

BIOSANTE PHARMACEUTICALS INC

Form 10-Q

August 07, 2009

[Table of Contents](#)

**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, 2009**

☐ 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)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

**111 Barclay Boulevard**

**Lincolnshire, Illinois 60069**

(Address of principal executive offices)

**(847) 478-0500**

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐  
Non-accelerated filer ☐  
(Do not check if smaller reporting company)

Accelerated filer ☒  
Smaller reporting company ☐

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

As of August 1, 2009, 27,042,764 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q

JUNE 30, 2009

TABLE OF CONTENTS

Description	Page
PART I.	FINANCIAL INFORMATION
ITEM 1.	Financial Statements
	<u>Condensed Balance Sheets as of June 30, 2009 and December 31, 2008 (unaudited)</u> 3
	<u>Condensed Statements of Operations for the three and six months ended June 30, 2009 and 2008 (unaudited)</u> 4
	<u>Condensed Statements of Cash Flows for the six months ended June 30, 2009 and 2008 (unaudited)</u> 5
	<u>Notes to the Condensed Financial Statements (unaudited)</u> 6-17
<u>ITEM 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 18
<u>ITEM 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 32
<u>ITEM 4.</u>	<u>Controls and Procedures</u> 32
PART II.	OTHER INFORMATION
<u>ITEM 1.</u>	<u>Legal Proceedings</u> 34
<u>ITEM 1A.</u>	<u>Risk Factors</u> 34
<u>ITEM 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 59
<u>ITEM 3.</u>	<u>Defaults Upon Senior Securities</u> 59
<u>ITEM 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u> 59
<u>ITEM 5.</u>	<u>Other Information</u> 59
<u>ITEM 6.</u>	<u>Exhibits</u> 59
<u>SIGNATURE PAGE</u>	61

---

*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®, Elestrin®, LibiGel®, Bio-T-Gel®, The Pill-Plus®, BioVant® and BioLook®. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.*

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Balance Sheets****June 30, 2009 and December 31, 2008 (Unaudited)**

	June 30, 2009	December 31, 2008
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 5,985,823	\$ 11,760,920
Short-term investments		3,026,334
Accounts receivable	117,333	229,775
Prepaid expenses	836,505	1,070,051
Deferred acquisition costs	793,398	
	7,733,059	16,087,080
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>752,970</b>	<b>814,894</b>
<b>OTHER ASSETS</b>		
Investment in MATC	140,000	140,000
Deposits	903,442	637,397
	\$ 9,529,471	\$ 17,679,371
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 2,550,227	\$ 3,182,089
Due to licensor - Antares	16,200	5,393
Accrued compensation	285,084	290,583
Other accrued expenses	865,011	374,887
	3,716,522	3,852,952
<b>STOCKHOLDERS' EQUITY</b>		
<b>Capital stock</b>		
<b>Issued and outstanding</b>		
2009 - 391,286; 2008 - 391,286 Class C special stock	391	391
2009 - 27,042,764; 2008 - 27,042,764 Common stock	86,390,531	85,732,688
	86,390,922	85,733,079
<b>Accumulated deficit</b>	<b>(80,577,973)</b>	<b>(71,906,660)</b>
	5,812,949	13,826,419
	\$ 9,529,471	\$ 17,679,371

See accompanying notes to the condensed financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Operations****Three and six months ended June 30, 2009 and 2008 (Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
<b>REVENUE</b>				
Licensing revenue	\$	\$ 4,546	\$	\$ 9,091
Grant revenue	29,714	10,242	92,657	35,890
Royalty revenue	85,449	11,081	90,934	26,485
Other revenue				17,400
	115,163	25,869	183,591	88,866
<b>EXPENSES</b>				
Research and development	3,493,576	3,934,118	6,565,816	6,612,064
General and administration	1,208,956	1,593,156	2,238,158	2,918,649
Depreciation and amortization	33,333	12,309	62,579	22,082
	4,735,864	5,539,583	8,866,552	9,552,795
OTHER - Impairment of short term investments		660,200		660,200
OTHER - Interest income		125,847	11,648	449,424
<b>NET LOSS</b>	\$ (4,620,701)	\$ (6,048,067)	\$ (8,671,313)	\$ (9,674,705)
<b>BASIC AND DILUTED NET LOSS PER SHARE (Note 4)</b>	\$ (0.17)	\$ (0.22)	\$ (0.32)	\$ (0.36)
<b>WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING</b>	27,434,050	27,232,272	27,434,050	27,209,082

See accompanying notes to the condensed financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Condensed Statements of Cash Flows**

Six months ended June 30, 2009 and 2008 (Unaudited)

	Six Months Ended June 30,	
	2009	2008
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>		
Net loss	\$ (8,671,313)	\$ (9,674,705)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	62,579	22,082
Impairment of short term investments		660,200
Employee & director stock-based compensation	641,318	559,886
Stock warrant expense - noncash	31,525	63,613
(Gain) on disposal of equipment		(951)
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(32,499)	(873,471)
Accounts receivable	112,442	(6,726)
Accounts payable and accrued liabilities	(721,068)	2,110,694
Due to licensor - Antares	10,807	3,909
Deferred revenue		(9,091)
<b>Net cash (used in) operating activities</b>	<b>(8,566,209)</b>	<b>(7,144,560)</b>
<b>CASH FLOWS PROVIDED BY INVESTING ACTIVITIES</b>		
Redemption of short term investments	3,037,982	2,000,000
Purchase of short term investments	(11,648)	(84,065)
Purchase of capital assets	(152,674)	(128,716)
<b>Net cash provided by investing activities</b>	<b>2,873,660</b>	<b>1,787,219</b>
<b>CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES</b>		
Cash paid for acquisition related costs	(67,548)	
Proceeds from sale or conversion of shares	(15,000)	33,970
<b>Net cash (used in) provided by financing activities</b>	<b>(82,548)</b>	<b>33,970</b>
<b>NET (DECREASE) CASH AND CASH EQUIVALENTS</b>	<b>(5,775,097)</b>	<b>(5,323,371)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>11,760,920</b>	<b>15,648,948</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>5,985,823</b>	<b>\$ 10,325,577</b>
<b>SUPPLEMENTARY INFORMATION</b>		
<b>Other information:</b>		
Accrued liabilities for deferred acquisition costs, noncash	\$ 725,850	\$

See accompanying notes to the condensed financial statements.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**FORM 10-Q**

**JUNE 30, 2009**

**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, menopause, contraception and male hypogonadism. BioSante's key products include: (1) LibiGel, a once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA), for the treatment of female sexual dysfunction (FSD); (2) Elestrin, a 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 United States; (3) The Pill-Plus (triple hormone contraceptive), a once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives; and (4) Bio-T-Gel, a once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men. The Company also is engaged in the development of its proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

**2. BASIS OF PRESENTATION**

The accompanying unaudited interim condensed financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America (U.S.) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. 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, 2009, the results of operations for the three and six months ended June 30, 2009 and 2008, and the cash flows for the six months ended June 30, 2009 and 2008, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009.

These unaudited interim condensed financial statements and notes should be read in conjunction with the audited financial statements and related notes contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

The Company has evaluated all subsequent events through August 7, 2009, the date the financial statements were issued.



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

Because of continuing expenditures related to the Company's research and development activities, including in particular the Phase III clinical study program for LibiGel, as well as additional expenditures incurred due to the Company's efforts at pursuing strategic alternatives, including in particular a proposed merger with Cell Genesys, Inc. (with which the Company entered into an agreement and plan of merger on June 29, 2009, and for which the Company currently is in the process of preparing customary filings with the SEC for purposes of submitting the proposed merger transaction for approval of the Company's stockholders and the stockholders of Cell Genesys, Inc.), the Company has

Table of Contents

incurred higher than anticipated expenses and liabilities. In addition, the Company has not raised additional funding through an equity offering, which historically has been the Company's primary method for raising additional financing. As a result, in connection with the re-issuance of the Company's financial statements for the year ended December 31, 2008 as a result of the Form S-4 registration statement to register the shares of the Company's common stock to be issued in connection with the proposed Cell Genesys merger, the Company's independent registered public accounting firm modified their report on the Company's financial statements for the year ended December 31, 2008 to include an explanatory paragraph that expresses substantial doubt regarding the Company's ability to continue as a going concern. The Company's financial statements for the year ended December 31, 2008, including a subsequent event footnote relating to the going concern modification, and the revised report of the Company's independent registered public accounting firm were attached as exhibits to a Current Report on Form 8-K filed by the Company with the SEC on August 7, 2009.

**3. NEW ACCOUNTING PRONOUNCEMENTS**

In December 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 (Revised 2007) Business Combinations ( SFAS 141(R) ) which is effective for fiscal years beginning after December 15, 2008. SFAS 141(R) retains the underlying fair value concepts of its predecessor (SFAS No. 141), but changes the method for applying the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. The Company adopted these standards on January 1, 2009. Because these standards are generally applied prospectively, the effect of adoption on the Company's financial statements will depend primarily on specific transactions, if any, completed after 2008. See Note 6 for discussion of the anticipated accounting impact of the Company's proposed merger with Cell Genesys.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS 165), which provides guidance on management's assessment of subsequent events. SFAS 165 clarifies that management must evaluate, as of each reporting period, events or transactions that occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date through the date that the financial statements are issued or are available to be issued. SFAS 165 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. The Company adopted SFAS 165 for the three months ended June 30, 2009. The implementation of SFAS 165 did not have a material impact on the Company's financial statements.

In June 2009, the FASB issued SFAS No. 168, the FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles ( SFAS 168 ), establishing the FASB Accounting Standards Codification ( Codification ) as the source of authoritative U.S. generally accepted accounting principles ( GAAP ) recognized by the FASB to be applied by nongovernmental entities. SFAS 168 replaces SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles and is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification reorganizes current GAAP into a topical format that eliminates the current GAAP hierarchy and establishes instead two levels of guidance authoritative and nonauthoritative. On the effective date, all then-existing non-SEC accounting literature and reporting standards are superseded and deemed nonauthoritative. The FASB will no longer update or maintain the superseded standards. The Company will adopt this standard for its quarter ended September 30, 2009. The adoption of the FAS 168 will not have a material impact on the Company's financial statements. However, because the

Table of Contents

Codification completely replaces existing standards, it will affect the way GAAP is referenced by the Company in its financial statements.

**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 and sublicensing transactions and from subcontracts. To date, the Company has used primarily equity financing, licensing income and interest income to fund its ongoing business operations and short-term liquidity needs, and the Company expects to continue this practice for the foreseeable future, although the Company recently has proposed to merge with a company as an alternative method for raising financing.

The Company has not commercially introduced any products and does not expect to do so in the foreseeable future. However, Nycomed US Inc. (Nycomed) (formerly Bradley Pharmaceuticals, Inc.), the Company's former marketing sublicensee for Elestrin, commercially launched Elestrin in June 2007. As a result, from June 2007 until the termination of the Company's agreement with Nycomed and reacquisition of the rights to Elestrin in August 2008, the Company received royalties on net sales of Elestrin by Nycomed. However, such royalties were minimal. Pursuant to the termination, release and settlement agreement with Nycomed, the Company reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin. In December 2008, the Company entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited (Azur) for the marketing of Elestrin and the sale of certain assets related to Elestrin. Azur has agreed to promote Elestrin using its women's health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. Azur commercially re-launched Elestrin in the U.S. in April 2009. The Company recognized royalty and other revenues from sales of Elestrin of \$85,449 and \$90,934 during the three and six month periods ended June 30, 2009, respectively.

The Company's business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. If and when the Company's proposed 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. The Company currently does not have sufficient resources on a long-term basis to complete the FDA approval process or commercialization of any of its current or proposed products for which the Company has not entered into marketing relationships. The Company expects the Phase III clinical study program of LibiGel, in particular, to continue to require significant resources.

In December 2008, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited 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 5,405,840 shares of the Company's common stock through the end of December 2010. The Company may access capital under the CEFF 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. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for the Company's 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 common stock issued or issuable to Kingsbridge; and the continued listing of the Company's common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting the Company's business, operations, properties or

Table of Contents

financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides the Company notice of such material and adverse event. As of June 30, 2009, the Company had not sold any shares to Kingsbridge under the CEFF.

In light of the Company's cash and cash equivalents balance of approximately \$10.2 million at the end of first quarter 2009 and to save costs, the Company decided to delay screening new subjects for its LibiGel Phase III safety study; those women already enrolled continue in the study. The delay in screening new subjects for the LibiGel Phase III safety study continued throughout the second quarter 2009. The Company intends to reinstate screening and enrollment in the safety study once it has secured adequate funding or closed the proposed merger with Cell Genesys, Inc. (described below). Currently, the Company continues to screen for and enroll new subjects in the LibiGel Phase III efficacy trials. This change in the Company's clinical study screening likely will delay the eventual submission of a new drug application (NDA) for LibiGel.

On June 30, 2009, the Company announced that it had entered into a merger agreement with Cell Genesys, Inc. (Cell Genesys) pursuant to which Cell Genesys will merge with and into the Company, with the Company as the surviving company. As a result of the merger, each share of Cell Genesys's common stock held immediately prior to the effective time of the merger will be converted into 0.1615 of a share of the Company's common stock, subject to potential upward or downward adjustment, in accordance with a formula set forth in the merger agreement which is based on Cell Genesys's net cash, less certain expenses and liabilities, on a date 10 calendar days preceding the anticipated closing date of the merger. As a result of the merger, the Company will issue an aggregate of approximately 17.7 million shares of its common stock to holders of Cell Genesys's common stock and current Company stockholders will own approximately 60.4 percent of the outstanding common stock of the combined company and current Cell Genesys stockholders will own approximately 39.6 percent of the outstanding common stock of the combined company, assuming the 0.1615 exchange ratio is not adjusted and the number of outstanding shares of the Company's and Cell Genesys's common stock remains unchanged until immediately prior to the effective time of the merger. Assuming the merger closes on or before October 31, 2009, the Company anticipates that Cell Genesys will have approximately \$21.5 million in cash and cash equivalents after the payment of Cell Genesys's anticipated liabilities. In addition, as of such date, it is anticipated that Cell Genesys will have outstanding, and if the merger is completed, the Company would assume, an aggregate of \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 and \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011. The merger is subject to customary closing conditions, including stockholder approval, as well as a condition requiring Cell Genesys's net cash, less certain expenses and liabilities, to be a specified minimum amount as of 10 calendar days prior to the anticipated closing date of the merger. The merger is expected to be completed in late third or fourth quarter of 2009. For additional discussion regarding the merger agreement with Cell Genesys, see Note 6.

