BIOSANTE PHARMACEUTICALS INC
Form 10-Q
November 09, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)

111 Barclay Boulevard

Lincolnshire, Illinois 60069

(Address of principal executive offices)

(847) 478-0500

(Registrant s telephone number including area code)

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

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

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company o

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

As of November 1, 2009, 53,262,896 shares of common stock and 391,286 shares of class C special stock of the registrant were outstanding.

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BIOSANTE PHARMACEUTICALS, INC.

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

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, 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.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Balance Sheets

September 30, 2009 and December 31, 2008 (Unaudited)

	September 30, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 13,169,258	$ 11,760,920
Short-term investments		3,026,334
Accounts receivable	38,271	229,775
Prepaid expenses	1,011,099	1,070,051
	14,218,628	16,087,080
PROPERTY AND EQUIPMENT, NET	720,403	814,894
OTHER ASSETS		
Investment in MATC	140,000	140,000
Deposits	879,956	637,397
	$ 15,958,987	$ 17,679,371
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,529,203	$ 3,182,089
Due to licensor - Antares	7,871	5,393
Accrued compensation	759,245	290,583
Other accrued expenses	480,909	374,887
	4,777,228	3,852,952
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2009 - 391,286; 2008 - 391,286 Class C special stock	391	391
2009 - 33,042,764; 2008 - 27,042,764 Common stock	98,129,898	85,732,688
	98,130,289	85,733,079
Accumulated deficit	(86,948,530)	(71,906,660)
	11,181,759	13,826,419
	$ 15,958,987	$ 17,679,371

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Operations

Three and nine months ended September 30, 2009 and 2008 (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
REVENUE				
Licensing revenue	$	$	$	$ 9,091
Grant revenue	10,492	21,082	103,149	56,972
Royalty revenue		3,734	90,934	30,219
Other revenue		57,396		74,796
	10,492	82,212	194,083	171,078
EXPENSES				
Research and development	3,371,217	5,322,472	9,937,033	11,934,536
General and administration	1,506,056	1,438,816	3,744,214	4,357,465
Acquisition related costs	1,470,467		1,470,467	
Depreciation and amortization	33,308	11,759	95,887	33,841
	6,381,048	6,773,047	15,247,601	16,325,842
OTHER - Impairment of short term investments				660,200
OTHER - Interest income		105,751	11,648	555,175
NET LOSS	$ (6,370,556)	$ (6,585,084)	$ (15,041,870)	$ (16,259,789)
BASIC AND DILUTED NET LOSS PER SHARE (Note 5)	$ (0.21)	$ (0.24)	$ (0.53)	$ (0.60)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	30,434,050	27,380,217	28,445,039	27,265,906

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows

Nine months ended September 30, 2009 and 2008 (Unaudited)

	Nine Months Ended September 30, 2009	2008
CASH FLOWS (USED IN) OPERATING ACTIVITIES		
Net loss	$ (15,041,870)	$ (16,259,789)
Adjustments to reconcile net loss to net cash (used in) operating activities		
Depreciation and amortization	95,887	33,841
Impairment of short term investments		660,200
Employee & director stock-based compensation	946,517	865,074
Stock warrant expense - noncash	34,734	113,650
Acquisition related costs	1,470,467	
Other noncash charges	75,342	
(Gain) on disposal of equipment		(951)
Changes in other assets and liabilities affecting cash flows from operations		
Prepaid expenses and other assets	(183,607)	(1,222,051)
Accounts receivable	191,504	(67,965)
Accounts payable and accrued liabilities	114,268	2,805,464
Due to licensor - Antares	2,478	3,600
Deferred revenue		(9,091)
Net cash (used in) operating activities	(12,294,280)	(13,078,018)
CASH FLOWS PROVIDED BY INVESTING ACTIVITIES		
Redemption of short term investments	3,037,982	3,101,354
Purchase of short term investments	(11,648)	(98,452)
Purchase of capital assets	(153,415)	(252,855)
Net cash provided by investing activities	2,872,919	2,750,047
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES		
Cash paid for acquisition related costs	(510,918)	
Proceeds from sale or conversion of shares, net	11,340,617	379,720
Net cash provided by financing activities	10,829,699	379,720
NET INCREASE (DECREASE) CASH AND CASH EQUIVALENTS	1,408,338	(9,948,251)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	11,760,920	15,648,948
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 13,169,258	$ 5,700,697
SUPPLEMENTARY INFORMATION		
Other information:		
Accrued liabilities for acquisition related costs, noncash	$ 959,549	$
Unrealized gain on available-for-sale securities, non-cash	$	$ 427,500
Purchase of capital assets on account, non-cash investing activity	$	$ 254,440

See accompanying notes to the condensed financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

FORM 10-Q

SEPTEMBER 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 developing its calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine and drug delivery.

On October 14, 2009, the Company completed its previously announced merger with Cell Genesys, Inc. (Cell Genesys). See Note 11 entitled Subsequent Event. As a result of the merger, although the Company will continue to focus primarily on its LibiGel clinical development program, the Company also will seek future development opportunities for GVAX immunotherapies acquired from Cell Genesys, including potential combination with BioVant, the Company s vaccine adjuvant, as well as possible external collaborations, and also will seek to outlicense other technologies acquired from Cell Genesys.

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 September 30, 2009, the results of operations for the three and nine months ended September 30, 2009 and 2008, and the cash flows for the nine months ended September 30, 2009 and 2008, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and nine month periods ended September 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 for the year ended December 31, 2008 contained in the Company s Current Report on Form 8-K filed by the Company with the SEC on August 7, 2009.

