BIOSANTE PHARMACEUTICALS INC
Form 10-K
February 28, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2012

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

For the transition period from to .

Commission file number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
111 Barclay Boulevard **Lincolnshire, Illinois** (Address of principal executive offices)	**60069** (Zip Code)

(847) 478-0500

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES o NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES o NO x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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. (Check

one):

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

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

The aggregate market value of the registrant s common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sale price at which the common stock was last sold as of June 30, 2012 (the last business day of the registrant s second fiscal quarter) as reported by The NASDAQ Global Market on that date was approximately $50.1 million.

As of February 28, 2013, 24,422,240 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

TABLE OF CONTENTS

		Page
PART I		1
ITEM 1.	BUSINESS	1
ITEM 1A.	RISK FACTORS	19
ITEM 1B.	UNRESOLVED STAFF COMMENTS	54
ITEM 2.	PROPERTIES	54
ITEM 3.	LEGAL PROCEEDINGS	54
ITEM 4.	MINE SAFETY DISCLOSURES	55
PART II		56
ITEM 5.	MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	56
ITEM 6.	SELECTED FINANCIAL DATA	58
ITEM 7.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	59
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK	74
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	75
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	107
ITEM 9A.	CONTROLS AND PROCEDURES	107
ITEM 9B.	OTHER INFORMATION	107
PART III		109
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	109
ITEM 11.	EXECUTIVE COMPENSATION	119
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	148
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	151
ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	153

PART IV 154

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES 154

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K 157

Table of Contents

This annual report on Form 10-K contains or incorporates by reference forward-looking statements. For this purpose, any statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as believe, may, could, would, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate and continue , the negative of these words, other words and terms of similar meaning and the use of future dates. In evaluating these forward-looking statements, you should consider various factors, including those listed in this report under the headings Part I. Item I. Business Forward-Looking Statements and Part I. Item 1A. Risk Factors. These factors may cause BioSante s actual results to differ materially from any forward-looking statement. BioSante assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

As used in this report, references to BioSante, the company, we, BioSante s or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc. References to ANI in this report refer to ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. References to the merger agreement refer to that certain agreement and plan of merger dated as of October 3, 2012 between BioSante and ANI, as amended from time to time. References to the combined company refer to BioSante, as the surviving entity after the merger and incorporating the merged business of ANI.

Except as otherwise noted, references to BioSante common stock refer to shares of common stock, par value $0.0001 per share, of BioSante, and references to BioSante class C special stock refer to shares of class C special stock, par value of $0.0001 per share, of BioSante. Except as otherwise noted, references to BioSante capital stock refer to shares of BioSante common stock and BioSante class C special stock. References to the BioSante stockholders refer to holders of shares of BioSante common stock and/or shares of BioSante class C special stock. All BioSante share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Except as otherwise noted, references to ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock, ANI series A preferred stock and ANI common stock refer to shares of series D convertible preferred stock, par value $0.10 per share, of ANI, series C convertible preferred stock, par value $0.10 per share, of ANI, series B convertible preferred stock, par value $0.10 per share, of ANI, series A convertible preferred stock, par value $0.10 per share, of ANI, and common stock, par value $0.10 per share, of ANI, respectively, and references to ANI preferred stock refer to shares of ANI series D preferred stock, ANI series C preferred stock, ANI series B preferred stock and ANI series A preferred stock, collectively. Except as otherwise noted, references to ANI capital stock refer to shares of ANI preferred stock and ANI common stock. References to the ANI stockholders refer to holders of shares of ANI capital stock.

BioSante owns or has rights to various trademarks, trade names or service marks, including BioSante®, LibiGel®, The Pill-Plus and Elestrin .

This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

Table of Contents

PART I

ITEM 1. BUSINESS

Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. BioSante s corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of BioSante s corporate strategy, BioSante seeks to implement strategic alternatives with respect to its products and its 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, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies, with the goal of maximizing stockholder value.

On October 3, 2012, BioSante entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI). The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. BioSante believes that the merger of the two companies will be able to create more value than BioSante could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. Although the exact timing of completion of the merger cannot be predicted with certainty, each company has scheduled a special meeting of its stockholders for March 15, 2013 to consider and vote on certain matters in connection with the merger. If the merger is approved by BioSante s and ANI s stockholders and the other conditions to closing are satisfied, it is anticipated that the merger will be completed as soon as reasonably practicable after the special meetings of stockholders. The proposed merger with ANI is described in more detail below under the heading BioSante s Proposed Merger with ANI and elsewhere in this report.