One of the primary reasons the Company is proposing to merge with Cell Genesys is the Company's need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other currently available acceptable alternatives for the Company to access capital, especially in light of the state of the markets for equity offerings, which historically has been the Company's method for raising additional financing. If the merger is completed, the Company expects that the cash resources of the combined company expected to be available at the closing of the merger would provide the Company sufficient capital to maintain its projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel.

The Company had cash and cash equivalents of approximately \$6.0 million at June 30, 2009. If the merger with Cell Genesys is not completed or is delayed, the Company will need to raise additional financing immediately. Even if the merger with Cell Genesys is completed, the Company likely will

Table of Contents

need to raise additional financing to continue its Phase III clinical studies for LibiGel, unless LibiGel is licensed or sold to another company. Due to the current economic recession and market conditions, as well as the status of product development programs, there is uncertainty regarding whether additional financing will be available to the Company on favorable terms, or at all. If adequate funds are not available or are not available on acceptable terms when needed, the Company may be required to delay, scale back or eliminate some or all of its programs designed to obtain regulatory approval of its proposed products, including most importantly, the Phase III clinical trial program for LibiGel. As an alternative to raising additional financing, the Company may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization, sell certain assets or rights under the Company's existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. The Company may be required to relinquish greater or all rights to its proposed products at an earlier stage of development or on less favorable terms than it otherwise would choose. Failure to obtain adequate financing also may adversely affect the Company's ability to operate as a going concern and cause the Company to significantly curtail or cease ongoing operations. The accompanying unaudited interim condensed financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should the Company be unable to continue as a going concern.

**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 and warrants are antidilutive; accordingly, there is no difference between 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, 2009 does not include options to purchase an aggregate of 2,736,691 and 2,753,358, respectively, shares of common stock with exercise prices ranging from \$1.27 to \$6.70 per share, and warrants to purchase an aggregate of 2,698,705 and 2,705,372, respectively, shares of common stock with exercise prices of \$2.75 to \$8.00 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, 2008 does not include options to purchase an aggregate of 2,053,191 and 1,977,316, respectively, shares of common stock, with exercise prices ranging from \$2.10 to \$6.70 per share, and warrants to purchase an aggregate of 2,573,352 and 2,614,502, respectively, shares of common stock, with exercise prices ranging from \$2.15 to \$8.00 per share, because of their antidilutive effect on net loss per share.

**6. PROPOSED MERGER WITH CELL GENESYS**

On June 29, 2009, the Company entered into an agreement and plan of merger with Cell Genesys, which provides that, upon the terms and subject to the conditions set forth in the merger agreement, Cell Genesys will merge with and into the Company, with the Company continuing as the surviving company. Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of Cell Genesys's common stock held immediately prior to the effective time of the merger will be converted into 0.1615 of a share of the Company's common stock, subject to potential upward or downward adjustment, in accordance with a formula set forth in the merger agreement which is based on Cell Genesys's net cash, less certain expenses and liabilities, on a date 10

Table of Contents

calendar days preceding the anticipated closing date of the merger. As a result of the merger, the Company will issue an aggregate of approximately 17.7 million shares of common stock to holders of Cell Genesys' s common stock and current Company stockholders will own approximately 60.4 percent of the outstanding common stock of the combined company and current Cell Genesys stockholders will own approximately 39.6 percent of the outstanding common stock of the combined company, assuming the 0.1615 exchange ratio is not adjusted and the number of outstanding shares of the Company' s and Cell Genesys' s common stock remains unchanged until immediately prior to the effective time of the merger. No fractional shares of the Company' s common stock will be issued in connection with the merger, and holders of Cell Genesys' s common stock will be entitled to receive cash in lieu thereof.

At the effective time of the merger, all outstanding warrants to purchase Cell Genesys' s common stock that are unexercised which by their terms will survive the merger will be assumed by the Company and become warrants to purchase the Company' s common stock, except for a warrant issued by Cell Genesys which is subject to a warrant exchange agreement dated May 17, 2009, which will be cashed out pursuant to the terms thereof prior to the merger. In addition, as of a date not less than 30 days prior to the anticipated effective time of the merger, all options to purchase Cell Genesys' s common stock, other than certain designated options held by Cell Genesys' s current officers, will become fully vested and exercisable until the merger is effective. Upon the effective time of the merger, such unexercised options, other than the assumed options, will terminate, and the assumed options will become options to purchase the Company' s common stock. In addition, as a result of the merger, the Company will assume the \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and the \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys, which will become convertible into shares of the Company' s common stock. The underlying number of shares and the exercise or conversion price of these warrants, options and convertible notes will be adjusted based on the final exchange ratio used in the merger. As a result of these adjustments and potential future issuances of the Company' s common stock after the merger, the Company will reserve an additional 5.5 million shares of its common stock, assuming the 0.1615 exchange ratio is not adjusted.

Consummation of the merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the merger agreement by both the Company' s and Cell Genesys' s stockholders and the approval of the issuance of shares of the Company' s common stock in the merger by the Company' s stockholders; (ii) the effectiveness of a Form S-4 registration statement to be filed by the Company with the SEC to register the shares of the Company' s common stock to be issued in connection with the merger, which will contain a joint proxy statement/prospectus; (iii) Cell Genesys' s net cash, less certain expenses and liabilities, being a specified minimum amount as of 10 calendar days prior to the anticipated closing date of the merger, which amount varies depending upon the closing date of the merger; (iv) the execution by the Company of a supplemental indenture with the trustee under both the indenture dated as of October 20, 2004 for the 3.125% convertible senior notes due in November 2011 issued by Cell Genesys and under the indenture dated as of June 24, 2009 for the 3.125% convertible senior notes due in May 2013 issued by Cell Genesys (together, the Indentures ); and (v) other customary closing conditions.

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

Table of Contents

shares of the Company's common stock in the merger; (v) the board of directors of Cell Genesys will recommend that its stockholders adopt and approve the merger agreement, subject to certain exceptions; (vi) the board of directors of the Company will recommend that its stockholders adopt and approve the merger agreement and approve the issuance of shares of the Company's common stock in the merger, subject to certain exceptions; and (vii) each party will take certain actions under the Indentures, including the execution by the Company of supplemental indentures as required under the terms of the Indentures.

The merger agreement contains certain termination rights for both the Company and Cell Genesys in certain circumstances. If the merger agreement is terminated due to certain triggering events specified in the merger agreement, Cell Genesys or the Company will be required to pay the other party a termination fee of \$1.0 million. The merger agreement also provides that under specified circumstances, Cell Genesys or the Company may be required to reimburse the other party up to \$500,000 for the other party's expenses in connection with the transaction. Any expenses paid by such party will be credited against the termination fee if the termination fee subsequently becomes payable by such party.

Assuming the merger closes on or before October 31, 2009, the Company anticipates that Cell Genesys will have approximately \$21.5 million in cash and cash equivalents after the payment of Cell Genesys's anticipated liabilities. In addition, as of such date, it is anticipated that Cell Genesys will have outstanding, and if the merger is completed, the Company would assume, an aggregate of \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 and \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011.

The merger is expected to be completed in the late third or fourth quarter of 2009. The merger is not intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

The Company anticipates that the merger will be accounted for under U.S. generally accepted accounting principles (U.S. GAAP) as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys will be recorded by the Company as of the completion of the merger based on their estimated fair values. As Cell Genesys has substantially ceased its operations, the acquisition is not considered to be a business combination, and the allocation of the purchase price will not result in recognition of goodwill. Following the completion of the merger, the future net income (loss) of the combined company will reflect charges resulting from the purchase price allocation related to the merger, which will include adjustments to carrying values of the acquired net assets based on the fair value of consideration measured as of the completion of the merger.

On July 1, 2009, a putative shareholder class action lawsuit was filed in California Superior Court in San Mateo County (Case No. 485528) naming Cell Genesys, Inc., its officers and directors, and the Company as defendants. The lawsuit alleges that defendants breached their fiduciary duties and/or aided and abetted the breach of fiduciary duties owed to Cell Genesys's stockholders in connection with the proposed merger between Cell Genesys and the Company, including by failing to engage in a fair process and obtain a fair price for the sale of Cell Genesys. Plaintiffs seek an order certifying the lawsuit as a class action, injunctive relief to enjoin the merger or, in the event the merger is completed, a rescission of the merger or rescissory damages. Plaintiffs further seek an accounting for all damages and an award of attorneys' fees and costs. On July 6, 2009, a second putative shareholder class action lawsuit naming the same parties and containing essentially identical allegations was filed in California Superior Court in San Mateo County (Case No. 485613). On July 8, 2009, a third putative shareholder class action lawsuit was filed in California Superior Court in San Mateo County (Case No. 485528), which also named the same parties and contained essentially identical allegations as the two prior lawsuits. On July 14, 2009, the parties to these three lawsuits filed a stipulation and proposed order consolidating the actions and appointing interim lead counsel, which was entered by the Court on July 15, 2009.





Table of Contents

On July 6, 2009, a putative shareholder class action lawsuit was filed in The Court of Chancery of the State of Delaware (Case No. 4715-VCP) naming Cell Genesys, its officers and directors, and the Company as defendants and alleging that the proposed merger between Cell Genesys and the Company does not provide Cell Genesys's stockholders fair compensation for the value of their stock. Plaintiffs seek an order certifying the lawsuit as a class action, injunctive relief to enjoin the merger or, in the event the merger is completed, a rescission of the merger or rescissory damages. Plaintiffs further seek an accounting for all damages and an award of attorneys' fees and costs. On July 27 and 28, 2009, Cell Genesys and the Company, respectively, filed motions to dismiss the Delaware action.

BioSante believes the actions are without merit and intends to defend the actions together with Cell Genesys vigorously. Because these matters are in early stages and because of the complexity of these cases, the Company cannot estimate the possible loss or range of loss, if any associated with their resolution. However, there can be no assurance that the ultimate resolution of these matters will not interfere with the Company's proposed merger with Cell Genesys or result in a material adverse effect on the Company's business, financial condition, results of operations or cash flows of a future period.

**7. LICENSE AGREEMENTS**

In November 2006, the Company entered into an exclusive sublicense agreement for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of \$3.5 million. In addition, during 2007, Nycomed paid the Company \$10.5 million triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter of 2006. Under the Company's license agreement with Antares, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or its sub-licensees sell incorporating the licensed technology. Specifically, the Company paid Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that the Company received, which the Company recognized as these payments were earned, based upon reported levels of Elestrin sales. The aggregate \$14.0 million received from Nycomed was recognized as revenue in 2006 since the entire \$14.0 million was non-refundable, the Company had a contractual right to receive such payments, the contract price was fixed, the collection of the resulting receivable was reasonably assured and the Company had no further performance obligations under the license agreement.

On August 6, 2008, the Company and Nycomed entered into a termination, release and settlement agreement pursuant to which the exclusive sublicense agreement dated November 7, 2006 between the Company and Nycomed was terminated and the Company reacquired the rights to Elestrin effective immediately. As a result, the Company paid Nycomed \$100,000 and an additional \$150,000 as a result of the December 2008 Elestrin sublicense to Azur as described below. Nycomed has agreed on behalf of itself and its affiliates not to market or sell any low-dose topical estrogen gel products for the treatment of menopausal hot flashes for a period of 12 months. The agreement also provides for a mutual release between the parties and the survival of the confidentiality, indemnification and insurance provisions of the exclusive sublicense agreement for a period of five years.

In December 2008, the Company signed an exclusive agreement with Azur for the marketing of Elestrin in the United States. Upon execution of the agreement, the Company received \$3.325 million comprised of a \$500,000 product licensing fee and \$2.825 million for transfer of the Elestrin trademark and inventories, among other items. The Company paid Antares \$462,500 as a result of signing the Azur agreement. The Company also is entitled to receive additional payments of up to an aggregate of \$144.5 million if certain sales-based milestones are achieved. In addition, Azur has agreed to pay to the Company royalties on sales of Elestrin ranging from 10 percent to 20 percent depending on the annual sales level. Azur has agreed to market Elestrin using its women's health and urology sales force of



Table of Contents

approximately 50 sales people that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. In April 2009, the Company announced the initiation of sales and marketing activity of Elestrin by Azur. Azur will market Elestrin to estrogen prescribing physicians, comprised mostly of gynecologists. Azur recently increased its Women's Health and Urology sales force to 65 people, in part to support the launch of Elestrin.

In December 2008, the Company signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. In June 2009, PharmaSwiss submitted a new drug application to the Israeli authorities based on the Company's approved U.S. NDA (new drug application) and manufacturing information. Approval in Israel is expected to take approximately one year from the date of such submission.

## 8. STOCK-BASED COMPENSATION

The Company has two stockholder-approved equity-based compensation plans under which stock options have been granted and currently are outstanding: the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan, which was terminated with respect to future grants upon the effectiveness of the 2008 Plan. As of June 30, 2009, there were 2,000,000 shares of the Company's common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan. Of the 2,000,000 authorized shares, none had been issued and 901,500 shares were subject to outstanding stock options as of June 30, 2009.

The Company believes that equity-based incentives, such as stock options, align the interest of its employees, directors and consultants with those of its stockholders. Options are granted with an exercise price equal to the market price of the Company's common stock on the date of the grant. Outstanding employee stock options generally vest ratably over a period of three years and have 10-year contractual terms. Certain of the Company's employee stock options had performance condition-based vesting provisions which resulted in expense when such performance conditions were satisfied. In these instances, stock-based compensation expense was recognized on the grant date in an amount equal to the fair value of the related options.

The non-cash, stock-based compensation cost that was incurred by the Company in connection with the Plans was \$325,067 and \$672,843 for the three and six months ended June 30, 2009, respectively, and \$329,760 and \$623,499 for the three and six months ended June 30, 2008, respectively. No income tax benefit was recognized in the Company's statements of operations for stock-based compensation arrangements due to the Company's net loss position.

The fair value of each option grant has been estimated on the date of grant using the Black-Scholes option-pricing model. The assumptions in the table below reflect the weighted average of all stock options granted during the six months ended June 30, 2009 and 2008.