In October 2009, the Company completed its previously announced merger with Cell Genesys. See Note 11 entitled Subsequent Event. These unaudited interim condensed financial statements do

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not include results from Cell Genesys since the merger occurred after the end of the quarter ended September 30, 2009. Unless otherwise indicated, references to the Company in the notes to these unaudited interim condensed financial statements relate to the Company as a stand-alone entity and do not reflect the effect of the merger with Cell Genesys.

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, completed after 2008. See Note 11 for discussion of the anticipated accounting impact of the Company s 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. 167, Amendments to FASB Interpretation No. 46(R) (SFAS 167). SFAS 167 replaces the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity s economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. The Company will adopt SFAS No. 167 on January 1, 2010. The Company is currently evaluating the impact, if any, that the adoption of SFAS 167 will have 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.

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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.

In September 2009, the FASB ratified Emerging Issues Task Force Issue 08-1, Revenue Arrangements with Multiple Deliverables (EITF 08-1). EITF 08-1 addresses the unit of accounting for arrangements involving multiple deliverables. It also addresses how arrangement consideration should be allocated to the separate units of accounting. EITF 08-1 removes the previous separation criterion that objective and reliable evidence of the fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. EITF 08-1 will ultimately be issued as an Accounting Standards Update (ASU) that will amend the FASB Accounting Standards Codification. The Company is currently evaluating the impact, if any, that the adoption of EITF 08-1 will have on the Company s financial statements.

4. LIQUIDITY AND CAPITAL RESOURCES

Substantially all of the Company s revenue has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. 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 as an alternative method of raising financing, on October 14, 2009 the Company acquired Cell Genesys. See Note 11 entitled Subsequent Event.

Other than Elestrin, the Company s once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S., the Company has not introduced commercially any products. The Company s business operations 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 to undertake the commercialization of any of its current or proposed products. The Company expects the Phase III clinical study program of LibiGel to continue to require significant resources.

In August 2009, the Company completed a registered direct offering of an aggregate of 6,000,000 shares of the Company s common stock and warrants to purchase up to 2,400,000 additional shares of its common stock, resulting in net proceeds to the Company of approximately $11.4 million, after deducting placement agent fees and other offering expenses. For additional discussion regarding the registered direct offering, see Note 8 entitled Stockholders Equity. The Company had cash and cash equivalents of approximately $13.2 million at September 30, 2009, which included the net proceeds from the registered direct offering.

Subsequent to September 30, 2009, the Company completed its merger with Cell Genesys. One of the primary reasons the Company merged with Cell Genesys was the Company s need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for the Company to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been the Company s primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately $23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses. In addition, the Company assumed by virtue of the merger, $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount

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of 3.125% convertible senior notes due in May 2013. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. For additional discussion regarding the merger with Cell Genesys and the assets and liabilities acquired, see Note 11 entitled Subsequent Event.

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 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 September 30, 2009, the Company had not sold any shares to Kingsbridge under the CEFF.

The Company expects that its current cash resources, including the cash, cash equivalents and short-term investments acquired as a result of the Company s merger with Cell Genesys, together any future royalty and other revenues from sales of Elestrin that the Company receives, will 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 believes it has sufficient cash resources to complete the LibiGel clinical development program to and through the planned submission of a new drug application (NDA) in the first half of 2011, however, the Company s estimate may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier. If additional funds are necessary and 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 study 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.

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 each of the three and nine months ended September 30, 2009 does not include

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options to purchase an aggregate of 2,736,691 shares of common stock with exercise prices ranging from $1.27 to $6.70 per share, and warrants to purchase an aggregate of 3,841,207 and 4,983,709, respectively, shares of common stock with exercise prices of $2.00 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 nine months ended September 30, 2008 does not include options to purchase an aggregate of 2,088,191 and 2,070,691, respectively, shares of common stock, with exercise prices ranging from $2.10 to $6.70 per share, and warrants to purchase an aggregate of 2,412,038 and 2,492,695, respectively, shares of common stock, with exercise prices ranging from $2.75 to $8.00 per share, because of their antidilutive effect on net loss per share.

6. LICENSE AGREEMENTS

In December 2008, the Company signed an exclusive agreement with Azur Pharma International II Limited (Azur) for the marketing of Elestrin in the United States. Azur agreed to promote Elestrin using its women s health sales force which targets estrogen prescribing physicians in the U.S., comprised mostly of gynecologists. Azur commercially re-launched Elestrin in the U.S. in April 2009. The Company recognized royalty and other revenues from sales of Elestrin of $90,934 during the nine month period ended September 30, 2009. Under the Company s license agreement with Antares, the Company is required to pay Antares Pharma, Inc. (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 (which products include 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.

7. 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 September 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 September 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 $305,199 and $946,517 for the three and nine months ended September 30, 2009, respectively, and $305,188 and $865,074 for the three and nine months ended September 30, 2008,

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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 nine months ended September 30, 2009 and 2008.

	Nine Months Ended September 30,	
	2009	2008
Expected life in years	6.0 years	6.0 years
Annualized volatility	76.81%	67.63%
Discount rate bond equivalent yield	2.76%	3.45%
Expected dividend yield	0.00%	0.00%

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 nine months ended September 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 September 30, 2009	2,736,691	$ 2.94
(weighted average contractual term)	*7.59 years*	
Exercisable at September 30, 2009	1,397,524	$ 3.46
(weighted average contractual term)	*5.79 years*	

The aggregate intrinsic values of the Company s outstanding and exercisable options as of September 30, 2009 were $399,115 and $0, respectively, and as of September 30, 2008 were $2,886,770 and $1,502,175, respectively.