BioSante s products, either approved or in clinical development, include:

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

- Male testosterone gel - once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).

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

- Elestrin - once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda Pharmaceuticals, Inc. (Meda), BioSante s licensee.

BioSante s lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and a LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and

Table of Contents

decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel s results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012, BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials. BioSante is in the process of developing a protocol for the two new efficacy trials and applying for an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials. BioSante expects that any potential new LibiGel Phase III efficacy trials would include the same FDA-required efficacy endpoints as its prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials would be similar to the cost of the previous trials, approximately $15 to $18 million each, or a combined $30 to $36 million spread over approximately 18 months. No assurance can be provided that these cost estimates will be correct or that BioSante, if it decides to pursue the trials, will be able to obtain the necessary working capital to fund the trials. In addition, no assurance can be provided that BioSante will be able to design the two new efficacy trials to the FDA s satisfaction or to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials.

With respect to BioSante s LibiGel Phase III safety study, in September 2012, BioSante announced that the independent Data Monitoring Committee (DMC) completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised BioSante that subjects in the cardiovascular event and breast cancer safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application (NDA), and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained.

Elestrin is BioSante s first FDA approved product and is one of BioSante s two FDA approved products. Meda (which acquired Jazz Pharmaceuticals, Inc. s women s health business and which in turn acquired Azur Pharma International II Limited (Azur), BioSante s prior original licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante s male testosterone gel is its second FDA approved product. This product initially was developed by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, AbbVie Inc., a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

Table of Contents

On January 31, 2013, BioSante entered into an asset purchase agreement with Aduro BioTech, Inc., a clinical-stage immunotherapy company (Aduro), pursuant to which BioSante sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

BioSante s Primary Product Portfolio

Product	Indication	Early Human Clinical	Late Human Clinical	FDA Approval	Collaborations
LibiGel® (testosterone gel)	Female sexual dysfunction (FSD)				Non-partnered
Male Testosterone Gel	Male hypogonadism				Teva
The Pill Plus (birth control with androgen)	Contraception				Pantarhei for oral use
Elestrin (estradiol gel)	Menopausal symptoms				Meda

BioSante s Proposed Merger with ANI

On October 3, 2012, BioSante entered into a merger agreement with ANI, which provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. BioSante believes that the merger of the two companies will be able to create more value than BioSante could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. Although the exact timing of completion of the merger cannot be predicted with certainty, each company has scheduled a special meeting of its stockholders on March 15, 2013 to consider and vote on certain matters in connection with the merger. If the merger is approved by BioSante s and ANI s stockholders and the other conditions to closing are satisfied, it is anticipated that the merger will be completed as soon as reasonably practicable after the special meetings of stockholders.

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI s certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following completion of the transactions contemplated by the merger agreement, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante s net cash as of the determination date is $18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of BioSante s net cash, as defined in the merger agreement and generally consisting of BioSante s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to

Table of Contents

the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

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

Completion of the merger is subject to a number of conditions, including, but not limited to (i) the adoption and approval of the merger agreement and the transactions contemplated thereby by both the BioSante and ANI stockholders and the approval of the two charter amendments described above by the BioSante stockholders; (ii) approval for the listing of shares of BioSante common stock to be issued in the merger on The NASDAQ Global Market or The NASDAQ Capital Market; (iii) written opinions of counsel that the merger will qualify as a reorganization within the meaning of Section 368(a) of the Code; and (iv) other customary closing conditions. In addition, the obligation of ANI to effect the merger is subject to a condition that BioSante s net cash, after deducting all remaining liabilities, as calculated and as adjusted pursuant to the terms of the merger agreement, be no less than $17.0 million immediately prior to the effective time of the merger. No fractional shares of BioSante common stock will be issued in connection with the reverse split and holders of BioSante common stock will be entitled to receive cash in lieu thereof.