	Six Months Ended June 30,	
	2009	2008
Expected life in years	6.0 years	6.00 years
Annualized volatility	76.81%	67.69%

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Discount rate	bond equivalent yield		2.76%	3.47%
Expected dividend yield			0.00%	0.00%

Table of Contents

The Company uses a volatility rate calculation based on the closing price for its common stock at the end of each calendar month as reported by the NASDAQ Global Market. Since the Company has a limited history with option exercises, the Company estimates the expected life of its options in a manner consistent with Staff Accounting Bulletin (SAB) 107, and SAB 110, which allows companies to use a simplified method to estimate the life of options meeting certain criteria. The Company believes that the use of the simplified method provides a reasonable term for purposes of determining compensation costs for these grants, and expects to use the simplified method to estimate the expected life of future options for eligible grants. The discount rate used is the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company has not in the past issued a cash dividend, nor does it have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

The Company expects all outstanding unvested stock options to vest in accordance with their normal vesting schedule. A summary of activity under the Plans during the six months ended June 30, 2009 is presented below:

Options	Option Shares	Weighted Average Exercise Price	
Outstanding December 31, 2008	2,038,191	\$	3.66
Granted	848,500		1.51
Exercised			
Forfeited or expired	150,000		4.73
Outstanding June 30, 2009	2,736,691	\$	2.94
(weighted average contractual term)	7.85 years		
Exercisable at June 30, 2009	1,379,191	\$	3.45
(weighted average contractual term)	6.00 years		

The aggregate intrinsic values of the Company's outstanding and exercisable options as of June 30, 2009 were \$416,085 and \$0 respectively, and as of June 30, 2008 were \$2,591,356 and \$1,361,234, respectively.

A summary of the Plans' non-vested options at December 31, 2008 and activity under the Plans during the six months ended June 30, 2009 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value	
Outstanding December 31, 2008	1,015,165	\$	3.74
Granted	848,500		1.51
Vested	(389,498)		3.60
Forfeited	(116,667)		4.42
Non-Vested at June 30, 2009	1,357,500	\$	2.43

As of June 30, 2009, there was \$1,571,568 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plans. The cost is expected to be recognized over a remaining weighted-average vesting period of 1.73 years.

There were no options exercised under the Plans for the six months ended June 30, 2009.

Table of Contents

The following table summarizes the stock option-based compensation expense for employees and non-employees recognized in the Company's statements of operations for each period:

	Three Months Ended June 30,			
	2009		2008	
<b>Stock-Based Compensation Expense:</b>				
Research and development	\$	100,712	\$	91,259
General and administrative		204,487		209,852
Total stock-based compensation expense	\$	305,199	\$	301,111

	Six Months Ended June 30,			
	2009		2008	
<b>Stock-Based Compensation Expense:</b>				
Research and development	\$	201,258	\$	175,641
General and administrative		440,060		384,245
Total stock-based compensation expense	\$	641,318	\$	559,886

In July 2007, the Company issued a warrant to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrant is exercisable at an exercise price equal to \$8.00 per share with 50 percent of the underlying warrant exercisable on July 19, 2008 and the remaining 50 percent becoming exercisable on July 19, 2009. The warrant is exercisable through and including July 18, 2010. The Company uses the Black-Scholes pricing model to value this warrant consideration and remeasures the award each quarter until the measurement date is established. During the six months ended June 30, 2009, the Company recorded \$24,042 in non-cash general and administrative expense pertaining to this warrant.

In May 2008, the Company issued warrants to purchase an aggregate of 80,000 shares of common stock to two individuals, the sole principal and a key executive officer, of an investor and public relations firm in return for various investor and public relations services. These warrants were originally exercisable at an exercise price equal to \$4.78 per share with 1/12 of the warrants becoming exercisable on June 15, 2008 and the remainder becoming exercisable on a monthly basis thereafter through May 15, 2009 so long as the investor and public relations firm continued to provide services to the Company. The Company terminated its relationship with the firm effective March 31, 2009, at which time 66,667 of the warrants were then exercisable. The warrants that were exercisable as of March 31, 2009 will remain exercisable through and including May 14, 2011. The Company used the Black-Scholes pricing model to value this warrant consideration and re-measured the award each quarter until the measurement date was established. During the six months ended June 30, 2009, the Company recorded \$7,483 in non-cash general and administrative expense pertaining to these warrants.

## 9. STOCKHOLDERS' EQUITY

During the six months ended June 30, 2009, options to purchase an aggregate of 848,500 shares of the Company's common stock were granted to certain employees of the Company and the Company's non-employee directors. No warrants were granted and no stock options or warrants were exercised during such period.





Table of Contents

**10. FAIR VALUE MEASUREMENTS**

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

The Company has adopted the fair value methods required under SFAS No. 157, Fair Value Measurements, (SFAS No. 157) to value its financial assets and liabilities. As defined in SFAS No. 157, 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, SFAS No. 157 establishes a fair value hierarchy 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.**

The table below presents a reconciliation of the level 3 fair value measurements, which are based on significant unobservable inputs, at June 30, 2009.

	Fair Value Measurements Using Significant Unobservable Inputs		Fair Value Measurements Using Significant Unobservable Inputs	
	Auction Rate Securities		Put Asset Related to Auction Rate Securities	
December 31, 2008	\$	2,534,820	\$	465,180
Transfers into Level 3				
Purchases, redemptions, issuances or settlements		(2,534,820)		(465,180)
Total gains or losses (realized/unrealized) included in net loss				
June 30, 2009	\$		\$	

In January 2009, all \$3.0 million of the Company's then short-term investments were converted into cash and cash equivalents as a result of the sale of \$3.0 million of the Company's auction rate securities to UBS Financial Services, Inc. and its affiliates for full par value plus accrued but unpaid interest.

Table of Contents

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

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

**Business Overview**

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

Our primary products are gel formulations of testosterone and estradiol. Our key products 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).
- 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.
- The Pill-Plus (triple hormone contraceptive) – once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.
- Bio-T-Gel – once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.

With respect to LibiGel, we believe based on agreements with the FDA, including an SPA received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD) in menopausal women. The January 2008 SPA agreement covers the 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, specifically, HSDD in naturally menopausal women.

Currently, three LibiGel Phase III trials are underway; two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months after which time we intend to submit an NDA to the FDA. In June 2009, we announced that based upon a review of study

Table of Contents

conduct and blinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the LibiGel Safety Study External Executive Committee recommended continuation of the LibiGel Phase III clinical program. The Executive Committee evaluated study information from over 1,000 women enrolled totaling approximately 600 women-years of exposure in the Phase III LibiGel safety study. All serious adverse events including those in the cardiovascular categories as well as non-serious adverse events experienced to date by the women enrolled in the study have been reviewed by the committee. In view of the very low cardiovascular event rate, the LibiGel Phase III clinical studies will continue. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years. We expect the Phase III clinical trial program of LibiGel to continue to require significant resources.

With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006 with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. (which was subsequently purchased by Nycomed US Inc. (Nycomed)) for the marketing of Elestrin in the United States, which agreement was subsequently terminated by the parties effective August 6, 2008. Upon execution of the sublicense agreement with Nycomed, we received an upfront payment of \$3.5 million. In addition, Nycomed paid us \$10.5 million in milestone payments during 2007 as a result of the FDA approval of Elestrin in the U.S., which occurred in December 2006 and royalties on sales of Elestrin commencing in June 2007, when Nycomed commercially launched Elestrin. We did not receive any meaningful royalties from Nycomed on sales of Elestrin.

In August 2008, we entered into a termination, release and settlement agreement with Nycomed, pursuant to which we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin in exchange for, among other things, a \$100,000 payment to Nycomed. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur for the marketing of Elestrin and the sale of certain assets related to Elestrin pursuant to which we received approximately \$3.3 million, comprised of a \$500,000 product sublicensing fee and approximately \$2.8 million for transfer of the Elestrin trademark and inventories, among other items. Under the sublicense agreement, we are entitled to receive additional payments of up to an aggregate of \$144.5 million if certain sales-based milestones are achieved. In addition, under the sublicense agreement, Azur has agreed to pay us royalties on sales of Elestrin ranging primarily from 10 percent to 20 percent depending primarily upon the annual sales levels. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. As a result of our sublicense agreement with Azur, under our agreement with Nycomed, we were required to pay Nycomed an additional \$150,000. In April 2009, we announced the initiation of sales and marketing activity of Elestrin by Azur. Azur will market Elestrin to estrogen prescribing physicians, comprised mostly of gynecologists. Azur recently increased its Women's Health and Urology sales force to 65 people, in part to support the launch of Elestrin. In December 2008, we signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. In June 2009, PharmaSwiss submitted a new drug application to the Israeli authorities based on our approved U.S. NDA (new drug application) and manufacturing information. Approval of Elestrin in Israel is expected approximately one year after such submission.

We license the technology underlying certain of our products, other than Bio-T-Gel, The Pill-Plus and the CaP technology, from Antares Pharma, Inc. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. We license the

Table of Contents

technology underlying our proposed triple hormone contraceptives 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 is subsequently marketed.

In September 2008, we announced positive results of clinical work on our Pill-Plus triple hormone therapy oral contraceptive. The Pill-Plus adds a third hormone, an androgen, to the normal two hormone (estrogen and progestogen) oral contraceptive to prevent androgen deficiency which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to improve FSD in oral contraceptive users, among other potential benefits.

Our strategy with respect to our CaP technology is to continue development of our nanoparticle technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. In addition to continuing our own product development in the potential commercial applications of our CaP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CaP technology. For example, in November 2007, we signed a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial line filler in aesthetic medicine (BioLook). Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received an ownership position in MATC of approximately five percent of the common stock of MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology. As another example, in November 2008, we announced that we had been awarded a \$150,000 Small Business Innovation Research grant from the National Institutes of Health (NIH) to support our development of formulations for the pulmonary delivery of interferon alpha (IFN- $\alpha$ ) using our CaP technology. The grant will be used to fund product development for IFN- $\alpha$  formulated with CaP particles for administration via inhalation. We have conducted extensive studies using our CaP vaccine adjuvant, BioVant, to increase the immune response of potential vaccines. We have focused our efforts on flu vaccines, most recently concentrating on a potential swine flu vaccine.

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 from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company. As part of this process, in June 2009, we entered into a merger agreement with Cell Genesys, Inc.

**Proposed Merger with Cell Genesys**

On June 29, 2009, we entered into an agreement and plan of merger with Cell Genesys, which provides that, upon the terms and subject to the conditions set forth in the merger agreement, Cell Genesys will merge with and into our company, with our company continuing as the surviving company. Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of Cell Genesys's common stock held immediately prior to the effective time of the merger will be converted into 0.1615 of a share of our common stock, subject to potential upward or



Table of Contents

downward adjustment, in accordance with a formula set forth in the merger agreement which is based on Cell Genesys' net cash, less certain expenses and liabilities, on a date 10 calendar days preceding the anticipated closing date of the merger. As a result of the merger, we will issue an aggregate of approximately 17.7 million shares of our common stock to holders of Cell Genesys' common stock and our current stockholders will own approximately 60.4 percent of the outstanding common stock of the combined company and current Cell Genesys stockholders will own approximately 39.6 percent of the outstanding common stock of the combined company, assuming the 0.1615 exchange ratio is not adjusted and the number of outstanding shares of our and Cell Genesys' common stock remains unchanged until immediately prior to the effective time of the merger.

Following the merger, the executive officers of the combined company will be the current executive officers of BioSante and the board of directors of the combined company will be comprised of eight members, including the six current members of our board of directors and two members of the current Cell Genesys board of directors, Stephen A. Sherwin, M.D. and John T. Potts, Jr., M.D., with Louis W. Sullivan, M.D. the current chairman of the board of BioSante, remaining as chairman of the combined company.

The merged company will focus primarily on LibiGel, but also will seek future development opportunities for Cell Genesys' GVAX Immunotherapies, including potential combination with BioVant, our vaccine adjuvant, as well as possible external collaborations, and also will seek to outlicense other of Cell Genesys' technologies. In addition, the merged company will own a 16 percent equity ownership position in Ceregene, Inc., a former subsidiary of Cell Genesys which is developing gene therapies for neurodegenerative disorders.

The merger agreement has been approved unanimously by the boards of directors of both our company and Cell Genesys and will need to be approved by both our and Cell Genesys' stockholders. The merger is subject to customary closing conditions as well as a condition requiring Cell Genesys' net cash, less certain expenses and liabilities, to be a specified minimum amount as of 10 calendar days prior to the anticipated closing date of the merger.

At the effective time of the merger, all outstanding warrants to purchase Cell Genesys' common stock that are unexercised which by their terms will survive the merger will be assumed by us and become warrants to purchase our common stock, except for the warrant subject to a certain warrant exchange agreement dated May 17, 2009, which will be cashed out pursuant to the terms thereof prior to the merger. In addition, as of a date not less than 30 days prior to the anticipated effective time of the merger, all options to purchase Cell Genesys' common stock, other than certain designated options held by Cell Genesys' current officers, will become fully vested and exercisable until the merger is effective. Upon the effective time of the merger, such unexercised options, other than the assumed options, will terminate, and the assumed options will become options to purchase our common stock. In addition, as a result of the merger, we will assume the \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and the \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys, which will become convertible into shares of our common stock. The underlying number of shares and the exercise or conversion price of these warrants, options and convertible notes will be adjusted based on the final exchange ratio used in the merger. As a result of these adjustments and potential future issuances of our common stock after the merger, we will reserve an additional 5.5 million shares of our common stock, assuming the 0.1615 exchange ratio is not adjusted.

The merger agreement contains certain termination rights for both us and Cell Genesys in certain circumstances. If the merger agreement is terminated due to certain triggering events specified in the merger agreement, Cell Genesys or we will be required to pay the other party a termination fee of \$1.0





Table of Contents

million. The merger agreement also provides that under specified circumstances, Cell Genesys or we may be required to reimburse the other party up to \$500,000 for the other party's expenses in connection with the transaction. Any expenses paid by such party will be credited against the termination fee if the termination fee subsequently becomes payable by such party.

Assuming the merger closes on or before October 31, 2009, the Company anticipates that Cell Genesys will have approximately \$21.5 million in cash and cash equivalents after the payment of Cell Genesys's anticipated liabilities.