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A summary of the Plans non-vested options at December 31, 2008 and activity under the Plans during the nine months ended September 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	(407,831)	3.62
Forfeited	(116,667)	4.42
Non-Vested at September 30, 2009	1,339,167	$ 2.40

As of September 30, 2009, there was $1,272,478 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 1.61 years.

There were no options exercised under the Plans during the nine months ended September 30, 2009.

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 September 30,	
	2009	2008
Stock-Based Compensation Expense:		
Research and development	$ 97,181	$ 98,754
General and administrative	208,018	206,434
Total stock-based compensation expense	$ 305,199	$ 305,188

	Nine Months Ended September 30,	
	2009	2008
Stock-Based Compensation Expense:		
Research and development	$ 298,439	$ 274,395
General and administrative	648,078	590,679
Total stock-based compensation expense	$ 946,517	$ 865,074

In each of July 2007 and July 2009, the Company issued warrants to purchase 180,000 shares of common stock to an investor relations firm in consideration for various investor relations services. The 2007 warrant has an exercise price equal to $8.00 per share, vested in two equal installments on the first and second year anniversary of the date of grant and is fully exercisable through July 18, 2010. The 2009 warrant has an exercise price equal to $2.00 per share, vests in two equal installments on the six-month and one-year anniversary of the date of grant and will remain exercisable through July 21, 2012. The Company uses the Black-Scholes option pricing model to value this warrant consideration and awards will be re-measured each period until the measurement date is established. During the nine months ended September 30, 2009, the Company recorded $27,251 in non-cash general and administrative expense pertaining to these warrants.

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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 consideration for various investor and public relations services. These warrants have an exercise price equal to $4.78 per share and were to become exercisable with respect to 1/12 of the underlying shares 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 May 14, 2011. The Company used the Black-Scholes option pricing model to value this warrant consideration and re-measured the award each quarter until the measurement date was established. During the nine months ended September 30, 2009, the Company recorded $7,483 in non-cash general and administrative expense pertaining to these warrants.

8. STOCKHOLDERS EQUITY

In August 2009, the Company completed the sale of an aggregate of 6,000,000 shares of the Company s common stock and warrants to purchase up to 2,400,000 additional shares of its common stock, to three institutional investors, resulting in net proceeds to the Company of approximately $11.4 million, after deducting placement agent fees and other offering expenses. The warrants are exercisable immediately, have an exercise price of $2.50 per share and will expire on August 12, 2014.

As described in Note 7, in July 2009, the Company issued a warrant to purchase 180,000 shares of common stock to an investor relations firm in consideration for various investor relations services. The warrant has an exercise price equal to $2.00 per share, vests in two equal installments on the six-month and one-year anniversary of the date of grant and will remain exercisable through July 21, 2012.

During the nine months ended September 30, 2009, the Company granted options to purchase an aggregate of 848,500 shares of the Company s common stock to certain employees of the Company and the Company s non-employee directors with a weighted average exercise price of $1.51. No other warrants were granted and no stock options or warrants were exercised during such period.

9. FAIR VALUE MEASUREMENTS

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. SFAS No. 157 was subsequently codified in ASC 820. ASC 820 defines 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, ASC 820 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.

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The table below presents a reconciliation of the Level 3 fair value measurements, which are based on significant unobservable inputs, from December 31, 2008 to September 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		
September 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.

10. CONTINGENCIES

The Company is from time to time subject to, and is presently involved in (described below), various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. The Company records a liability in its financial statements for costs related to claims, including future legal costs, settlements and judgments, where the Company has assessed that a loss is probable and an amount can be reasonably estimated. The Company s legal proceedings are discussed below.

On July 1, 2009, a putative shareholder class action lawsuit concerning the then proposed merger between Cell Genesys and the Company was filed in California Superior Court in San Mateo County (Case No. 485528) naming Cell Genesys, its officers and directors, and the Company as defendants. 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 15, 2009, the Court consolidated these three lawsuits into one action and appointed interim lead counsel. On August 13, 2009, plaintiffs filed a consolidated class action complaint alleging that defendants breached their fiduciary duties and/or aided and abetted the breach of fiduciary duties owed to Cell Genesys stockholders in connection with the then proposed merger, including by failing to engage in a fair sales process, failing to obtain a fair price for the sale of Cell Genesys, and failing to provide Cell Genesys stockholders with material information regarding the merger. Plaintiffs sought an order certifying the lawsuit as a class action, injunctive relief to enjoin the merger or, in the event the then merger was completed, a rescission of the merger or rescissory damages. Plaintiffs further sought an accounting for all damages and an award of attorneys fees and costs.

Solely to avoid the costs, risks and uncertainties inherent in litigation, on September 18, 2009, Cell Genesys and the Company entered into a memorandum of understanding with plaintiffs counsel in

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the San Mateo County action (Memorandum of Understanding) pursuant to which Cell Genesys and the Company, the other named defendants and the plaintiffs agreed to settle the lawsuits subject to court approval. If the court approves the settlement, the lawsuits will be dismissed with prejudice. Pursuant to the Memorandum of Understanding, Cell Genesys agreed to pay to plaintiffs counsel an amount not more than $240,000 as is approved by court order for plaintiffs attorneys fees, costs and expenses in the San Mateo County action and to make additional disclosures in a current report on Form 8-K, without admitting in any way that the certain disclosures are material or otherwise required by law. Pursuant to the Memorandum of Understanding, plaintiffs counsel conducted confirmatory discovery to confirm the fairness and adequacy of the settlement. The parties intend to file a Stipulation of Settlement with the Court and to move the Court for Preliminary Approval and issuance of a Notice of Settlement to the potential class members, after which the parties intend to seek final Settlement approval and dismissal of the action with prejudice. The Company believes that the resolution of this matter will not have a material impact on the Company s financial position, cash flows or results of operations.

