20,782,000	20,782,000	$ 17,436,201
Average Interest Rate	3.125%	3.125%	3.125%	3.125%	

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to provide reasonable assurance that the information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we are required to apply our judgment in evaluating the cost-benefit relationship of possible internal controls. Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this quarterly report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that material information relating to our company is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our quarter ended June 30, 2011 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Condition and Future Capital Requirements

We have a history of operating losses, expect continuing losses and may never become profitable.

We are not profitable. We incurred a net loss of $46.2 million for the year ended December 31, 2010 and as of December 31, 2010, our accumulated deficit was $165.6 million. For the six months ended June 30, 2011, we incurred a net loss of $32.2 million and as of June 30, 2011, our accumulated deficit was $197.9 million. Substantially all of our revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. We expect to continue to incur substantial and continuing losses over the next 18 to 24 months as our own product development programs continue and various preclinical and clinical trials commence or continue, including in particular our Phase III clinical study program for LibiGel. In order to generate new and significant revenues, we must develop and commercialize successfully our own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully. Because of the numerous risks and uncertainties associated with our and our strategic partners product development programs, we are unable to predict when we may become profitable, if at all. Even if our products are introduced commercially, they may never achieve market acceptance and we may never generate sufficient revenues or receive sufficient license fees or royalties on our licensed products and technology in order to achieve or sustain future profitability.

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

Developing products requires substantial amounts of capital. In particular, we expect the Phase III clinical study program of LibiGel to continue to require significant resources. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our LibiGel Phase III clinical development program;

- the cost, timing and outcome of regulatory reviews of our products;

- our ability to license LibiGel or our other products for development and commercialization;

- the rate of technological advances;

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- the commercial success of our products;

- our general and administrative expenses; and

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

We may need to continue to raise substantial additional capital to fund our operations. Although we believe that our cash and cash equivalents of $37.1 million at June 30, 2011, together with the net proceeds we received from our August 2011 public offering, will be sufficient to meet our liquidity requirements through at least the next 18 months, this estimate may prove incorrect since it is based on our currently projected expenditures for the remainder of 2011 and 2012. Our projected expenditures are based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may differ significantly from our projections. Alternatively, we may decide to raise additional financing earlier in order to create a cash cushion and take advantage of favorable financing conditions.

To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. 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 economic and market conditions deteriorate, our Phase III clinical study program for LibiGel is unsuccessful or takes longer than we anticipate to complete or the FDA decides not to approve LibiGel during the time frame within which we anticipate or at all. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to delay our Phase III clinical study program for LibiGel or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, e.g., our cancer vaccines, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

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

If we raise additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of our stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. If we incur additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on the ability of us to create liens, pay dividends, redeem our stock or make investments. As an alternative to raising additional financing by issuing additional equity or debt securities, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product to a third party, e.g., our cancer vaccines, who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company. If we raise additional funds through licensing arrangements, we may be

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required to relinquish greater or all rights to our products at an earlier stage of development or on less favorable terms than we otherwise would choose.

Our committed equity financing facility with Kingsbridge Capital Limited may not be available to us if we elect to make a draw down.

We have a committed equity financing facility with Kingsbridge that expires in December 2011. The committed equity financing facility entitles us to sell and obligates Kingsbridge to purchase, from time to time through the expiration date, up to the lesser of (i) an aggregate of $25 million in or (ii) approximately 5.4 million shares of our common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include a minimum price for our common stock of $1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of our common stock issued or issuable to Kingsbridge; and the continued listing of our stock on The NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the facility if Kingsbridge determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. If we are unable to access funds through the committed equity financing facility, or if the facility is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all. As of the date of this prospectus supplement, we had not sold any shares to Kingsbridge under the committed equity financing facility.

As a result of our merger with Cell Genesys, we have substantial indebtedness, which we may not be able to pay when it becomes due and payable.

As a result of our merger with Cell Genesys, we assumed $22.0 million aggregate principal amount of outstanding convertible senior notes, $1.2 million of which will be due in November 2011 and $20.8 million of which will be due in May 2013. The annual interest payment on these notes is approximately $0.7 million. We do not have any significant source of revenues and thus although we intend to continue to seek additional financing to support our operations, it is possible that we may not have sufficient funds to pay the principal on our convertible notes when it becomes due, especially if an event of default were to occur under the indentures governing the convertible notes.

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

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

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As a result of our merger with Cell Genesys, we possess not only all of the assets but also all of the liabilities of Cell Genesys. Discovery of previously undisclosed liabilities could have an adverse effect on our business, operating results and financial condition.