The merger is expected to be completed in late third or fourth quarter of 2009. The merger is not intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

For additional discussion regarding the merger with Cell Genesys, see Note 6 to our condensed financial statements.

**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 financing, licensing income and interest income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future, although we recently have proposed to merge with a company as an alternative method for raising financing.

Our business operations to date have consisted mostly of licensing and research and development activities and we expect this to continue for the immediate future. If and when our proposed 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. We currently do not have sufficient resources on a long-term basis to complete the FDA approval process or commercialization of any of our current or proposed products for which we have not entered into marketing relationships. We expect the Phase III clinical study program of LibiGel to continue to require significant resources.

One of the primary reasons we are proposing to merge with Cell Genesys is our need for additional financing to continue our Phase III clinical studies for LibiGel and our lack of other currently available acceptable alternatives to access capital, especially in light of the state of the markets for equity offerings, which historically has been our method for raising additional financing. If the merger is completed, we expect that the cash resources of the combined company expected to be available at the closing of the merger will provide us sufficient capital to maintain our projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel.

Our cash and cash equivalent balances of \$6.0 million as of June 30 will not be sufficient to meet our liquidity requirements through the next 12 months. If adequate funds are not available or are not available on acceptable terms when we need them, we may be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, including most importantly, as mentioned above, our Phase III clinical study program for LibiGel. Failure to obtain adequate financing also may cause us to curtail significantly or even cease our ongoing operations. As an alternative to raising additional financing, we may choose to sublicense LibiGel or

another product to a third party, 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. We may be required

Table of Contents

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

To save costs, in April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study; those women already enrolled continue in the study. We intend to reinitiate screening and enrollment in the safety study once we have secured adequate funding or closed the proposed merger with Cell Genesys. Currently, we continue to screen for and enroll new subjects in the LibiGel Phase III efficacy trials. This change in our clinical study screening likely will delay the eventual submission of the LibiGel NDA.

If our merger with Cell Genesys is not completed or is delayed, we will need to raise additional financing immediately. Even if the merger with Cell Genesys is completed, we likely will need to raise additional financing to continue our Phase III clinical studies for LibiGel in the near future, unless LibiGel is licensed or sold to another company. Due to the current economic recession and market conditions, as well as the status of product development programs, there is uncertainty regarding whether additional financing will be available to us on favorable terms, or at all.

We recognized royalty and other revenues from sales of Elestrin of \$85,449 and \$90,934 during the three and six month periods ended June 30, 2009, respectively. Our corresponding obligation to pay Antares a portion of the royalties received equaled \$16,200 and \$21,101 for the three and six month period ended June 30, 2009, and is recorded within general and administrative expenses.

We incurred expenses of approximately \$1.1 million per month on research and development activities during the six months ended June 30, 2009. Our research and development expenses decreased 11 percent to \$3.5 million for the second quarter 2009 compared to \$3.9 million for the second quarter 2008, primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study. If we are unable to obtain additional financing prior to the completion of our merger with Cell Genesys, we expect our monthly research and development expenses to remain at approximately \$1.0 million until such time as we no longer have sufficient resources to continue our research and development activities, or until additional funding sources become available. If, however, we obtain adequate funding or once we complete our merger with Cell Genesys, we expect our monthly research and development expenses to increase to approximately \$1.5 million. The amount of our actual research and development expenditures, however, may fluctuate from period-to-period depending upon: (1) the amount of resources, including cash and cash equivalents, available; (2) our development schedule, including the timing 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 second quarter 2009 decreased \$384,200, or 24 percent, compared to the second quarter 2008. This decrease was due primarily to a decrease in business development and other personnel-related costs. Our general and administrative expenses may fluctuate from period-to-period depending upon the amount of non-cash, stock-based compensation expense, legal, public and investor relations, business development, accounting and corporate governance and other fees and expenses incurred.

We recognized a net loss for the three and six months ended June 30, 2009 of approximately \$4.6 million and \$8.7 million, respectively, compared to a net loss of approximately \$6.0 million and \$9.7 million, respectively, for the three and six months ended June 30, 2008. These decreases primarily were due to the decreased LibiGel clinical development expenses discussed above and impairment charges incurred in 2008 related to other-than-temporary impairment of auction rate securities, which more than



Table of Contents

offset lower interest income as a result of depositing all of our cash into a non-interest bearing, 100% FDIC-insured checking account during the first quarter of 2009.

We expect to incur substantial and continuing losses for the foreseeable future. This is true especially as our own product development programs expand and various clinical studies continue, including in particular the Phase III clinical study program for LibiGel. The actual amount of these losses, however, may vary significantly from period-to-period and will depend on, among other factors:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;
- the commercial success and net sales of Elestrin;
- our ability to license LibiGel or our other products for development and commercialization;
- the cost, timing and outcome of regulatory reviews of our proposed products;
- the rate of technological advances;
- ongoing determinations of the potential markets for and commercial success of our proposed products;
- the timing and cost of various cash and non-cash general and administrative expenses;
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts to evaluate various strategic alternatives available with respect to our products and our company;

- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

## Results of Operations

### *Three Months Ended June 30, 2009 Compared to Three Months Ended June 30, 2008*

The following table sets forth our results of operations for the three months ended June 30, 2009 and 2008.

	Three Months Ended June 30,			
	2009	2008	\$ Change	% Change
Revenue	\$ 115,163	\$ 25,869	\$ 89,294	345.2%
Expenses				
Research and development	3,493,576	3,934,118	(440,542)	(11.2)%
General and administrative	1,208,956	1,593,156	(384,200)	(24.1)%
Impairment of short-term investments	0	660,200	(660,200)	(100.0)%
Interest income	0	125,847	(125,847)	(100.0)%
Net loss	\$ (4,620,701)	\$ (6,048,067)	\$ (1,427,366)	(23.6)%

## Table of Contents

Revenue increased \$89,294 for the three months ended June 30, 2009 compared to the three months ended June 30, 2008 primarily as a result of the recognition of Elestrin royalty revenue and grant revenue from a Small Business Innovation Research grant from the NIH to support our development of formulations for the pulmonary delivery of interferon alpha (IFN- $\alpha$ ) using our CaP technology during the three months ended June 30, 2009.

Research and development expenses for the three months ended June 30, 2009 decreased 11 percent compared to the three months ended June 30, 2008 primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study.

General and administrative expenses for the three months ended June 30, 2009 decreased 24 percent compared to the three months ended June 30, 2008 primarily as a result of a decrease in business development and other personnel-related costs.

Net loss for the three months ended June 30, 2008 included impairment charges related to other-than-temporary impairment of auction rate securities totaling \$660,200. No such charges were incurred during the three months ended June 30, 2009.

Interest income for the three months ended June 30, 2009 decreased 100 percent compared to interest income for the three months ended June 30, 2008 as a result of depositing all of our cash into a non-interest bearing, 100% FDIC insured checking account during the first quarter of 2009.

## Six Months Ended June 30, 2009 Compared to Six Months Ended June 30, 2008

The following table sets forth our results of operations for the six months ended June 30, 2009 and 2008.

	Six Months Ended June 30,			
	2009	2008	\$ Change	% Change
Revenue	\$ 183,591	\$ 88,866	\$ 94,725	106.6%
Expenses				
Research and development	6,565,816	6,612,064	(46,248)	(0.7)%
General and administrative	2,238,158	2,918,649	(680,491)	(23.3)%
Impairment of short-term investments	0	660,200	(660,200)	(100.0)%
Interest income	11,648	449,424	(437,776)	(97.4)%
Net loss	\$ (8,671,313)	\$ (9,674,705)	\$ (1,003,392)	(10.4)%

Revenue increased \$94,725 for the six months ended June 30, 2009 compared to the six months ended June 30, 2008 primarily as a result of the recognition of Elestrin royalty revenue and grant revenue from a Small Business Innovation Research grant from the NIH to support our development of formulations for the pulmonary delivery of interferon alpha (IFN- $\alpha$ ) using our CaP technology.





Table of Contents

Research and development expenses for the six months ended June 30, 2009 decreased 0.7 percent compared to the six months ended June 30, 2008 primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study.

General and administrative expenses for the six months ended June 30, 2009 decreased 23 percent compared to the six months ended June 30, 2008 primarily as a result of a decrease in business development and other personnel-related costs.

Non-cash, stock option and warrant expense for the six months ended June 30, 2009 increased to \$672,843 compared to \$623,499 for the six months ended June 30, 2008 due to an increase in the number of stock options granted during the six months ended June 30, 2009.

Net loss for the six months ended June 30, 2008 included impairment charges related to other-than-temporary impairment of auction rate securities totaling \$660,200. No such charges were incurred during the six months ended June 30, 2009.

Interest income for the six months ended June 30, 2009 decreased 97 percent compared to interest income for the six months ended June 30, 2008 as a result of lower average invested cash balances during the six months ended June 30, 2009, and depositing all of our cash in a non-interest bearing, 100% FDIC-insured checking account during the first quarter 2009.

**Liquidity and Capital Resources**

***Working Capital***

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. Our business operations to date have consisted mostly of licensing and research and development activities and we expect this to continue for the immediate future. If and when our other products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including material sales and marketing and other expenses if we choose to market the products ourselves. We currently do not have sufficient resources to establish our own sales and marketing function, obtain regulatory approval of our other proposed products or complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. We expect the ongoing Phase III clinical study program of LibiGel to continue to require significant resources.

To date, we have used primarily equity financings, licensing income and interest income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future, although we recently have proposed to merge with a company as an alternative method for raising financing. We recognized royalty and other revenues from sales of Elestrin of \$85,449 and \$90,934 during the three and six month periods ended June 30, 2009, respectively. As of June 30, 2009, we had approximately \$6.0 million of cash and cash equivalents. In January 2009, all \$3.0 million of our then short-term investments were converted into cash and cash equivalents as a result of the sale of \$3.0 million of our auction rate securities to UBS Financial Services, Inc. and its affiliates for full par value plus accrued but unpaid interest. We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations. As of June 30, 2009, we did not have any outstanding debt or existing credit facilities under which we could borrow funds, other than the Committed Equity Financing

Facility described below.

In December 2008, we entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at our

Table of Contents

sole discretion, up to the lesser of \$25.0 million or 5,405,840 shares of our common stock through the end of December 2010. Under the terms of the CEFF, we are not obligated to utilize any of the \$25.0 million available under the CEFF and there are no minimum commitments or minimum use penalties. We have access, at our discretion, to the funds through the sale of newly-issued shares of our common stock. The funds that can be raised under the CEFF over the two-year term will depend on the then-current price for our common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. We may access capital under the CEFF by 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 CEFF 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 common stock issued or issuable to Kingsbridge; and the continued listing of our common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it 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. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase 300,000 shares of our common stock at an exercise price of \$4.00. The warrant became exercisable on June 15, 2009 and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys' fees and other direct costs related to the registration of these shares, we did not make any other payments to secure the CEFF. The CEFF does not impose any material restrictions on our operating or financial activities. During the term of the CEFF, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to our common stock. As of June 30, 2009, we had not sold any shares to Kingsbridge under the CEFF.

As of June 30, 2009, we had cash and cash equivalents of \$6.0 million, all of which resided in a 100% FDIC insured, non-interest bearing checking account.

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

- our ability to complete our proposed merger with Cell Genesys;
- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;
- the commercial success and net sales of Elestrin;
- our ability to license LibiGel or our other products for development and commercialization;

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

- the cost, timing and outcome of regulatory reviews of our proposed products;
- the rate of technological advances;
- the commercial success of our proposed products;
- our general and administrative expenses;

Table of Contents

- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts to continue to evaluate various strategic alternatives available with respect to our products and our company; and
- the activities of our competitors.

In April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study; those women already enrolled continue in the study. We intend to reinstate screening and enrollment in the safety study once we have secured adequate funding or closed the proposed merger with Cell Genesys. Currently, we continue to screen for and enroll new subjects in the LibiGel Phase III efficacy trials. This change in our clinical study screening likely will delay the eventual submission of the LibiGel NDA.

One of the primary reasons we are proposing to merge with Cell Genesys is our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other currently available acceptable alternatives for us to access capital, especially in light of the state of the markets for equity offerings, which historically has been our method for raising additional financing. Assuming the merger closes on or before October 31, 2009, we anticipate that Cell Genesys will have approximately \$21.5 million in cash and cash equivalents after the payment of Cell Genesys's anticipated liabilities. In addition, as of such date, Cell Genesys will have outstanding, and if the merger is completed, we would assume, an aggregate of \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 and \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011. If the merger with Cell Genesys is completed, we expect that the cash resources of the combined company expected to be available at the closing of the merger would provide us sufficient capital to maintain our projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. The merger is expected to be completed in the late third or fourth quarter of 2009.

If the merger with Cell Genesys is not completed or is delayed, we will need to raise additional financing immediately. Even if the merger with Cell Genesys is completed, we likely will need to raise additional financing to continue our Phase III clinical studies for LibiGel, unless LibiGel is licensed or sold to another company. Due to the current economic recession and market conditions, as well as the status of product development programs, there is uncertainty regarding whether additional financing will be available to us on favorable terms, or at all. If adequate funds are not available or are not available on acceptable terms when needed, we may be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, including most importantly, the Phase III clinical study program for LibiGel. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and the newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. If we incur debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting 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 our ability to create liens, pay dividends, redeem its stock or make investments. As an alternative to raising additional financing, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization, 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. We may be required to relinquish greater or all rights to our proposed products at an earlier

Table of Contents

stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern and cause us to significantly curtail or cease ongoing operations. The accompanying unaudited interim condensed financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result should we be unable to continue as a going concern.

***Uses of Cash and Cash Flow***

Net cash used in operating activities was \$8.6 million for the six months ended June 30, 2009 compared to net cash used in operating activities of \$7.1 million for the six months ended June 30, 2008. Net cash used in operating activities for the six months ended June 30, 2009 was primarily the result of the net loss for that period which was slightly lower compared to the prior year period due to lower clinical trial related expenses, and to a lesser extent, changes in accounts payable and accrued liabilities. Net cash used in operating activities of \$7.1 million for the six months ended June 30, 2008 was primarily the result of the net loss for that period, and to a lesser extent, changes in prepaid expenses and other assets, offset primarily by an increase in accounts payable and accrued liabilities.