11. SUBSEQUENT EVENT

On October 14, 2009, the Company completed its previously announced merger with Cell Genesys. At the effective time of the merger, Cell Genesys merged with and into BioSante, with BioSante continuing as the surviving company. One of the primary reasons the Company merged with Cell Genesys was the Company s need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for the Company to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been the Company s primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately $23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses.

In addition to the $23.2 million in cash, the Company obtained, as a result of the merger, a portfolio of cancer immunotherapies (known as GVAX Immunotherapies) and other technologies. Acquisition of these assets significantly expands the Company s product portfolio. The GVAX Immunotherapies now are in human clinical trials at minimal cost to the Company.

The merger is not intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. The merger will be accounted for under U.S. generally accepted accounting principles 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 had substantially ceased its operations, the merger is not considered to be a business combination, and the allocation of the purchase price will not result in recognition of goodwill. Effective October 14, 2009, the financial position and net income (loss) of the combined company will reflect the purchase price allocation and 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.

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 was converted into the right to receive 0.1828 of a share of the Company s common stock. In the aggregate, the Company issued approximately 20.2 million shares of its common stock to former Cell Genesys stockholders in connection with the merger. All options to purchase shares of Cell Genesys common stock, other than certain designated options held by certain of Cell Genesys s former officers (Assumed Options), became fully vested and exercisable until immediately prior to the effective time of the merger. At the effective time of the merger, such unexercised options other than the Assumed Options terminated. The Assumed Options were assumed

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by the Company and will remain outstanding following the merger, but converted into and became options to purchase shares of the Company s common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, the Assumed Options converted into options to purchase an aggregate of 234,429 shares of the Company s common stock at a weighted average exercise price of $19.73 per share. All warrants to purchase shares of Cell Genesys common stock which by their terms survived the merger (Assumed Warrants) were assumed by the Company, but were converted into and became warrants to purchase shares of the Company s common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, these Assumed Warrants converted into warrants to purchase an aggregate of 395,246 shares of the Company s common stock at a weighted average exercise price of $39.27 per share.

In addition, as a result of the merger, the Company assumed $1.2 million in principal amount of outstanding 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are payable on May 1 and November 1 of each year through maturity. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between the Company and the trustees thereunder, the November 2011 convertible notes became convertible into an aggregate of 24,789 shares of the Company s common stock at an initial conversion price of $49.78 per share and the May 2013 convertible notes became convertible into an aggregate of 5,586,559 shares of the Company s common stock at a conversion price of $3.72 per share, in each case subject to adjustments for stock dividends, stock splits, and other similar events. The indentures governing the convertible notes, as supplemented by the supplemental indentures reflecting the Company s assumption of the convertible notes, do not contain any financial covenants and do not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company s other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of the Company, except in certain circumstances specified in the indentures.

The Company has evaluated all subsequent events through November 9, 2009, the date the financial statements were issued and concluded that no additional subsequent events have occurred that would require recognition in the financial statements or disclosure in the notes to the financial statements.

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

This Management s Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the 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 developing our calcium phosphate technology (CaP) for aesthetic medicine, as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine and drug delivery. As a result of the merger, although we will continue to focus primarily on our LibiGel clinical development program, we also will seek future development opportunities for GVAX immunotherapies acquired from Cell Genesys, including potential combination with BioVant, our vaccine adjuvant, as well as possible external collaborations, and also will seek to outlicense other technologies acquired from Cell Genesys.

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 studies 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

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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 October 2009, we announced that based upon a review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee (DMC) unanimously recommended continuing the study as described in the study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in 1,055 women with 883 women-years of exposure. To date, there have been no deaths, one myocardial infarction and only three breast cancers reported. In view of the DMC recommendation, we will continue the LibiGel Phase III development program as planned. Although we delayed screening new subjects for our LibiGel Phase III safety study beginning in second quarter 2009 to save costs and conserve our cash resources, we reinitiated screening in the safety study after we completed our registered direct offering in August 2009. We continue to target submission to the FDA of an NDA by mid-2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

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 from 10 percent to 20 percent depending primarily upon the annual sales levels. In April 2009, we announced the initiation of sales and marketing activity of Elestrin by Azur. Azur markets Elestrin to estrogen prescribing physicians, comprised mostly of gynecologists. It is our understanding that Azur increased its women s health sales force to 72 people, in part to support the marketing 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 and manufacturing information.

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 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

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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 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. 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-) using our CaP technology. The grant is being used to fund product development of IFN- 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 potentially enhancing the current H1N1, or swine flu, vaccine. We believe BioVant can effectively deliver flu vaccines while concurrently enhancing the body s natural immune responses to flu virus antigens. A BioVant/M1 protein flu vaccine has been shown in preclinical studies to protect 100% of the animals from lethal doses of live H1N1 flu virus. We believe the use of a BioVant H1N1 vaccine may allow more people to be protected by a single current dose leading to a wider supply of vaccine and potentially leading to a higher survival rate and fewer pandemics.

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 or sale of our company. As part of this process and as an alternative method of raising financing to continue primarily our LibiGel clinical development program, we merged with Cell Genesys, Inc. (Cell Genesys) on October 14, 2009, as described in more detail below under the heading Recent Merger with Cell Genesys. As a result of this transaction, although we will continue to focus primarily on our LibiGel clinical development program, we also will seek future development opportunities for GVAX Immunotherapies, including potential combination with BioVant, our vaccine adjuvant, as well as possible external collaborations, and also will seek to outlicense other of technologies acquired as a result of our merger with Cell Genesys. In addition, as a result of our merger with Cell Genesys, we now own a 16 percent equity ownership position in Ceregene, Inc., a former subsidiary of Cell Genesys, which is developing gene therapies for neurodegenerative disorders.