Acquisitions often involve known and unknown risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. In October 2008, in view of the termination of both its VITAL-1 and VITAL-2 Phase III clinical trials, Cell Genesys discontinued further development of its cancer vaccines for prostate cancer. Cell Genesys subsequently implemented a substantial restructuring plan to wind down its business operations and seek strategic alternatives. Under the restructuring plan, Cell Genesys terminated approximately 280 employees, closed two facilities and terminated two leases. As a result of our merger with Cell Genesys, we possess not only all of the assets, but also all of the potential liabilities of Cell Genesys. Although we conducted a due diligence investigation of Cell Genesys and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise, which could have an adverse effect on our business, operating results and financial condition.

Risks Related to Our Business

Several of our products are in the human clinical development stages and, depending on the product, likely will not be introduced commercially for at least one year and likely more, if at all.

Several of our products are in the human clinical development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. Other than Elestrin, none of our products has been introduced commercially and most are not expected to be for at least one year and likely more, if at all. Some of our products are not in active development. We cannot assure you that any of our products in human clinical development will:

- be developed successfully;
- prove to be safe and effective in clinical studies;
- meet applicable regulatory standards or obtain required regulatory approvals;
- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs;

- obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or

- be successfully marketed or achieve market acceptance by physicians and patients.

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

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

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

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

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

- slow subject enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and
- lack of funding.

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

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Although we have reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trial protocols for LibiGel, we still may not obtain FDA approval of LibiGel within a reasonable period of time or ever, which would harm our business and likely decrease our stock price.

LibiGel has not been approved for marketing by the FDA and is still subject to risks associated with its clinical development and obtaining regulatory approval. We believe based on discussions with the FDA, including a Special Protocol Assessment received in January 2008 relating to the design of our two LibiGel Phase III safety and efficacy trials, that these trials and minimum average exposure to LibiGel per subject of 12 months in our Phase III cardiovascular and breast cancer safety study are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, HSDD in menopausal women. Pursuant to the SPA process the FDA has agreed that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance the FDA will not later alter its perspective on issues of design execution or analysis, with certain exceptions that are discussed below. These SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the protocols for our pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD in naturally menopausal women. We have an additional SPA agreement which covers the LibiGel stability, or shelf life studies for the intended commercialization of LibiGel product. The SPA agreements, however, are not guarantees of LibiGel approval by the FDA or approval of any permissible claims about LibiGel. In particular, SPA agreements are not binding on the FDA if previously unrecognized public health concerns later comes to light, other new scientific concerns regarding product safety or effectiveness arise, we fail to comply with the protocol agreed upon, or the FDA s reliance on data, assumptions or information are determined to be wrong. Even after an SPA agreement is finalized, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. In addition, the data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval.

Delays in the completion of our Phase III clinical study program for LibiGel, which can result from unforeseen issues, FDA interventions and other potential reasons, could delay significantly FDA approval and commercial launch of LibiGel and adversely affect our product development cost estimates. Moreover, results from these clinical studies may not be as favorable as the results we obtained in prior, completed studies. Although it is our objective to submit an NDA for LibiGel to the FDA by the end of 2012, we cannot ensure that we will meet this objective or that even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

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

Our objective is to submit an NDA for LibiGel to the FDA by the end of 2012. We cannot ensure that we will meet this objective, however, or that even after extensive clinical studies, regulatory approval ever will be obtained for LibiGel.

The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional

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studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

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

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

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

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

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

We set goals and objectives for, and make public statements regarding, the timing of certain accomplishments and milestones regarding our business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the filing of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our current clinical studies, the amount of time, effort and resources committed to our programs by us and our current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving our products in development will advance or be completed in the time periods that we or our strategic partners announce or expect, that we or our current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future strategic partners will be able to adhere to our current schedule for the achievement of key milestones under any of our development programs. If we or any of our strategic partners fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

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

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

We believe there is significant market opportunity for LibiGel. Our belief is based on certain market data information, off-label use of products for HSDD, numerous publications reporting on the

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incidence of HSDD, the urgency placed on the condition by various medical societies and a recent survey of over 100 obstetrician/gynecologists and primary care physicians regarding the need for an FDA-approved drug to treat FSD and specifically HSDD conducted independently for us by Campbell Alliance Group, Inc. Our projection of the market opportunity for LibiGel is based on certain market data information, including this survey and thus estimates of the number of physicians that believe that FSD is an important and legitimate disorder requiring treatment and the number of physicians that would prescribe LibiGel to treat FSD. If these estimates prove to be incorrect, the market opportunity for LibiGel may be smaller than we anticipate. If the market opportunity for LibiGel is smaller than we anticipate, then it may be difficult for us to find a strategic partner to assist us in the development and commercialization of LibiGel and our prospects for generating LibiGel revenue and business may be adversely affected. This is also true with respect to our other products in development, although to a lesser extent, since LibiGel is our lead product in development.