Net cash provided by investing activities was \$2.9 million for the six months ended June 30, 2009 compared to net cash provided by investing activities of \$1.8 million for the six months ended June 30, 2008. Net cash provided by investing activities for the six months ended June 30, 2009 was due to the redemption of approximately \$3.0 million in short-term investments, partially offset by purchases of capital assets. Net cash provided by investing activities for the six months ended June 30, 2008 was due to the redemption of \$2.0 million in short-term investments, partially offset by purchases of capital assets.

Net cash used in financing activities was \$82,548 for the six months ended June 30, 2009 which related primarily to payment of acquisition related costs, compared to net cash provided by investing activities of \$33,970 for the six months ended June 30, 2008, which was the result of a warrant exercise.

Accrued liabilities for acquisition related costs were \$725,850 as of June 30, 2009.

***Commitments and Contractual Obligations***

We did not have any material commitments for capital expenditures as of June 30, 2009. We have, however, several potential financial commitments, including product development milestone payments to the licensors of certain of our products, payments under our license agreement with 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, 2008 as set forth in our annual report on Form 10-K for the year ended December 31, 2008. Other than obligations and commitments as a result of our merger agreement with Cell Genesys, there were no material changes to such information since that date through June 30, 2009.

*Off-Balance Sheet Arrangements*

We do not have any off-balance sheet arrangements that have or are reasonably 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 materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.



Table of Contents

**Critical Accounting Policies**

The discussion and analysis of our condensed financial statements and results of operations are based upon our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these condensed financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified certain of our accounting policies as critical accounting policies. Our critical accounting policies are described in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. There have been no changes to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2008.

**Recently Issued Accounting Pronouncements**

On January 1, 2008, we adopted the required provisions of Statement of Financial Accounting Standards No. 157, Fair Value Measurements, (SFAS 157) for financial assets and liabilities.

In February 2008, the Financial Accounting Standards Board (FASB) issued Staff Position ( FSP ) No. FAS 157-2, Effective Date of FASB Statement No. 157, (FSP 157-2) which delays the effective date of SFAS 157 for certain non-financial assets and liabilities to fiscal years beginning after November 15, 2008. We adopted these standards on January 1, 2009. The adoption of FSP 157-2 did not have a material impact on our financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active, (FSP 157-3), which clarifies the application of SFAS 157 in an inactive market and illustrates how an entity would determine fair value when the market for a financial asset is not active. FSP 157-3 is effective immediately and applies to prior periods for which financial statements have not been issued. The implementation of FSP 157-3 did not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007) Business Combinations ( SFAS 141(R) ) which is effective for fiscal years beginning after December 15, 2008. SFAS 141(R) retains the underlying fair value concepts of its predecessor (SFAS No. 141), but changes the method for applying the acquisition method in a number of significant respects, including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. We adopted these standards on January 1, 2009. Because these standards are generally applied prospectively, the effect of adoption on our financial statements will depend primarily on specific transactions, if any, completed after 2008. See Note 6 for discussion of the anticipated accounting impact of the merger with Cell Genesys.

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

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS 165), which provides guidance on management's assessment of subsequent events. SFAS 165 clarifies that management must evaluate, as of each reporting period, events or transactions that occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date through the date that the financial statements are issued

Table of Contents

or are available to be issued. SFAS 165 requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for that date. We adopted SFAS 165 for the three months ended June 30, 2009. The implementation of SFAS 165 did not have a material impact on our financial statements.

In June 2009, the FASB issued SFAS No. 168, the FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles ( SFAS 168 ), establishing the FASB Accounting Standards Codification ( Codification ) as the source of authoritative U.S. generally accepted accounting principles ( GAAP ) recognized by the FASB to be applied by nongovernmental entities. SFAS 168 replaces SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles and is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification reorganizes current GAAP into a topical format that eliminates the current GAAP hierarchy and establishes instead two levels of guidance authoritative and nonauthoritative. On the effective date, all then-existing non-SEC accounting literature and reporting standards are superseded and deemed nonauthoritative. The FASB will no longer update or maintain the superseded standards. We will adopt this standard for our quarter ended September 30, 2009. The adoption of the FAS 168 will not have a material impact on our financial statements. However, because the Codification completely replaces existing standards, it will affect the way GAAP is referenced by us in our financial statements.

**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, might, possible, potential, project, will, intend, plan, predict, anticipate, estimate, hope, approximate, contemplate or continue and other words and terms of similar meaning. Forward-looking statements may be contained in the notes to our condensed financial statements and elsewhere in this report, including under the caption 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 and other aspects regarding our proposed merger with Cell Genesys;
- the timing of the commencement, enrollment and successful completion of our clinical studies and other regulatory status of our proposed products;
- approval of our drugs by the U.S. Food and Drug Administration that are currently in clinical development;
- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market and market acceptance of our products;

- the effect of new accounting pronouncements;

Table of Contents

- whether and how long our existing cash and our cash if we merge with Cell Genesys 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. Some of the uncertainties and factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see Part II Item 1A. Risk Factors 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 under the heading Part II Item 1A. Risk Factors in this report 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 under the heading Part II Item 1A. Risk Factors in this report. The risks and uncertainties described under the heading Part II Item 1A. Risk Factors in this report are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. Except as otherwise required by law, 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**

The primary objective of our investment activities is to preserve principal. To achieve this objective, we typically in the past have sought to invest in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically seek to invest our excess funding in cash and cash equivalents and high-quality, short-term securities with maturities of less than one year. Currently, all of our cash and cash equivalents reside in our 100% FDIC-insured non-interest bearing checking account.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

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

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 reasonably ensure that 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

Table of Contents

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 necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. 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, 2009 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

A description of our legal proceedings in Note 6 to our financial statements included within this report is incorporated herein by reference.

**ITEM 1A. RISK FACTORS**

The following are significant risk factors known to us that could materially adversely affect our business, financial condition or operating results.

**Risks Related to BioSante's Proposed Merger with Cell Genesys**

*The exchange ratio in the merger agreement is subject to adjustment based on Cell Genesys's net cash 10 days prior to the anticipated closing date, which could further dilute the ownership of BioSante's stockholders in the combined company.*

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of common stock of Cell Genesys issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive 0.1615 of a share of BioSante's common stock, subject to potential adjustment as described in the merger agreement depending upon the amount of net cash of Cell Genesys, less certain expenses and liabilities, 10 calendar days prior to the anticipated closing date of the merger. If the net cash of Cell Genesys 10 days prior to the anticipated closing date is more than \$500,000 greater than or less than the target net cash set forth in the merger agreement, then the exchange ratio will be adjusted as follows:

- If the net cash of Cell Genesys is more than \$500,000 greater than the target net cash set forth in the merger agreement, the merger agreement provides for an adjustment to the exchange ratio to increase the number of shares of BioSante's common stock that Cell Genesys's stockholders will be entitled to receive pursuant to the merger, which would further dilute the ownership of the current BioSante's stockholders in the combined company.
- If the net cash of Cell Genesys is more than \$500,000 less than the target net cash set forth in the merger agreement, the merger agreement provides for an adjustment to the exchange ratio to decrease the number of shares of BioSante's common stock that Cell Genesys's stockholders will be entitled to receive pursuant to the merger, which would further dilute the ownership of the current Cell Genesys's stockholders in the combined company.



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

The items that will constitute Cell Genesys's net cash at the determination date set forth in the merger agreement are subject to a number of factors, many of which are outside the control of BioSante and some of which are outside the control of Cell Genesys.

*The exchange ratio is not adjustable based on the market price of BioSante's common stock so the merger consideration at the closing may have a greater or lesser value than at the time the merger agreement was signed.*

Although the exchange ratio set forth in the merger agreement is potentially adjustable upward or downward depending upon Cell Genesys's net cash at the determination date set forth in the merger agreement, the exchange ratio and the number of shares to be issued by BioSante, is not adjustable based

Table of Contents

on the market price of BioSante's or Cell Genesys's common stock and the merger agreement may not be terminated for any such changes. If the market price of BioSante's common stock increases from the market price on the date of the merger agreement prior to the closing of the merger, Cell Genesys's stockholders could receive merger consideration with considerably more value than their shares of Cell Genesys's common stock and BioSante's stockholders immediately prior to the merger will not be compensated for the increased market value of BioSante's common stock. Similarly, if the market price of BioSante's common stock declines from the market price on the date of the merger agreement prior to the closing of the merger, Cell Genesys's stockholders could receive merger consideration with substantially lower value. Because the exchange ratio does not adjust as a result of changes in the value of BioSante's common stock, for each one percentage point that the market value of BioSante's common stock rises or declines, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration issued to Cell Genesys's stockholders. Assuming that a total of approximately 17.7 million shares of BioSante's common stock are issuable to Cell Genesys's stockholders in connection with the merger at an assumed price per share equal to the execution date closing price of BioSante's common stock, the aggregate merger consideration for Cell Genesys's stockholders would be valued at approximately \$38.1 million. If, however, the closing price of BioSante's common stock on the date of closing of the merger increases from the closing price on the date of the merger agreement to, for example, \$2.58 per share, an increase of 20 percent, the aggregate merger consideration to be issued to Cell Genesys's stockholders in the merger would increase from approximately \$38.1 million to approximately \$45.7 million, an increase of \$7.6 million, or 20 percent.

***The exchange ratio is not adjustable based on issuances by BioSante or Cell Genesys of additional shares of BioSante's common stock or Cell Genesys's common stock upon the exercise of options or warrants or the conversion of convertible securities or otherwise, which issuances would result in additional dilution to BioSante's stockholders.***

It is BioSante's understanding that as of June 30, 2009, Cell Genesys had outstanding options to purchase an aggregate of approximately 2.7 million shares of Cell Genesys's common stock, warrants to purchase an aggregate of approximately 4.8 million shares of Cell Genesys's common stock and an aggregate of \$22.0 million in convertible senior notes that are convertible into an aggregate of approximately 30.7 million shares of Cell Genesys's common stock. As of June 30, 2009, BioSante had outstanding options to purchase an aggregate of approximately 2.7 million shares of BioSante's common stock, warrants to purchase an aggregate of approximately 2.7 million shares of BioSante's common stock and an aggregate of 391,286 shares of BioSante class C special stock that are convertible into an equal number of shares of BioSante's common stock. Although Cell Genesys is prohibited under the terms of the merger agreement from issuing additional equity securities other than pursuant to the exercise of outstanding options or warrants or the conversion of outstanding convertible notes, BioSante is not. It is possible that prior to the completion of the merger BioSante may issue additional equity securities in order to raise additional financing. The exchange ratio is not adjustable based on issuances by BioSante or Cell Genesys of additional shares of BioSante's common stock or Cell Genesys's common stock for any reason. Therefore, any such issuances by BioSante or Cell Genesys would result in additional dilution to BioSante's and Cell Genesys's stockholders.

***The merger is subject to certain conditions to closing that could result in the merger not being consummated or being delayed, either of which could negatively impact the market price of BioSante and its business and operating results.***

Consummation of the merger is subject to a number of customary conditions, including, but not limited to, the approval of the merger agreement by BioSante's and Cell Genesys's stockholders. If any of the conditions to the merger are not satisfied or, where waiver is permissible, not waived, the merger

Table of Contents

will not be consummated. Failure to complete the merger could result in a number of adverse effects, including:

- preventing BioSante from realizing any benefits from the merger;
- requiring BioSante to incur significant transaction costs without realizing any benefits of the merger, and depending upon the circumstances of the failure to complete the merger, requiring BioSante to pay Cell Genesys a \$1.0 million termination fee or expense reimbursement of up to \$500,000;
- a decline in the market price of BioSante's common stock to the extent the market price of BioSante's common stock positively reflects a market assumption that the merger will occur; and
- uncertainty surrounding the future direction of the product offerings, available alternatives and strategy of BioSante on a standalone basis or a negative perception by the market of BioSante generally.

Any delay in the consummation of the merger or any uncertainty about the consummation of the merger also could impact negatively the market price of BioSante's common stock and its business and operating results or prevent, delay or eliminate realization of some or all of the anticipated benefits of the merger. It is possible that the merger will not be consummated or the consummation may be delayed or consummated on different terms than those contemplated by the merger agreement.

***The announcement and pendency of the merger may have and could impact or cause disruptions in BioSante's business, which could have an adverse effect on its business, operating results and financial condition and, if the merger is completed, the business, operating results and financial condition of the combined company.***

The announcement and pendency of the merger may have and could cause disruptions in or otherwise negatively impact BioSante's business, operating results and financial condition and if the merger is completed, the business, operating results and financial condition of the combined company. Among others:

- the diversion of the attention of BioSante's management to the merger and transaction-related considerations instead of BioSante's day-to-day business operations and the pursuit of other opportunities that could have been beneficial to BioSante's business; and
- vendors, suppliers or other business partners may seek to modify or terminate their business relationships with BioSante or the combined company.

These disruptions could be exacerbated by a delay in the completion of the merger or termination of the merger agreement and could have an adverse effect on BioSante's business, operating results or financial condition, and if the merger is completed, the business, operating results or financial condition of the combined company.

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

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

Table of Contents

Most of these costs will be paid by BioSante even if the merger is not completed. In addition, if the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante may be required to pay Cell Genesys a termination fee of \$1.0 million. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse Cell Genesys \$500,000 for its expenses in connection with the transaction, which would be credited against the termination fee if the termination fee subsequently becomes payable by BioSante. If the merger is not completed, BioSante will bear the transaction costs of the merger, including financial advisor, legal and accounting fees and expenses, which currently are estimated to be approximately \$1.2 million.

***The deal-protection provisions of the merger agreement may deter alternative transactions which could be advantageous to BioSante when compared to the terms and conditions of the merger transaction, and, in certain circumstances, may require BioSante to pay Cell Genesys a \$1.0 million termination fee or reimburse Cell Genesys \$500,000 for its expenses.***

As a result of certain deal-protection provisions of the merger agreement, it is possible that a third party who might be interested in pursuing an alternative transaction with BioSante would be discouraged from doing so. Any such proposal might be advantageous to the stockholders of BioSante when compared to the merger transaction. In particular, provisions of the merger agreement which require BioSante to pay Cell Genesys a \$1.0 million termination fee or reimburse Cell Genesys of up to \$500,000 of expenses may deter third parties from proposing alternative business transactions that might result in greater value to BioSante's stockholders than the merger. In addition, in the event the merger agreement is terminated by BioSante in circumstances that may obligate BioSante to pay Cell Genesys a termination fee or reimburse Cell Genesys up to \$500,000 for its expenses, BioSante's stock price may decline as result of this reimbursement, its financial condition could be adversely affected and/or a potential competing third party proposing an alternative transaction may propose less favorable terms than it might otherwise have proposed.