Recent Merger with Cell Genesys

On October 14, 2009, we completed our previously announced merger with Cell Genesys. At the effective time of the merger, Cell Genesys merged with and into us, with BioSante continuing as the surviving company. As a result of the merger, each share of common stock of Cell Genesys issued and

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outstanding immediately prior to the effective time of the merger was converted into the right to receive 0.1828 of a share of our common stock. No fractional shares of our common stock were issued in connection with the merger, and holders of Cell Genesys fractional shares of common stock are entitled to receive cash in lieu thereof. As a result of the merger, we issued an aggregate of approximately 20.2 million shares of our common stock to former Cell Genesys stockholders. Immediately after the merger, our then current stockholders owned approximately 62 percent of the outstanding common stock of the combined company and former Cell Genesys stockholders owned approximately 38 percent of the outstanding common stock of the combined company.

All options to purchase shares of Cell Genesys common stock, other than certain designated options held by certain of Cell Genesys s former officers (Assumed Options), became fully vested and exercisable until immediately prior to the effective time of the merger. At the effective time of the merger, such unexercised options other than the Assumed Options terminated. The Assumed Options were assumed by us and will remain outstanding following the merger, but converted into and became options to purchase shares of our common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, the Assumed Options converted into options to purchase an aggregate of 234,429 shares of our common stock at a weighted average exercise price of $19.73 per share. All warrants to purchase shares of Cell Genesys common stock which by their terms survived the merger (Assumed Warrants) were assumed by us, but were converted into and became warrants to purchase shares of our common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, these Assumed Warrants converted into warrants to purchase an aggregate of 395,246 shares of our common stock at a weighted average exercise price of $39.27 per share. In addition, as a result of the merger, we assumed $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between us and the trustees thereunder, the November 2011 convertible notes became convertible into an aggregate of 24,789 shares of our common stock at a conversion price of $49.78 per share and the May 2013 convertible notes became convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of $3.72 per share, in each case subject to adjustments for stock dividends, stock splits, and other similar events.

One of the primary reasons we merged with Cell Genesys was our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for us to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been our primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately $23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses.

In addition to the $23.2 million in cash, we obtained, as a result of the merger, a portfolio of cancer immunotherapies (known as GVAX Immunotherapies) and other technologies. Acquisition of these assets significantly expands our product portfolio. The GVAX Immunotherapies now are in human clinical trials at minimal cost to us.

Our executive officers remained the same after the merger, but our board of directors is now comprised of eight members instead of six members and includes two former members of Cell Genesys s

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board of directors, Stephen A. Sherwin, M.D. and John T. Potts, Jr., M.D. Louis W. Sullivan, M.D. remains our chairman of the board.

The merger is not intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. The merger will be accounted for under U.S. generally accepted accounting principles as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys will be recorded by us as of the completion of the merger based on their estimated fair values. As Cell Genesys had substantially ceased its operations, the transaction is not considered to be a business combination, and the allocation of the purchase price will not result in recognition of goodwill. Effective October 14, 2009, the financial position and net income (loss) of the combined company will reflect the purchase price allocation and 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.

For additional discussion regarding the merger with Cell Genesys, see Note 11 to our unaudited interim 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.

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 may not have sufficient resources 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.

In August 2009, we completed a registered direct offering of an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to 2,400,000 additional shares of our common stock, resulting in net proceeds to us of approximately $11.4 million, after deducting placement agent fees and other offering expenses. We had cash and cash equivalents of approximately $13.2 million at September 30, 2009, which included the net proceeds from the registered direct offering.

Subsequent to September 30, 2009, we completed our merger with Cell Genesys. One of the primary reasons we merged with Cell Genesys was our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for us to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been our primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately $23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses. As of such date, Cell Genesys also had, and we assumed by virtue of the merger, $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013.

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We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel clinical development program. We expect that our current cash resources, including the cash, cash equivalents and short-term investments acquired as a result of our recent merger with Cell Genesys, together any future royalty and other revenues from sales of Elestrin that we receive, 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. Although we believe we have sufficient cash resources to complete our LibiGel clinical development program to and through the planned submission of an NDA in the first half of 2011, our estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. 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 recognized royalty and other revenues from sales of Elestrin of $90,934 during nine month period ended September 30, 2009.

We incurred expenses of approximately $1.1 million per month on research and development activities during the nine months ended September 30, 2009. Our research and development expenses decreased 37 percent to $3.4 million for the third quarter 2009 compared to $5.3 million for the third quarter 2008, primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study. Since we have since reinitiated screening in our safety study, we expect our monthly research and development expenses to increase to approximately $1.5 million in the fourth quarter. The amount of our actual research and development expenditures, however, may fluctuate from period-to-period depending upon: (1) patient recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel; (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; (5) the amount of resources, including cash and cash equivalents, available; and (6) competitive developments.

Our general and administrative expenses for the third quarter 2009 increased $67,240, or 5 percent, compared to the third quarter 2008. 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.

For the nine months ended September 30, 2009, we recognized acquisition related costs of $1,470,467 related to our merger with Cell Genesys, which was completed on October 14, 2009.