Important Merger Information and Additional Information and Where to Find It

This report does not constitute an offer to sell or the solicitation of an offer to buy any securities of BioSante or ANI or the solicitation of any vote or approval. In connection with the proposed merger, BioSante filed with the Securities and Exchange Commission (SEC), and the SEC has declared effective, a registration statement on Form S-4 that includes a joint proxy statement/prospectus of BioSante and ANI and that also constitutes a prospectus of BioSante. The definitive joint proxy statement/prospectus of BioSante and ANI has been sent to the stockholders of BioSante and the stockholders of ANI. Investors are strongly urged to read the definitive joint proxy statement/prospectus regarding the proposed merger and other documents filed with the SEC by BioSante, because they contain important information about BioSante, ANI and the proposed merger.

Investors and security holders of BioSante and ANI may obtain free copies of the definitive joint proxy statement/prospectus for the proposed merger and other documents filed with the SEC by BioSante through the website maintained by the SEC at www.sec.gov. In addition, investors and security holders of BioSante will be able to obtain free copies of the joint proxy statement/prospectus for the proposed merger by directing a request for such filing to (i) BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, Attention: Investor Relations or (ii) BioSante s proxy solicitor, AST Phoenix Advisors, 110 Wall Street, 27th Floor, New York, New York 10005, or by calling AST Phoenix Advisors at (877) 478-5038. Investors and security holders of ANI will be able to obtain free copies of the joint proxy statement/prospectus for the merger by contacting ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota 56623, Attention: Investor Relations or by calling (218) 634-3500.

BioSante and ANI, and their respective directors and certain of their executive officers, may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the agreement between BioSante and ANI. Information regarding BioSante s directors and executive officers is contained in this report. Information regarding ANI s directors and officers and a more complete description

Table of Contents

of the interests of BioSante s and ANI s respective directors and officers in the proposed transaction is available in the definitive joint proxy statement/prospectus of BioSante and ANI as filed by BioSante with the SEC on January 22, 2013.

Description of BioSante s Female Sexual Health, Menopause, Contraception and Male Hypogonadism Products

Overview. BioSante s products for female sexual health, menopause, contraception and male hypogonadism include its gel formulations of estradiol or testosterone and combinations of estrogen, progestogen and androgen.

BioSante s gel products are designed to be absorbed quickly through the skin after application on the upper arm for the women s products, delivering the active component to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue and to dry in under one to two minutes. BioSante believes its gel products have a number of benefits over competitive products, including the following:

- BioSante s transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus transdermal patches;

- BioSante s transdermal gels have been shown to be well absorbed, thus allowing effective therapeutic levels to reach the systemic circulation;

- transdermal gels may allow for better dose adjustment than either transdermal patches or oral tablets or capsules; and

- transdermal gels may be more appealing to patients since they are less conspicuous than transdermal patches, which may be aesthetically unattractive.

BioSante licenses the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). BioSante s male testosterone gel was developed initially by BioSante and licensed to Teva. BioSante licenses the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center.

LibiGel. BioSante s lead product in development is LibiGel, a once daily transdermal testosterone gel designed to treat FSD, specifically HSDD in postmenopausal women.

Although generally thought of as being limited to men, testosterone also is important to women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone therapy in women can boost sexual desire, sexual activity and pleasure, increase bone density, raise energy levels and improve mood. According to a study published in the *Journal of the American Medical Association*, 43 percent of American women between the ages of 18 to 59, or about 40 million women, experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex (low sexual desire). Furthermore, according to a study published in the *New England Journal of Medicine*, 43 percent of American women between the ages of 57 to 85 experience low sexual desire. Importantly, according to IMS data, approximately two million testosterone prescriptions were written off-label for women in the U.S. in 2010. In addition, according to independent primary market research, approximately two million additional prescriptions of compounded testosterone were written for women in the U.S. in 2010. Female sexual dysfunction is defined as a consistent lack of sexual desire, arousal or pleasure. The majority of women with FSD are postmenopausal, experiencing symptoms due to hormonal changes that occur with aging or following surgical menopause.

Table of Contents

Although treatment with LibiGel in BioSante s Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD, the Phase III efficacy trials did not meet the co-primary endpoints of increase in satisfying sexual events or increase in sexual desire or the secondary endpoint of decrease in sexual distress. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline; this increase also was significant versus placebo. In this trial, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, in surgically menopausal women distressed by their low sexual desire and activity.