***Certain directors and executive officers of BioSante and Cell Genesys have entered into voting agreements that require them to vote in favor of the adoption of the merger agreement and the transactions contemplated thereby and against any competing business transaction, which could discourage third parties from making an alternative business transaction proposal to BioSante and deprive BioSante's stockholders of the benefit of a more advantageous business transaction.***

Certain directors and executive officers of BioSante and Cell Genesys, who in the aggregate beneficially owned as of June 30, 2009 approximately 9.5 percent of the issued and outstanding shares of BioSante's common stock and less than 1 percent of the issued and outstanding shares of Cell Genesys's common stock, respectively, have entered into voting agreements, pursuant to which they have agreed, during the term of such agreements and subject to certain exceptions, to vote their shares of common stock in favor of the adoption of the merger agreement and the transactions contemplated thereby and against any competing business transaction. In addition, Tang Capital Partners, LP, which according to public filings as of July 1, 2009 held 9,502,089 shares, or 8.7 percent, of Cell Genesys's common stock, agreed pursuant to the terms of a settlement agreement and exchange agreement with Cell Genesys to vote any shares of Cell Genesys's common stock owned by it only (i) pro rata with the votes of other Cell Genesys's stockholders or (ii) at its option in accordance with the recommendation of the Cell Genesys board of directors. The existence of these voting agreements may discourage third parties from making an alternative business transaction proposal to BioSante and deprive BioSante's stockholders of the benefit of a more advantageous business transaction.

Table of Contents

***Charges resulting from the allocation of the purchase consideration may adversely affect the market value of the combined company's common stock following the merger.***

The merger will be accounted for under U.S. generally accepted accounting principles, or U.S. GAAP, as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys will be recorded by BioSante as of the completion of the merger based on their estimated fair values. Following the completion of the merger, the future net income (loss) of the combined company will reflect charges resulting from the purchase price allocation related to the merger, which will include adjustments to carrying values of the acquired net assets based on the fair value of consideration measured as of the completion of the merger. The purchase price adjustments and potential corresponding charges could have a material impact on the combined company's results of operations which could have an adverse impact on the market value of the combined company's common stock.

***BioSante may waive one or more of the conditions to the merger without resoliciting BioSante stockholder approval for the merger.***

Each of the conditions to BioSante's obligations to complete the merger may be waived, in whole or in part, to the extent legally allowed, either unilaterally or by agreement of BioSante and Cell Genesys. The board of directors of BioSante will evaluate the materiality of any such waiver to determine whether resolicitation of proxies from BioSante's stockholders is necessary. In the event that the board of directors of BioSante determines any such waiver is not significant enough to require resolicitation of BioSante's stockholders, it will have the discretion to complete the merger without seeking further stockholder approval. Approval of the merger agreement by BioSante's stockholders cannot be waived.

***Litigation is pending against Cell Genesys, the members of the Cell Genesys board of directors and BioSante challenging the merger and an adverse judgment in any of those lawsuits may prevent the merger from becoming effective within the expected timeframe or at all.***

Cell Genesys, the members of the Cell Genesys board of directors and BioSante are named as defendants in four purported class action lawsuits brought by Cell Genesys's stockholders challenging Cell Genesys's proposed merger with BioSante, seeking to rescind the merger agreement and an injunction prohibiting the parties from completing the merger. If the plaintiffs in any of these cases are successful in obtaining an injunction prohibiting the parties from completing the merger on the agreed upon terms, the injunction may prevent the completion of the merger in the expected timeframe (if at all). Even if the plaintiffs in these actions are not successful, the costs of defending against such claims could adversely affect the financial condition of BioSante to the extent not covered by insurance.

Table of Contents

**Risks Related to BioSante Financial Condition and Capital Requirements**

*BioSante has a history of operating losses, expects continuing losses and may never become profitable.*

BioSante has a history of operating losses. BioSante incurred a net loss of \$8.7 million for the six months ended June 30, 2009 and a net loss of \$17.4 million for the year ended December 31, 2008. As of June 30, 2009, BioSante's accumulated deficit was \$80.6 million. Substantially all of BioSante's revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions, revenue earned from subcontracts with various parties and royalty revenue. BioSante expects to incur substantial and continuing losses for the foreseeable future as its own product development programs continue and various preclinical and clinical trials commence or continue, including in particular its Phase III clinical study program for LibiGel. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the progress, timing, cost and results of BioSante's preclinical and clinical development programs, including in particular its Phase III clinical study program for LibiGel, and its other product development efforts;
- patient recruitment and enrollment in BioSante's current and future clinical studies, including in particular its Phase III clinical study program for LibiGel;
- the commercial success and net sales of Elestrin;
- BioSante's ability to license LibiGel or its other products for development and commercialization;
- the cost, timing and outcome of regulatory reviews of BioSante's proposed products;
- the rate of technological advances;
- ongoing determinations of the potential markets for and commercial success of BioSante's proposed products;
- the timing and cost of various cash and non-cash general and administrative expenses;

- the success, progress, timing and costs of BioSante's business development efforts to implement business collaborations, licenses and other business combinations or transactions, including its efforts to evaluate various strategic alternatives available with respect to its products and BioSante;
- the activities of BioSante's competitors; and
- BioSante's opportunities to acquire new products or take advantage of other unanticipated opportunities.

In order to generate new and significant revenues, BioSante successfully must develop its own proposed products and enter into collaborative agreements with others who successfully can commercialize them. Even if BioSante's proposed products and the products it may license or otherwise acquire are introduced commercially, they may never achieve market acceptance and BioSante may not generate additional revenues or achieve profitability in future years.



Table of Contents

***BioSante needs to raise substantial additional capital in the near future to fund its operations. If additional capital is not available, BioSante may have to curtail significantly or even cease its ongoing operations.***

BioSante currently does not have sufficient resources to obtain regulatory approval of its proposed products or to complete the commercialization of any of its proposed products. BioSante expects the Phase III clinical study program of LibiGel to continue to require significant resources. As of June 30, 2009, BioSante had \$6.0 million in cash and cash equivalents. Since then, BioSante has continued to spend cash on operations, particularly the Phase III LibiGel clinical study program. Given the poor economic conditions, BioSante has reviewed every aspect of its operations for cost and spending reductions to assure its long term survival while maintaining the resources necessary to achieve its primary objectives of developing its proposed products and obtaining regulatory approval of such products, including in particular LibiGel. To save costs, BioSante decided to delay screening new subjects for its LibiGel Phase III safety study; those women already enrolled continue in the study. BioSante intends to reinitiate screening and enrollment in the safety study once it has secured adequate funding or closed the proposed merger with Cell Genesys. Currently, BioSante continues to screen for and enroll new subjects in the LibiGel Phase III efficacy trials. This change in BioSante's clinical study screening may delay the eventual submission of the LibiGel NDA depending on how long BioSante needs to continue this change.

One of the primary reasons BioSante is proposing to merge with Cell Genesys is BioSante's need for additional financing to continue its Phase III clinical studies for LibiGel and the lack of other currently available acceptable alternatives for BioSante to access capital, especially in light of the state of the markets for equity offerings, which historically has been BioSante's method for raising additional financing. If the merger with Cell Genesys is completed, BioSante expects that the cash resources of the combined company expected to be available at the closing of the merger would provide the combined company sufficient capital to maintain its projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. If the merger with Cell Genesys is not completed or is delayed, BioSante will need to raise additional financing immediately. Even if the merger with Cell Genesys is completed, BioSante likely will need to raise additional financing to continue its Phase III clinical studies for LibiGel, unless LibiGel is licensed or sold to another company.

BioSante's future capital requirements will depend upon numerous factors, including:

- its ability to complete the merger with Cell Genesys and acquire the cash and cash equivalents of Cell Genesys;
- the success, progress, timing and costs of its business development efforts to implement business collaborations, licenses and other business combinations or transactions;
- the progress, timing, cost and results of its preclinical and clinical development programs, including in particular its Phase III clinical study program for LibiGel, and its other product development efforts;
- patient recruitment and enrollment in its current and future clinical studies, including in particular its Phase III clinical study program for LibiGel;

- the commercial success and net sales of Elestrin;
- its ability to license LibiGel or its other products for development and commercialization;

Table of Contents

- the cost, timing and outcome of regulatory reviews of its proposed products;
- the rate of technological advances;
- the commercial success of its proposed products;
- its general and administrative expenses; and
- the activities of its competitors.

BioSante has on file an effective shelf registration statement that allows it to raise up to \$75 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, under applicable SEC rules, so long as BioSante has a public float of less than \$75 million, it can only offer to sell under the registration statement up to one-third of its public float during any 12 month period. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have made equity and debt financing more difficult to obtain, and may negatively impact BioSante's ability to complete financing transactions. In addition, the stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of listed companies. There have been dramatic fluctuations in the market prices of securities of biopharmaceutical companies such as BioSante's. Broad market and industry factors may seriously harm the market price of BioSante's common stock, regardless of its operating performance, and may adversely impact its ability to raise additional funds. Due to such market conditions, as well as the status of its product development programs, BioSante can provide no assurance that additional financing will be available on terms favorable to it, or at all. If adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may be required to delay, scale back or eliminate some or all of its programs designed to obtain regulatory approval of its proposed products, including most importantly, as mentioned above, its Phase III clinical study program for LibiGel. Failure to obtain adequate financing also may cause BioSante to curtail significantly or even cease its ongoing operations.

***Raising additional funds by issuing securities or through licensing arrangements may cause dilution to existing BioSante's stockholders, restrict BioSante's operations or require BioSante to relinquish proprietary rights.***

If BioSante raises additional funds through the issuance of equity or convertible debt securities, the percentage ownership of BioSante's stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing BioSante's stockholders. If BioSante incurs debt financing, a substantial portion of its operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for its business activities, and BioSante could be subject to covenants that restrict its ability to operate its business and make distributions to its stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of BioSante's assets, as well as prohibitions on the ability of BioSante to create liens, pay dividends, redeem its stock or make investments. As an alternative to raising additional financing by issuing securities, BioSante may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may

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

finance a portion or all of the continued development and, if approved, commercialization, sell certain assets or rights BioSante has under its existing license agreements or enter into other business collaborations or combinations, including the possible sale of its company. If BioSante raises additional

Table of Contents

funds through licensing arrangements, BioSante may be required to relinquish greater or all rights to its proposed products at an earlier stage of development or on less favorable terms than BioSante otherwise would choose.

***The committed equity financing facility that BioSante entered into with Kingsbridge Capital Limited may not be available to BioSante if BioSante elects to make a draw down.***

In December 2008, BioSante entered into a committed equity financing facility, or CEFF, with Kingsbridge. The CEFF entitles BioSante to sell and obligates Kingsbridge to purchase, from time to time over a period of two years, up to the lesser of (i) an aggregate of \$25 million in or (ii) 5,405,840 shares of BioSante's common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for BioSante's 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 BioSante's common stock issued or issuable to Kingsbridge; and the continued listing of BioSante stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting BioSante's business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides BioSante notice of such material and adverse event. If BioSante is unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, BioSante may be unable to access capital on favorable terms or at all. As of the date of the filing of this report, BioSante had not sold any shares to Kingsbridge under the CEFF.

***The report of BioSante's independent registered public accounting firm expresses substantial doubt about BioSante's ability to continue as a going concern which may adversely affect its ability to raise additional financing and close its proposed merger with Cell Genesys.***

Because of continuing expenditures related to BioSante's research and development activities, including in particular the Phase III clinical study program for LibiGel, as well as additional expenditures incurred due to BioSante's efforts at pursuing strategic alternatives, including in particular the proposed merger with Cell Genesys, BioSante has incurred higher than anticipated expenses and liabilities. In addition, BioSante has not raised additional financing through an equity offering, which historically has been its primary method for raising additional financing. As a result, in connection with the re-issuance of BioSante's financial statements for the year ended December 31, 2008 as a result of the Form S-4 registration statement to register the shares of BioSante common stock to be issued in connection with the proposed Cell Genesys merger, BioSante's independent registered public accounting firm has included an explanatory paragraph in their report on BioSante's financial statements for the year ended December 31, 2008 that expresses substantial doubt regarding BioSante's ability to continue as a going concern. BioSante's condensed financial statements for the year ended December 31, 2008 and the unaudited condensed financial statements contained in this report have been prepared assuming that BioSante will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The going concern qualification could adversely affect BioSante's relationships with third parties, which could further exacerbate its current liquidity issues and impact its ability to continue as a going concern, and negatively impact the trading price of its common stock. The recent inclusion of the going concern qualification in BioSante's financial statements also may influence BioSante's stockholders or the stockholders of Cell Genesys not to vote in favor of the approval and adoption of the proposed merger with Cell Genesys or may adversely affect BioSante's ability to obtain additional financing.

Table of Contents

**Risks Related to BioSante's Business**

*BioSante's proposed products are in the development stages and likely will not be commercially introduced for several years, if at all.*

BioSante's proposed products are in the 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 BioSante's products have been introduced commercially nor does BioSante expect them to be for several years. Some of BioSante's products are not in active development. For example, at this time, BioSante believes that its estrogen/progestogen combination transdermal gel product sublicensed to Solvay Pharmaceuticals, B.V. is not in active development by Solvay, and BioSante does not expect its active development to occur at any time in the near future. BioSante cannot assure you that any of its proposed products 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 BioSante fails to obtain regulatory approval to manufacture commercially or sell any of its future products, or if approval is delayed or withdrawn, BioSante will be unable to generate revenue from the sale of its products.*

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

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

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, BioSante's proposed products could take a significantly longer time to gain regulatory approval than BioSante expects or may never gain approval. If regulatory approval is delayed or never obtained, the credibility of BioSante's management, the value of BioSante and its operating results and liquidity would be adversely affected. Even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. In addition, even after obtaining regulatory approval, BioSante may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture are subsequently discovered. The FDA also may require BioSante to commit to perform

Table of Contents

lengthy post-approval studies, for which BioSante would have to expend significant additional resources, which could have an adverse effect on its operating results and financial condition.