We recognized a net loss for the three and nine months ended September 30, 2009 of approximately $6.4 million and $15.0 million, respectively, compared to a net loss of approximately $6.6 million and $16.3 million, respectively, for the three and nine months ended September 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 offset costs related to the acquisition of Cell Genesys and 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 2009. We expect to incur cash interest payment obligations of approximately $687,500 per year as a result of our assumption of convertible notes as a result of our merger with Cell Genesys.

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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;

- our opportunities to acquire new products or take advantage of other unanticipated opportunities; and

- potential expenses for further development of GVAX Immunotherapies and other new technology acquired as a result of our merger with Cell Genesys.

Results of Operations

Three Months Ended September 30, 2009 Compared to Three Months Ended September 30, 2008

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

	Three Months Ended September 30,			
	2009	**2008**	**$ Change**	**% Change**
Revenue	$ 10,492	$ 82,212	$ (71,720)	(87.2)%
Expenses				
Research and development	3,371,217	5,322,472	(1,951,255)	(36.7)%
General and administrative	1,506,056	1,438,816	67,240	4.7%

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	Three Months Ended September 30,			
	2009	2008	$ Change	% Change
Acquisition related costs	1,470,467		1,470,467	100.0%
Interest income		105,751	(105,751)	(100.0)%
Net loss	$ (6,370,556)	$ (6,585,084)	$ (214,528)	(3.3)%

Revenue decreased $71,720 for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 primarily as a result of a decrease in grant and other revenue during the three months ended September 30, 2009.

Research and development expenses for the three months ended September 30, 2009 decreased 37 percent compared to the three months ended September 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 September 30, 2009 increased 5 percent compared to the three months ended September 30, 2008.

For the three months ended September 30, 2009, we recognized acquisition related costs of $1,470,467 related to our merger with Cell Genesys, which was completed on October 14, 2009.

Interest income for the three months ended September 30, 2009 decreased to $0 compared to $105,751 in interest income for the three months ended September 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 2009. We expect to incur significantly increased interest expense in future periods as a result of our assumption of convertible notes as a result of our merger with Cell Genesys.

Nine months Ended September 30, 2009 Compared to Nine months Ended September 30, 2008

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

	Nine months Ended September 30,			
	2009	2008	$ Change	% Change
Revenue	$ 194,083	$ 171,078	$ 23,005	13.4%
Expenses				
Research and development	9,937,033	11,934,536	(1,997,503)	(16.7)%
General and administrative	3,744,214	4,357,465	(613,251)	(14.1)%
Acquisition related costs	1,470,467		1,470,467	100.0%
Impairment of short-term investments		660,200	(660,200)	(100.0)%
Interest income	11,648	555,175	(543,527)	(97.9)%

Net loss	$ (15,041,870)	$ (16,259,789)	$ (1,217,919)	(7.5)%

Revenue increased $23,005 for the nine months ended September 30, 2009 compared to the nine months ended September 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-) using our CaP technology.

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Research and development expenses for the nine months ended September 30, 2009 decreased 17 percent compared to the nine months ended September 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 nine months ended September 30, 2009 decreased 14 percent compared to the nine months ended September 30, 2008 primarily as a result of a decrease in business development and other personnel-related costs.

For the nine months ended September 30, 2009, we recognized acquisition related costs of $1,470,467 related to our merger with Cell Genesys, which was completed on October 14, 2009.

Non-cash, stock option and warrant expense for the nine months ended September 30, 2009 increased to $981,251 compared to $978,724 for the nine months ended September 30, 2008 due to an increase in the number of stock options granted during the nine months ended September 30, 2009.

Net loss for the nine months ended September 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 nine months ended September 30, 2009.

Interest income for the nine months ended September 30, 2009 decreased 98 percent compared to interest income for the nine months ended September 30, 2008 as a result of lower average invested cash balances during the nine months ended September 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 has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. Our business operations 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.

In August 2009, we completed a registered direct offering of an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to 2,400,000 additional shares of our common stock, resulting in net proceeds to us of approximately $11.4 million, after deducting placement agent fees and other offering expenses. Each unit sold in the offering consisted of one share of common stock and a warrant to purchase approximately 0.40 of a share of common stock and was sold for a purchase price of $2.00 per unit. The warrants were exercisable immediately, have an exercise price of $2.50 per share and will expire on August 12, 2014. The August 2009 registered direct offering was made pursuant to our effective June 2009 shelf registration statement on Form S-3 in which we registered $75.0 million of

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securities, consisting of common stock, preferred stock and warrants to purchase common stock or preferred stock. As of September 30, 2009, approximately $57.0 million was available for issuance under the shelf registration statement. However, under applicable SEC rules, if we have a public float of less than $75 million, we can only offer to sell under the registration statement up to one-third of our public float during any 12 month period.

We had cash and cash equivalents of approximately $13.2 million at September 30, 2009, which included the net proceeds from the registered direct offering. All of our cash and cash equivalents as of September 30, 2009 resided in a 100% FDIC insured, non-interest bearing checking account in order to ensure maximum safety of principal.

Subsequent to September 30, 2009, we completed our merger with Cell Genesys on October 14, 2009. One of the primary reasons we merged with Cell Genesys was our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for us to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been our primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately $23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses. As of such date, Cell Genesys also had, and we assumed by virtue of the merger, $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013. For a more complete description of these notes, see Convertible Senior Notes Due November 2011 and May 2013.

In addition to the $23.2 million in cash, we were able to acquire, as a result of the merger, a portfolio of cancer immunotherapies (known as GVAX Immunotherapies) and other technologies. Acquisition of these assets significantly expands our product portfolio. The GVAX Immunotherapies now are in human clinical trials at minimal cost to us.