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

The market for hormone therapy products has been affected negatively by the Women s Health Initiative (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. Our products differ from the products used in the WHI study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

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

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

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

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

- delay in developing, or our inability to obtain, a clinical dosage form, insufficient supply or deficient quality of our products or other materials necessary to conduct our clinical studies;

- negative or inconclusive results from clinical studies, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;

- serious and/or unexpected product-related side effects experienced by subjects in our clinical studies; or

- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

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

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

We rely on a few third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist us in certain aspect of our clinical studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations

and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on these few third parties does not relieve us of these responsibilities. If the third parties assisting us with certain aspects of our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA s good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory

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approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, our ability to collect damages may be limited contractually.

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

Even if we receive regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of our approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy, or REMS. If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug s risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

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

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;

- suspension or withdrawal of regulatory approvals;

- total or partial suspension of production; and

- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

We intend to enter into additional strategic relationships with third parties to develop and commercialize our products in development, including in particular LibiGel. If we do not enter into such relationships, we will need to undertake development and commercialization efforts on our own, which would be costly and could delay our ability to commercialize our future products.

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A key element of our business strategy is our intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have entered into a strategic relationship with Azur with respect to Elestrin, with Teva with respect to Bio-T-Gel and with Pantarhei Science with respect to The Pill Plus. We currently do not have a strategic partner for LibiGel.

We intend to enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, our products in development, including in particular LibiGel. We face significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic relationships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If we are unable to negotiate additional strategic relationships for our products, such as LibiGel, we may be forced to curtail the development of a particular product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development and commercialization of that product. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our products in development if they receive regulatory approvals to market and generate product revenue.

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

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

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

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

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

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

A key element of our business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have entered into a strategic relationship with Azur with respect to Elestrin, with Teva with respect to Bio-T-Gel and with Pantarhei Science with respect to The Pill Plus and certain other companies with respect to our cancer vaccines. We currently do not have a strategic partner for LibiGel.

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

- business combinations or significant changes in a strategic partner s business strategy may adversely affect a strategic partner s willingness or ability to complete its obligations under any arrangement;

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our partnered products;

- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;

- strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;

- strategic partners may not commit adequate resources to the marketing and distribution of our partnered products, limiting our potential revenues from these products;

- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our partnered products or that result in costly litigation or arbitration that diverts management s attention and consumes resources;

- strategic partners may experience financial difficulties;

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- strategic partners may not maintain properly or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including our competitors; and

- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing or commercializing our products.

Although we maintain the right to receive sales-based milestones of up to $140 million, our ability to receive these milestones is dependent upon Azur s ability to market and sell Elestrin, and based on Elestrin sales during 2010, we believe it is unlikely that we will receive any sales-based milestone payments from Azur in the foreseeable future or at all.

Elestrin is our first FDA approved product. Azur Pharma International II Limited is marketing Elestrin in the U.S. using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received $3.15 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur s sales of Elestrin. We continue to recognize certain royalty revenue from Azur s sales of Elestrin; however, such revenue is offset by our corresponding obligation to pay royalties to Antares, from whom we licensed the technology underlying our Elestrin product. We maintain the right to receive up to $140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year. We cannot assure you that Azur will be successful in marketing Elestrin, Elestrin will be widely accepted in the marketplace or that Azur will remain focused on the commercialization of Elestrin, especially if Azur does not experience significant Elestrin sales. Market penetration of Elestrin during 2010 was relatively low. Based on such low sales of Elestrin, we believe it is unlikely that we will receive any sales-based milestone payments from Azur in the foreseeable future, or at all.

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

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

- demonstration of efficacy and safety in clinical trials;

- the existence, prevalence and severity of any side effects;

- the availability of alternative treatments and potential or perceived advantages or disadvantages compared to alternative treatments;

- perceptions about the relationship or similarity between our products and the parent drug compound upon which the product is based;

- the timing of market entry relative to competitive treatments;

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- the ability to offer our products for sale at competitive prices;

- relative convenience, product dependability and ease of administration;

- the strength of marketing and distribution support;

- the sufficiency of coverage and reimbursement of our products by third-party payors and governmental and other payors; and

- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Some of these factors are not within our control, especially if we have transferred all of the marketing rights associated with the product, as we have with the U.S. marketing rights to Elestrin to Azur, the U.S. development and marketing rights to Bio-T-Gel to Teva and the U.S. marketing rights to The Pill Plus to Pantarhei Science. Our products may not achieve expected levels of market acceptance.

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

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

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

- private health insurers;

- health maintenance organizations;

- pharmacy benefit management companies;

- government health administration authorities; and

- other healthcare-related organizations.

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

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or offer inadequate levels of reimbursement, we or any of our strategic partners may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA. This legislation may have far reaching consequences for life science companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for our products, if approved, is substantially less that we expect in the future, our business could be affected materially and adversely.