To obtain regulatory approval to market BioSante's products, costly and lengthy pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain. As part of the FDA approval process, BioSante must conduct, at its own expense or the expense of current or potential licensees, clinical trials on humans on each of its proposed products. Pre-clinical studies on animals must be conducted on some of BioSante's proposed products. BioSante expects the number of pre-clinical studies and 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. BioSante may need to perform multiple pre-clinical studies using various doses and formulations before BioSante can begin human clinical trials, which could result in delays in its ability to market any of its products. Furthermore, even if BioSante obtains favorable results in pre-clinical studies on animals, the results in humans may be different.

After BioSante has conducted pre-clinical studies in animals, BioSante must demonstrate that its 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. BioSante faces the risk that the results of its 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 BioSante from filing for regulatory approval of BioSante's products. Additional factors that can cause delay or termination of BioSante's human clinical trials include:

- slow patient 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 patients;
- lack of effectiveness of the product being tested; and
- lack of funding.



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

Delays in BioSante's clinical trials could allow its 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.

*Although BioSante successfully has completed and reached agreement with the FDA under the SPA process for its Phase III safety and efficacy clinical trial program for LibiGel, BioSante still may not obtain FDA approval of LibiGel within a reasonable period of time or ever, which would harm its business and likely decrease its stock price.*

BioSante anticipates that LibiGel, if approved by the FDA, could be a very successful product. However, 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. BioSante believes based on agreements

Table of Contents

with the FDA, including an SPA received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval 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. The SPA process and agreement affirms that the FDA agrees 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 that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel. These SPA trials use BioSante's validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, BioSante received another SPA for its LibiGel program in the treatment of FSD, specifically, HSDD in naturally menopausal women. 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, BioSante fails 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 BioSante 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 these clinical trials, which can result from unforeseen issues, FDA interventions, problems with enrolling patients and other reasons, could delay significantly commercial launch and affect BioSante's product development costs. Moreover, results from these clinical studies may not be as favorable as the results BioSante obtained in prior, completed studies. BioSante cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

***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 hormone therapy products and the trading price of BioSante's 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 exceed the benefits from the use of those products among healthy 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 healthy 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 healthy 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. BioSante's 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

Table of Contents

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 BioSante's products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms have declined as a result of these published studies. The release of any follow-up or other studies that show adverse affects from hormone therapy, including in particular, hormone therapies similar to BioSante's products, also would adversely affect its business and likely decrease its stock price.

***If clinical trials for BioSante's proposed products are prolonged or delayed, BioSante may be unable to commercialize its proposed products on a timely basis, which would require it to incur additional costs and delay its receipt of any revenue from potential product sales or licenses.***

BioSante may encounter problems with its completed, ongoing or planned clinical trials for its proposed products that will cause it or any regulatory authority to delay or suspend those clinical trials 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, BioSante's ongoing and planned clinical trials for its proposed products and negatively impact its ability to obtain regulatory approval or enter into collaborations for, or market or sell, a particular proposed product:

- conditions imposed on BioSante by the FDA or any foreign regulatory authority regarding the scope or design of its clinical trials;
- delay in developing, or its inability to obtain, a clinical dosage form, insufficient supply or deficient quality of its proposed products or other materials necessary to conduct its clinical trials;
- negative or inconclusive results from clinical trials, 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 clinical trials; or
- failure of its third-party contractors or its investigators to comply with regulatory requirements or otherwise meet their contractual obligations to BioSante in a timely manner.

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

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which BioSante's clinical trials are conducted all have the power to stop its clinical trials prior to completion. BioSante's clinical trials for its products may not begin as planned, may need to be restructured, and may not be completed on schedule, if at all. This is particularly true if BioSante no longer has the financial resources to dedicate to its clinical trial program.

*BioSante entered into an exclusive sublicense agreement Azur Pharma International II, Limited for the marketing of Elestrin in the United States as a result of which BioSante is dependent upon Azur for the marketing and sale of Elestrin.*

Table of Contents

In December 2008, BioSante entered into an exclusive sublicense agreement with Azur for the marketing of Elestrin in the United States pursuant to which BioSante received an upfront license payment and has the right to receive certain sales-based milestone payments, plus royalties on sales of Elestrin. As a result of this agreement, Elestrin is subject to not only general market acceptance of the product, but also the success of Azur in marketing and selling the product. Sales of Elestrin by BioSante's former sublicensee, Nycomed US Inc. (which acquired Bradley Pharmaceuticals, Inc. in February 2008), were minimal and did not result in BioSante's receipt of any meaningful royalty revenue. Azur launched sales and marketing activities related to Elestrin in April 2009. Sales of Elestrin were \$90,934 for the six months ended June 20, 2009. BioSante cannot assure you that Azur will be successful in marketing Elestrin or that Azur will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of its agreement with BioSante, especially if Azur does not experience significant Elestrin sales. Any breach by Azur of its obligations under BioSante's agreement or a termination of the agreement could adversely affect the success of Elestrin if BioSante is unable to sublicense the product to another party on substantially the same or better terms or continue the future commercialization of the product itself.

***Elestrin, which is FDA approved, and BioSante's other proposed products, if they receive FDA approval, may not achieve expected levels of market acceptance, which could have a material adverse effect on BioSante's business, financial position and operating results and could cause the market value of BioSante's common stock to decline.***

The commercial success of BioSante's FDA-approved product, Elestrin, and its other proposed products, if they receive the required regulatory approvals, is dependent upon market acceptance by physicians and patients. Levels of market acceptance for BioSante's products could be affected by several factors, including:

- the availability of alternative products from competitors;
- the price of BioSante's products relative to that of its competitors;
- the timing of market entry; and
- the ability to market its products effectively.

Some of these factors are not within BioSante's control, especially if it has transferred all of the marketing rights associated with the product, as BioSante has with Elestrin to Azur. Elestrin and BioSante's proposed 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 the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on BioSante's business, financial position and results of operations, and the market value of BioSante's common stock could decline.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

*BioSante and its sublicensees depend on third-party manufacturers to produce BioSante's proposed products and if these third parties do not successfully manufacture these products its business would be harmed.*

BioSante has no manufacturing experience or manufacturing capabilities for the production of its proposed products for clinical trials or commercial sale. In order to continue to develop proposed

Table of Contents

products, apply for regulatory approvals and commercialize its proposed products following approval, BioSante or its sublicensees must be able to manufacture or contract with third parties to manufacture its products in clinical and commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of BioSante's 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 BioSante's products may make them prohibitively expensive. If supplies of any of BioSante's products become unavailable on a timely basis or at all or are contaminated or otherwise lost, clinical trials by it could be seriously delayed.

To the extent that BioSante or its sublicensees seek to enter into manufacturing arrangements with third parties, BioSante and such sublicensees will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond BioSante's control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for BioSante. If third-party manufacturers fail to perform their obligations, BioSante's competitive position and ability to generate revenue may be adversely affected in a number of ways, including:

- BioSante and its collaborators may not be able to initiate or continue clinical trials of product candidates that are under development;
- BioSante and its collaborators may be delayed in submitting applications for regulatory approvals for its product candidates; and
- BioSante and its collaborators may not be able to meet commercial demands for any approved products.

***BioSante has very limited staffing and will continue to be dependent upon key employees.***

BioSante's success is dependent upon the efforts of a small management team and staff. BioSante has employment arrangements in place with both of its two executive officers, but neither of its executive officers is legally bound to remain employed for any specific term. BioSante does not have key man life insurance policies covering its executive officers or any of its other employees. If key individuals leave BioSante, it could be adversely affected 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 BioSante's business. BioSante's future success depends upon its ability to continue to attract and retain qualified personnel.

***Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on BioSante's stock price.***

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires BioSante's management to assess and its independent registered public accounting firm to provide an opinion on the effectiveness of its internal controls over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission provides a framework for companies to assess and improve their internal control systems. If BioSante is unable to maintain effective internal controls, BioSante might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the



Table of Contents

NASDAQ Stock Market. Any such action could adversely affect BioSante's financial results, financial position and the market price of BioSante's common stock. In addition, if one or more material weaknesses is identified in BioSante's internal controls over financial reporting, BioSante will be unable to assert that its internal controls over financial reporting is effective. If BioSante is unable to assert that its internal controls over financial reporting is effective (or if its independent registered public accounting firm is unable to express an opinion or issues an adverse opinion on the effectiveness of its internal controls over financial reporting), BioSante could lose investor confidence in the accuracy and completeness of its financial reports, which in turn could have an adverse effect on its stock price. If BioSante fails to maintain the adequacy of its internal controls, as such standards are modified, supplemented or amended from time to time, BioSante may not be able to ensure that it can conclude on an ongoing basis that it has effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal controls over financial reporting could have an adverse effect on BioSante's common stock price.

**Risks Related to BioSante's Industry**

***Because BioSante's industry is very competitive and many of its competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than BioSante, BioSante may not succeed in developing its proposed products and bringing them to market.***

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

***Because the pharmaceutical industry is heavily regulated, BioSante faces significant costs and uncertainties associated with its efforts to comply with applicable regulations. Should BioSante fail to comply, it could experience material adverse effects on its business, financial position and results of operations, and the market value of BioSante's common stock could decline.***

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, BioSante must comply with FDA requirements with respect to the development of its proposed products and its clinical trials, and if any of its proposed products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of its products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Despite BioSante's efforts at compliance, there is no guarantee that BioSante may not be deemed to be deficient in some manner in the future. If BioSante were deemed to be deficient in any significant way, its business, financial position and results of operations could be materially affected and the market value of BioSante's common stock could decline.



Table of Contents

**Risks Related to BioSante's Intellectual Property**

***BioSante licenses the technology underlying most of its products and a portion of its CaP technology from third parties and may lose the rights to license them, which could have a material adverse effect on its business, financial position and operating results and could cause the market value of its common stock to decline.***

BioSante licenses certain of the technology underlying its products from Antares Pharma, Inc., a portion of its CaP technology from the University of California and the Pill-Plus from Wake Forest University. BioSante may lose its right to license these technologies if it breaches its obligations under the license agreements. Although BioSante intends to use its reasonable best efforts to meet these obligations, if BioSante violates or fails to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve BioSante of its obligation to pay any royalty or license fees owed at the time of termination. BioSante's failure to retain the right to license the technology underlying its proposed products or CaP technology could harm its business and future operating results. For example, if BioSante were to enter into a sublicense agreement with a third party under which BioSante agrees to sublicense its hormone therapy technology or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc., the University of California or Wake Forest University could either, depending upon the terms of the sublicense agreement, cause BioSante to breach its obligations under the sublicense agreement or give the other party a right to terminate that agreement, thereby causing BioSante to lose future revenue generated by the sublicense fees.

***BioSante has licensed some of its products to third parties and any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect the development and marketing of its licensed products. In addition, these third parties also may compete with BioSante with respect to some of its proposed products.***

BioSante has licensed its CaP technology for use as a facial line filler to Medical Aesthetics Technology Corporation and some of its hormone therapy product to third parties, including Azur, Solvay Pharmaceuticals, B.V., Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA. All of these parties, except for Azur as to development, have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. In addition, BioSante in the future may enter into additional similar license agreements. BioSante's products that it has 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. BioSante's current and future licensees may have different and, sometimes, competing priorities. BioSante cannot assure you that its partners or any future third party to whom BioSante may license its proposed products will remain focused on the development and commercialization of its partnered products or will not otherwise breach the terms of its agreements with them, especially since these third parties also may compete with BioSante with respect to some of its proposed products. For example, at this time, BioSante believes that its estrogen/progestogen combination transdermal hormone therapy gel product licensed to Solvay is not in active development by Solvay, and BioSante does not expect its active development to occur at any time in the near future.

Table of Contents

*If BioSante is unable to protect its proprietary technology, it 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. BioSante's success will depend, in part, upon its ability to obtain, enjoy and enforce protection for any products it develops or acquires under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of its trade secrets and operate without infringing the proprietary rights of third parties. BioSante relies on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect its proprietary technology. However, these legal means afford only limited protection and may not adequately protect BioSante's rights or permit it to gain or keep any competitive advantage.

Where appropriate, BioSante seeks patent protection for certain aspects of its technology. However, BioSante's owned and licensed patents and patent applications may not ensure the protection of its intellectual property for a number of other reasons:

- BioSante does not know whether its licensor's patent applications will result in issued patents.
- Competitors may interfere with BioSante's patents and patent process in a variety of ways. BioSante's issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit its ability to stop competitors from marketing related products. Competitors may claim that they invented the claimed invention before BioSante or may claim that BioSante is infringing on their patents and therefore BioSante cannot use its technology as claimed under its patent. Competitors also may have BioSante's patents reexamined by demonstrating to the patent examiner that the invention was not original or novel or was obvious.
- BioSante is engaged in the process of developing proposed products. Even if BioSante receives a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around BioSante's patents. If BioSante receives a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on its patent. Even if the development of BioSante's proposed 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. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of BioSante's proposed products.
- Litigation also may be necessary to enforce patent rights BioSante holds or to protect trade secrets or techniques BioSante owns. Intellectual property litigation is costly and may adversely affect BioSante's operating results. Such litigation also may require significant time by BioSante's management. In litigation, a competitor could claim that BioSante's issued patents are not valid for a number of reasons. If the court agrees, BioSante would lose protection on products covered by those patents.
- BioSante also may support and collaborate in research conducted by government organizations or universities. BioSante cannot guarantee that it will be able to acquire any exclusive rights to technology or products derived from these collaborations. If BioSante does not obtain required licenses or rights, BioSante could encounter delays in product development while it attempts to design around other patents or it may be prohibited from



Table of Contents

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.

BioSante also relies on unpatented proprietary technology. It is unclear whether efforts to secure BioSante's trade secrets will provide useful protection. BioSante relies on the use of registered trademarks with respect to the brand names of some of its products. BioSante also relies on common law trademark protection for some brand names, which are not protected to the same extent as its rights in the use of its registered trademarks. BioSante cannot assure you that it will be able to meaningfully protect all of its rights in its unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to its unpatented proprietary technology. BioSante seeks to protect its know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with its employees and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for BioSante's proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that its competitors discover or independently develop similar or identical designs or other proprietary information. Enforcing a claim that someone else illegally obtained and is using BioSante's 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.