We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel clinical development program. We expect that our current cash resources, including the cash, cash equivalents and short-term investments acquired as a result of our recent merger, together with any future royalty and other revenues from sales of Elestrin that we receive, 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. Although we believe we have sufficient cash resources to complete our LibiGel clinical development program to and through the planned submission of an NDA in the first half of 2011, our estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. 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. As of September 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.

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

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

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- 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;

- the commercial success of our proposed products;

- our 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 obtain value for any acquired GVAX Immunotherapies and other technologies as a result of our recent merger and our efforts to continue to evaluate various strategic alternatives available with respect to our products and our company; and

- the activities of our competitors.

If we are unable to raise additional financing when needed, we may be required to relinquish greater or all rights to our proposed products at an earlier stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing, if necessary, 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.

Committed Equity Financing Facility with Kingsbridge Capital Limited

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 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,

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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 September 30, 2009, we had not sold any shares to Kingsbridge under the CEFF.

Convertible Senior Notes Due November 2011 and May 2013

As a result of our merger with Cell Genesys, we assumed $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between us and the trustees thereunder, the November 2011 convertible notes became convertible into an aggregate of 24,789 shares of our common stock at a conversion price of $49.78 per share and the May 2013 convertible notes became convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of $3.72 per share, in each case subject to adjustments for stock dividends, stock splits, and other similar events. The convertible notes are our general, unsecured obligations, ranking equally with all of our existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of our subsidiaries. The convertible notes are subject to repurchase by us at each holder s option, if a fundamental change (as defined in the indentures), occurs, at a repurchase price equal to 100% of the principal amount of the convertible notes, plus accrued and unpaid interest (and additional amounts, if any) to, but not including, the repurchase date and are subject to redemption for cash by us at any time in the case of the convertible notes due in 2011 and at any time on or after May 1, 2011, in the case of the convertible notes due in 2013, in whole or in part, at a redemption price equal to 100% of the principal amount of such notes if the closing price of our common stock has exceeded 150% of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. The indentures governing the convertible notes, as supplemented by the supplemental indentures, do not contain any financial covenants and do not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indentures.

Uses of Cash and Cash Flow

Net cash used in operating activities was $12.3 million for the nine months ended September 30, 2009 compared to net cash used in operating activities of $13.1 million for the nine months ended September 30, 2008. Net cash used in operating activities for the nine months ended September 30, 2009 was primarily the result of the net loss for that period which was lower compared to the prior year period due to lower clinical trial related expenses, and to a lesser extent, changes in prepaid expenses and other assets and accounts payable and accrued liabilities. Net cash used in operating activities of $13.1 million for the nine months ended September 30, 2008 was primarily the result of the net loss for that period, and

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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 nine months ended September 30, 2009 compared to net cash provided by investing activities of $2.8 million for the nine months ended September 30, 2008. Net cash provided by investing activities for the nine months ended September 30, 2009 and 2008 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 financing activities was $10.8 million for the nine months ended September 30, 2009 which related primarily to our August 2009 registered direct offering, resulting in net proceeds to us of approximately $11.4 million, after deducting placement agent fees and other offering expenses. This was partially offset by the payment of acquisition related costs for the same period. Net cash provided by financing activities of $379,720 for the nine months ended September 30, 2008 was the result of a warrant exercise.

Accrued liabilities for acquisition related costs were $959,549 as of September 30, 2009.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of September 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 September 30, 2009. Subsequent to September 30, 2009, as a result of our merger with Cell Genesys, we assumed $22.0 million in principal amount of 3.125% convertible senior notes issued by Cell Genesys, $1.2 million of which notes are due in November 2011 and $20.8 million of which notes are due in May 2013. We expect contractual interest payments on these notes to be approximately $687,500 per year.

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.

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

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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

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. 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, completed after 2008. See Note 11 for discussion of the anticipated accounting impact of our 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. 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 SFASF No. 167, Amendments to FASB Interpretation No. 46(R) (SFAS 167). SFAS 167 replaces the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity s economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. We will adopt SFAS No. 167 on January 1, 2010. We are currently evaluating the impact, if any, that the adoption of SFAS No. 167 will have 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

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and deemed nonauthoritative. The FASB will no longer update or maintain the superseded standards. We adopted 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 affects the way GAAP is referenced by us in our financial statements.

In September 2009, the FASB ratified Emerging Issues Task Force Issue 08-1, Revenue Arrangements with Multiple Deliverables (EITF 08-1). EITF 08-1 addresses the unit of accounting for arrangements involving multiple deliverables. It also addresses how arrangement consideration should be allocated to the separate units of accounting. EITF 08-1 removes the previous separation criterion that objective and reliable evidence of the fair value of any undelivered items must exist for the delivered items to be considered a separate unit or separate units of accounting. EITF 08-1 will ultimately be issued as an Accounting Standards Update (ASU) that will amend the FASB Accounting Standards Codification. We are currently evaluating the impact, if any, that the adoption of EITF 08-1 will have on 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 mea 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 commencement, enrollment and successful completion of our clinical studies and the submission of new drug applications and other regulatory status of our proposed products;
- approval of our products which are currently in clinical development by the U.S. Food and Drug Administration;
- 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 size and market acceptance of our products;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- whether and how long our existing cash will be sufficient to fund our operations;
- identification of the acquired assets and liabilities of Cell Genesys and anticipated impacts of the merger with Cell Genesys;

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

- our substantial and continuing losses.