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

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

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

To the extent that we or our licensees enter into manufacturing arrangements with third parties, we and such licensees will depend upon these third parties to perform our obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate

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or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

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

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

- we and our strategic partners may be unable to initiate or continue clinical studies of our products that are under development;

- we and our strategic partners may be delayed in submitting applications for regulatory approvals for our products that are under development; and

- we and our strategic partners may be unable to meet commercial demands for any approved products.

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

We have very limited staffing and will continue to be dependent upon key employees.

Our success is dependent upon the efforts of a relatively small management team and staff. We have employment arrangements in place with our executive officers, but none of these executive officers is bound legally to remain employed for any specific term. We do not have key man life insurance policies covering our executive officers or any of our other employees. If key individuals leave our company, our business could be affected adversely if suitable replacement personnel are not recruited quickly.

There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business. Our future success depends upon our ability to continue to attract and retain qualified

personnel.

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

We face an inherent risk of product liability as a result of the clinical testing of our products in development and the commercial sale of our products that have been or will be approved for commercial

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

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

We may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify us against damages and other liabilities arising from their activities do not fulfill their obligations, then we may be held responsible for those damages and other liabilities.

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

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

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

We are subject to changing rules and regulations of federal and state governments as well as the stock exchange on which our common stock is listed. These entities, including the SEC and The NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional

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regulations and requirements in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management s time from our other business activities.

Risks Related to Our Industry

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

We have licensed some of our gel products to third parties, including Azur, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA (acquired by Valeant Pharmaceuticals). All of these parties, except for Azur, have agreed to be responsible for continued development, regulatory filings and all have agreed to manufacturing and marketing associated with the products. In addition, in the future we may enter into additional similar license agreements. Our products that we have licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. Our current and future licensees may have different and, sometimes, competing priorities. We cannot assure you that our strategic partners or any future third party to whom we may license our products will remain focused on the development and

commercialization of our partnered products or will not otherwise

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breach the terms of our agreements with them, especially since these third parties also may compete with us with respect to some of our products. Any breach of this agreement by Teva or any other breach by our strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered products in these agreements if we are unable to license the products to another party on substantially the same or better terms or continue the development and future commercialization of the products ourselves.

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

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

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

- We do not know whether our licensor s patent applications will result in issued patents.

- Competitors may interfere with our patents and patent process in a variety of ways. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Competitors also may have our patents reexamined by demonstrating to the patent examiner that the invention was not original or novel or was obvious.

- We are engaged in the process of developing products. Even if we receive a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around our patents. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Though patent term extension may be possible for particular products, any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our products.

- Litigation also may be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may adversely affect our operating results. Such litigation also may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose protection on products covered by those patents.

- We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required

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licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

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

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

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which we license from Antares Pharma are scheduled to expire in June 2022. Although we have filed additional U.S. patent applications covering LibiGel, we can provide no assurance that such applications will be granted and that the patents will issue. In addition to patents, we may receive three years of marketing exclusivity for LibiGel under the Hatch-Waxman Act and an additional six months of pediatric exclusivity. Depending upon if and when we receive regulatory approval for LibiGel and our other products in development and the then expiration dates of the patents underlying LibiGel and such other products, we may not have sufficient time to recover our development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

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

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

- result in costly litigation;

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

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our potential gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results. With respect to products which we have licensed to others, our licensees may be responsible for the defense of any patent infringement claims, which would result in our dependence upon them to defend our intellectual property rights. With respect to Bio-T-Gel, which was developed initially by BioSante and then was licensed to Teva for late stage clinical development, Abbott Laboratories, a marketer of a testosterone gel, in April 2011 filed a complaint against Teva alleging patent infringement. Under our agreement with Teva, Teva must assume the direction, control and disposition of the defense of such claims. There can be no assurance that Teva will be successful in the infringement claim. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent owned by Abbott related to testosterone gels for men. In addition, although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

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

Recent Sales of Unregistered Equity Securities

During the three months ended June 30, 2011, we did not issue or sell any shares of our common stock or other equity securities of ours that were not registered under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended June 30, 2011. Our Board of Directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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ITEM 4. [REMOVED AND RESERVED]

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
10.1	BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812))
10.2	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812))
10.3	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812))
10.4	BioSante Pharmaceuticals, Inc. Performance Incentive Plan (Incorporated by reference to Exhibit 10.4 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812))
10.5	BioSante Pharmaceuticals, Inc. Officer Severance Policy (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 June 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the unaudited Condensed Balance Sheets, (ii) the unaudited Condensed Statements of Operations, (iii) the unaudited Condensed Statements of Cash Flows, and (iv) Notes to

Condensed Financial Statements.*

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

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SIGNATURES

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

August 5, 2011

BIOSANTE PHARMACEUTICALS, INC.

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

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

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

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