*Claims by others that BioSante's products infringe their patents or other intellectual property rights could adversely affect BioSante's 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, BioSante can conduct only limited searches to determine whether its technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

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

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

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 BioSante's potential gross margins. In addition, BioSante cannot be sure that the necessary licenses would be available to it on satisfactory terms, or that BioSante could redesign its 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 BioSante from developing, manufacturing and selling some of BioSante's products, which could harm its business, financial condition and operating results.

Table of Contents

**Risks Related to the Combined Company if the Merger with Cell Genesys is Completed**

*If the merger with Cell Genesys is completed, the combined company of BioSante and Cell Genesys will be subject not only to the risks described above, but also the risks described below:*

***Upon completion of the merger, the combined company will have substantial indebtedness, which increases the vulnerability of the combined company to general adverse economic and industry conditions and may limit the combined company's ability to pursue strategic alternatives and react to changes in its business and industry.***

Upon completion of the merger, the combined company will have a significant amount of debt and no significant source of revenues. As of June 30, 2009, Cell Genesys had outstanding \$20.8 million aggregate principal amount of convertible senior notes due in May 2013 and \$1.2 million aggregate principal amount of convertible senior notes due in November 2011. It is anticipated that upon completion of the merger, the combined company will have \$22.0 million aggregate principal amount of outstanding convertible 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 anticipated to be approximately \$0.7 million. This substantial indebtedness could harm the combined company's business, results of operations, financial condition, cash flow and future prospects. For example, it could:

- make it more difficult for the combined company to pay its debts and meet other financial obligations as they become due;
- require the combined company to dedicate a substantial portion of its cash flows to make principal and interest payments which will reduce the combined company's cash flow available for operations and future business opportunities;
- limit the combined company's ability to raise or borrow additional funds for future working capital, capital expenditures, research and development and other general corporate requirements;
- increase the combined company's vulnerability to general adverse economic and industry conditions;
- limit the combined company's ability to pursue strategic alternatives, including merger or acquisition transactions; and
- limit the combined company's flexibility to react to changes in its business and the industry in which it will operate.



*The combined company may not have sufficient funds to pay principal and interest on its outstanding convertible notes as they become due, which would have a material adverse effect on the combined company's financial condition.*

It is anticipated that upon completion of the merger, the combined company will have \$22.0 million aggregate principal amount of outstanding convertible 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 anticipated to be approximately \$0.7 million. Although it is anticipated that upon completion of the merger, the combined company will have approximately \$21.5 million in cash and cash equivalents, assuming a closing date of October 31, 2009, the combined company will not have any significant source of revenues. Although the combined company intends to continue to seek additional financing, it is possible that the combined company may not have sufficient funds to pay the principal

Table of Contents

and interest on its convertible notes when they become due, especially if an event of default were to occur under the indentures governing the convertible notes.

***The indentures to be assumed by the combined company 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 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 indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC, which if not complied with, could result in an event of default and the acceleration of all amounts due under the notes. 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 is also 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.

***The combined company likely will need to raise additional financing to fund its Phase III clinical study program for LibiGel, and if the combined company is unable to raise such financing when needed, it may have to curtail significantly or even cease its ongoing operations.***

The combined company will not have sufficient resources to obtain regulatory approval of its proposed products or to complete the commercialization of any of its proposed products, including LibiGel. If the merger is completed, BioSante expects that the cash resources of the combined company expected to be available at the closing of the merger would provide the combined company sufficient capital to maintain its projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. Like BioSante, the combined company's future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of its preclinical and clinical development programs, including in particular its Phase III clinical study program for LibiGel, and its other product development efforts;
- patient recruitment and enrollment in its current and future clinical studies, including in particular its Phase III clinical study program for LibiGel;
- the commercial success and net sales of Elestrin;
- its ability to license LibiGel or its other products for development and commercialization;

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

- the cost, timing and outcome of regulatory reviews of its proposed products;
- the rate of technological advances;
- the commercial success of its proposed products;
- its general and administrative expenses;
- the timing and cost of obtaining third party reimbursement for its products;

Table of Contents

- the activities of its competitors; and
- the success, progress, timing and costs of its business development efforts to implement business collaborations, licenses and other business combinations or transactions;

Additional financing may not be available to the combined company on terms favorable to it, or at all. If adequate funds are not available or are not available on acceptable terms when the combined company needs them, the combined company may be required to delay, scale back or eliminate some or all of its programs designed to obtain regulatory approval of its proposed products, including most importantly, its Phase III clinical study program for LibiGel. Failure to obtain adequate financing also may cause the combined company to curtail significantly or even cease its ongoing operations.

***After the completion of the merger, the combined company will possess not only all of the assets but also all of the liabilities of both BioSante and Cell Genesys. Discovery of previously undisclosed liabilities could have an adverse effect on the combined company's business, operating results and financial condition.***

Acquisitions involve 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 placed on hold the further development of GVAX immunotherapy 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 over 280 employees, closed two facilities and terminated the related leases. After the completion of the merger, the combined company will possess not only all of the assets, but also all of the liabilities of both BioSante and Cell Genesys. Although BioSante conducted a due diligence investigation of Cell Genesys and its known and potential liabilities and obligations and Cell Genesys conducted a due diligence investigation of its known and potential liabilities and obligations, it is possible that, undisclosed, contingent or other liabilities or problems may arise after the completion of the merger, which could have an adverse effect on the combined company's business, operating results and financial condition.

***The combined company's stock price may be volatile, and the market price of its common stock may decline in value following the merger.***

The market price of the combined company's common stock could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies historically have been particularly volatile. Some of the factors that may cause the market price of the combined company's common stock to fluctuate include:

- general stock market and general economic conditions in the United States and abroad, not directly related to the combined company or its business;
- the ability of the combined company to obtain additional financing when needed and on acceptable terms;

- governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to the combined company's products or its competitors' products;
- the results of the combined company's current and any future clinical studies, including in particular the LibiGel Phase III clinical study program;

Table of Contents

- the results of clinical trials conducted by others on products that would compete with the combined company's proposed products;
- the results and timing of regulatory reviews relating to the approval of the combined company's products, including in particular LibiGel;
- failure of any of the combined company's products, if approved, to achieve commercial success;
- public concern as to the safety or efficacy of or market acceptance of products developed by the combined company or its competitors;
- the entry into, or termination of, key license and sublicense agreements;
- announcements by licensors or licensees of the combined company's technology;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of the combined company's intellectual property rights;
- general and industry-specific economic conditions that may affect the combined company's research and development expenditures;
- issues in manufacturing the combined company's proposed products;
- the loss of key employees;
- the introduction of technological innovations or new commercial products by competitors of the combined company;
- changes in estimates or recommendations by securities analysts, if any, who cover the combined company's common stock;

- future sales of the combined company's securities;
- changes in the structure of health care payment systems;
- period-to-period fluctuations in the combined company's financial results, including its cash, cash equivalents and short-term investment balance, operating expenses, cash burn rate or revenues; and
- other potentially negative financial announcements, including delisting of the combined company's common stock from the NASDAQ Global Market, changes in accounting treatment or restatement of previously reported financial results, delays in the combined company's filings with the SEC or the combined company's failure to maintain effective internal control over financial reporting.

Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in the combined company's stock and cause a price decline. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor's ability to sell the combined company's common stock, which could result in substantial economic loss as well. In addition, due in large part to the current global economic crisis

Table of Contents

many institutional investors that historically had invested in specialty pharmaceutical companies have ceased operations or further investment in these companies, which has negatively impacted trading volume for stocks such as the combined company's common stock.

Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. Subsequent to the June 30, 2009 announcement of the proposed merger, Cell Genesys, the members of the Cell Genesys board of directors and BioSante were named as defendants in purported class action lawsuits brought by Cell Genesys stockholders challenging the proposed merger. The combined company may become the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm the combined company's business and financial condition, as well as the market price of its common stock.

***If the combined company fails to meet the continued listing standards of the NASDAQ Global Market, its common stock may be delisted which could have a material adverse effect on the liquidity of its common stock.***

In order for the combined company's common stock to be eligible for continued listing on the NASDAQ Global Market after the completion of the merger, the combined company will need to remain in compliance with certain listing standards, including a \$1.00 minimum closing bid price per share requirement, a minimum stockholders' equity requirement and certain corporate governance standards. There can be no assurance that the combined company will meet all requirements for continued listing on the NASDAQ Global Market. If BioSante is unable to raise additional financing prior to the completion of the merger, it is likely that the combined company will not meet the minimum \$10.0 million stockholders' equity requirement. If the combined company's common stock were to be delisted from the NASDAQ Global Market, the combined company could apply to list its common stock on the NASDAQ Capital Market or its common stock could be traded in the over-the-counter market on an electronic bulletin board established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. Any delisting could adversely affect the market price of, and liquidity of the trading market for, the combined company's common stock, its ability to obtain financing for the continuation of its operations and could result in the loss of confidence by investors.

***A substantial number of shares of the combined company's common stock will be eligible for future sale in the public market. The sale of these shares could cause the market price of the combined company's common stock to fall.***

Upon completion of the merger, it is anticipated that the combined company will have approximately 44.7 million shares of common stock outstanding, 391,286 shares of class C special stock outstanding, options and warrants to purchase an aggregate of approximately 5.6 million shares and \$22.0 million principal amount of convertible notes that will be convertible into approximately 5.0 million shares of common stock of the combined company, assuming the 0.1615 exchange ratio is not adjusted and the number of outstanding shares of BioSante and Cell Genesys's common stock remains unchanged until immediately prior to the effective time of the merger. A substantial number of such shares, when the combined company issues them upon exercise or conversion, will be available for immediate resale in the public market. If existing stockholders of BioSante and Cell Genesys sell, or indicate an intention to sell, substantial amounts of combined company common stock in the public market after the merger, the trading price of the common stock of the combined company could decline.

***Exercise of outstanding and future options and warrants and the conversion of outstanding convertible notes and any future equity issuances will dilute the combined company's stockholders and could decrease the market price of the combined company's common stock.***



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

Upon completion of the merger, it is anticipated that the combined company will have approximately 44.7 million shares of common stock outstanding, 391,286 shares of class C special stock

Table of Contents

outstanding, options and warrants to purchase an aggregate of approximately 5.6 million shares outstanding and \$22.0 million principal amount of convertible notes that will be convertible into approximately 5.0 million shares of common stock of the combined company, assuming the 0.1615 exchange ratio is not adjusted and the number of outstanding shares of BioSante and Cell Genesys' common stock remains unchanged until immediately prior to the effective time of the merger. The existence of the outstanding options and warrants and the conversion of convertible notes may adversely affect the market price of the combined company's common stock and the terms under which the combined company could obtain additional equity capital. In addition, the combined company may grant additional options and warrants and issue additional convertible equity securities in the future, which would further dilute its then current stockholders and could decrease the market price of its common stock.

It is anticipated that on a long-term basis, in the absence of recurring operating or licensing revenues, the combined company will need to finance a large portion of its operating cash requirements by issuing and selling equity securities. The combined company will have a shelf registration statement to sell, subject to certain limitations, up to approximately \$75 million of its securities, some or all of which may be shares of its common stock or securities convertible into or exercisable for shares of its common stock, and all of which would be available for resale in the market. Any issuances by the combined company of equity securities may be at or below the prevailing market price of the combined company's common stock and may have a dilutive impact on its existing stockholders. These issuances or other dilutive issuances also would cause the combined company's net income, if any, per share to decrease in future periods. As a result, the market price of the combined company's common stock could decrease.

***Provisions in the combined company's charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to its stockholders.***

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

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

***BioSante has never paid cash dividends on its capital stock, and does not anticipate that the combined company will pay any cash dividends in the foreseeable future.***

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

BioSante has not paid any cash dividends on any of its classes of capital stock to date, and the current expectation is that the combined company will retain its future earnings to fund the development and growth of the combined company business. As a result, capital appreciation, if any, of the common stock of the combined company will be stockholders' sole source of gain, if any, for the foreseeable future.

Table of Contents**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS****Recent Sales of Unregistered Equity Securities**

During the three months ended June 30, 2009, 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, 2009. Our Board of Directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

(a) The Annual Meeting of Stockholders of BioSante was held on June 9, 2009.

(b) The results of the stockholder votes were as follows:

	For	Against/ Withheld	Abstain	Broker Non-Vote
<b>1. Election of Directors</b>				
Fred Holubow	14,029,157	89,341	0	0
Peter Kjaer	12,337,958	1,780,540	0	0
Ross Mangano	14,048,939	69,559	0	0
Edward C. Rosenow, M.D.	13,599,074	519,424	0	0

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-Q

Stephen M. Simes	13,608,343	510,155	0	0
Louis W. Sullivan, M.D.	13,599,074	519,424	0	0
<b>3. Ratification of Selection of Independent Registered Public Accounting Firm</b>	14,069,814	44,832	3,852	0

**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:

Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
2.1	Agreement and Plan of Merger dated as of June 29, 2009 by and between BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc.* (Incorporated by reference to Exhibit 2.1 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812))
10.1	Voting Agreement dated as of June 29, 2009 by and between Stephen A. Sherwin, M.D. and BioSante Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812))
10.2	Form of Voting Agreement dated as of June 29, 2009 by and between certain directors and officers of BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc. (Incorporated by reference to Exhibit 10.2 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812))
10.3	Amendment dated as of June 26, 2009 to Registration Rights Agreement between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited (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)

---

\* All exhibits and schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante Pharmaceuticals, Inc. will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Commission.

Table of Contents

**SIGNATURES**

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

August 7, 2009

**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  
Chief Financial Officer, Treasurer and Secretary  
(principal financial and accounting officer)

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
2.1	Agreement and Plan of Merger dated as of June 29, 2009 by and between BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc.*	Incorporated by reference to Exhibit 2.1 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812)
10.1	Voting Agreement dated as of June 29, 2009 by and between Stephen A. Sherwin, M.D. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812)
10.2	Form of Voting Agreement dated as of June 29, 2009 by and between certain directors and officers of BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc.	Incorporated by reference to Exhibit 10.2 contained in BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812)
10.3	Amendment dated as of June 26, 2009 to Registration Rights Agreement between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	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

---

\* All exhibits and schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante Pharmaceuticals, Inc. will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Commission.