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

The following are some of the uncertainties and factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results:

- risks associated with our recently completed merger with Cell Genesys, including the identification of unanticipated, contingent or other liabilities or problems;

- risks associated with the 3.125% convertible senior notes due in November 2011 and May 2013 that we assumed as a result of our merger with Cell Genesys;

- the level of market acceptance of Elestrin and our other products if and when they are commercialized;

- our dependence upon our licensees for the development, marketing and sale of certain of our products;

- our dependence upon the maintenance of our licenses with Antares Pharma IPL AG and Wake Forest University Health Sciences and Cedars-Sinai Medical Center;

- subject recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical study program for LibiGel;

- uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy;

- the failure of certain of our products to be introduced commercially for several years or at all;

- our failure to obtain and maintain required regulatory approvals on a timely basis or at all;

- our ability to implement strategic alternatives with respect to our products and our company, including licenses, business collaborations, and other business combinations or transactions with other pharmaceutical and biotechnology companies;

- our ability to obtain additional capital when needed or on acceptable terms;

- the effects of the current global economic crisis on our business and our ability to seek strategic alternatives or raise additional capital;

- risk that our common stock may be delisted from the NASDAQ Global Market if we are unable to continue to meet the continued listing requirements;

- our ability to compete in a competitive industry;

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- our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties;
- our dependence upon key employees;
- our ability to maintain effective internal controls over financial reporting;
- adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations;
- changes in generally accepted accounting principles and the effect of new accounting pronouncements; or
- conditions and changes in the biopharmaceutical industry or in general economic or business conditions.

For more information regarding these and other uncertainties and factors that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements or otherwise could materially adversely affect our business, financial condition or operating results, see our quarterly report on Form 10-Q for the quarter ended June 30, 2009 under the heading Part II Item 1A. Risk Factors.

All forward-looking statements included in this report are expressly qualified in their entirety by the foregoing cautionary statements. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the uncertainties and factors described above and in our quarterly report on Form 10-Q for the quarter ended June 30, 2009 under the heading Part II Item 1A. Risk Factors as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown uncertainties and factors, including those described above and in our quarterly report on Form 10-Q for the quarter ended June 30, 2009 under the heading Part II Item 1A. Risk Factors. The risks and uncertainties described above and in our quarterly report on Form 10-Q for the quarter ended June 30, 2009 under the heading Part II Item 1A. Risk Factors are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. 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.

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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 in order to ensure maximum safety of principal.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to 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 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 September 30, 2009 that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

A description of our legal proceedings in Note 10 to our financial statements included within this report is incorporated herein by reference.

ITEM 1A. RISK FACTORS

We are affected by risks specific to us as well as factors that affect all businesses operating in the pharmaceutical business and in a domestic and global market. In addition to the other information set forth in this report, careful consideration should be taken of the factors described in our quarterly report on Form 10-Q for the quarter ended June 30, 2009, which could materially adversely affect our business, financial condition or operating results. There have been no material changes to such disclosures.

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

Recent Sales of Unregistered Equity Securities

During the three months ended September 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, other than in July 2009, we issued a warrant to purchase 180,000 shares of common stock to a certain investor relations firm in consideration for various investor relations services. The warrant has an exercise price equal to $2.00 per share, vests in two equal installments on the six-month and one-year anniversary of the date of grant and will remain exercisable through July 21, 2012. The sale of the warrant to the investor relations firm was made in reliance on either Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering or Regulation D of the Securities Act. Certain inquiries of the investor relations firm were made by BioSante to establish that the offer and sale qualified for such exemption from the registration requirements. In particular, BioSante confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) the offer and sale of the warrant was made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) the investor relations firm made representations that it was sophisticated in relation to its investment (and BioSante has no reason to believe that such representations were incorrect), (iii) the investor relations firm gave assurance of investment intent and the warrant, as well as the certificate representing the shares of our common stock issuable upon exercise of the warrant, will bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the three months ended September 30, 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.

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

(a) A Special Meeting of Stockholders of BioSante was held on September 30, 2009.

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

	For	Against	Abstain	Broker Non-Votes
1. Adoption of Agreement and Plan of Merger and Transactions Contemplated Thereby, including the Merger and the Issuance of Shares of Common Stock in the Merger				
Common Stock	18,089,222	222,285	28,143	0
Class C Special Stock	250,000	0	0	0
2. Approval of Amendment to Certificate of Incorporation to Increase Authorized Capital Stock				
Common Stock	17,434,146	860,123	45,380	0
Class C Special Stock	200,000	50,000	0	0
3. Approval of Adjournment of the Special Meeting, If Necessary				
Common Stock	17,857,490	431,807	50,352	0
Class C Special Stock	200,000	50,000	0	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:

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812))

4.1	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investor Relations Firm in July 2009 (Filed herewith)
4.2	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and Placements Agent in BioSante s August 2009 Registered Direct Offering (Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812))
4.3	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of June 24, 2009, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2013 (Incorporated by reference to Exhibit 4.2 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812))
4.4	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of October 20, 2004, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2011 (Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812))

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Exhibit No.	Description
4.5	Indenture, dated as of June 24, 2009, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee (Incorporated by reference to Exhibit 4.1 to Cell Genesys s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-19986))
4.6	Indenture, dated as of October 20, 2004, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee (Incorporated by reference to Exhibit 4.1 to Cell Genesys s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on December 29, 2004 (File No. 333-121732))
10.1	Placement Agent Agreement dated as of August 13, 2009 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC (Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812))
10.2	Form of Securities Purchase Agreement, dated August 13, 2009, between BioSante Pharmaceuticals, Inc. and each of the Investors in BioSante s August 2009 Registered Direct Offering (Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812))
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a) (Filed herewith)
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Furnished herewith)

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SIGNATURES

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

November 9, 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)

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BIOSANTE PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q

EXHIBIT INDEX

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