The Phase III safety and efficacy trials were randomized, double-blind, placebo-controlled, multi-center trials of a total of 1,172 menopausal women, exposed to LibiGel or placebo for six months. Subjects in the first trial, called BLOOM-1, who were treated with LibiGel showed an increase of 1.47 days with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.26 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.463. (The smaller the p value, the stronger the statistical significance. A p-value of .05 or less is typically used to represent statistical significance of trial results.) In BLOOM 1, there was an increase in the total number of satisfying sexual events of 3.87 from baseline (an increase of 83 percent) in the LibiGel group and in the placebo group there was an increase of 3.52 satisfying sexual events from baseline (an increase of 65 percent) for a p value of 0.698. Subjects in BLOOM-2 who were treated with LibiGel showed an increase of 1.0 day with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.28 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.214. Subjects in BLOOM-1 showed an increase in mean sexual desire of 0.03 over placebo, a p value of 0.672, while subjects in BLOOM-2 demonstrated an increase in mean sexual desire of 0.03 compared to placebo, a p value of 0.48. Subjects in both trials demonstrated a decrease in sexual distress when treated with LibiGel (p=0.569 and p=0.26) compared to baseline.

As seen in previous pharmacokinetic data, the LibiGel groups in both Phase III efficacy trials showed an increase in free testosterone levels compared to baseline and placebo. In BLOOM-1, mean free testosterone at baseline was approximately 1.19 picograms per milliliter (pg/ml) and 1.10 pg/ml in the placebo and LibiGel groups, respectively. In month six of the trial, free testosterone levels were approximately 1.35 pg/ml and 4.01 pg/ml in the placebo and LibiGel groups, respectively. In BLOOM-2, mean free testosterone at baseline was approximately 1.06 pg/ml and 1.19 pg/ml in the placebo and LibiGel group, respectively. In month six of the trial, free testosterone levels were approximately 1.09 pg/ml and 3.70 pg/ml in the placebo and LibiGel groups, respectively.

Results of the two Phase III efficacy trials were announced on December 14, 2011. Subsequently, BioSante continued to analyze the data from the Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012, BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

In September 2012, BioSante announced that the independent DMC completed its ninth unblinded review of the LibiGel Phase III cardiovascular events and breast cancer safety study and recommended that the LibiGel safety study should continue as per the FDA-agreed protocol, without modifications. At the time of the DMC review, there were 53 adjudicated CV events, with a lower than anticipated event rate of approximately 0.72 percent. In the same population of subjects, there were 27 breast cancers reported, a rate of approximately 0.37 percent, which is in line with the expected rate based on the ages of the subjects enrolled in the study. Given this latest review during which no specific or general safety issues were raised, and after extensive consideration, BioSante announced in September 2012 the conclusion of the LibiGel Phase III safety study effective immediately. Prior to the initiation of the LibiGel safety study in 2008, the FDA had advised

Table of Contents

BioSante that subjects in the safety study were required to have a minimum average exposure in the safety study of 12 months prior to submitting a LibiGel new drug application, and prior to a potential FDA approval of LibiGel. As of the date of the conclusion of the safety study, subjects had been in the study for an average time of 24.8 months; more than 3,200 subjects had been in the study for more than one year and over 1,850 subjects had been enrolled for more than two years. With this ninth positive unblinded review of the study by the DMC, and over 7,400 women-years of exposure, BioSante believes that adequate safety data of LibiGel use in menopausal women has been obtained. BioSante remains blinded as to whether the CV events and breast cancers are experienced by subjects in the LibiGel arm or the placebo arm of the study.

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and will seek an FDA Special Protocol Assessment agreement covering aspects of the two new efficacy trials.

Male Testosterone Gel. BioSante s once daily transdermal testosterone gel indicated for the treatment of hypogonadism, or testosterone deficiency, in men is BioSante s second FDA approved product.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone also may experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Testosterone therapy has been shown to restore levels of testosterone with minimal side effects.

There are currently several products on the market for the treatment of low testosterone levels in men. As opposed to estrogen therapy products, oral administration of testosterone is currently not possible as the hormone is, for the most part, rendered inactive in the liver making it difficult to achieve adequate levels of the compound in the bloodstream. Current methods of administration include testosterone injections, patches and gels. Testosterone injections require large needles, are often painful and not effective for maintaining adequate testosterone blood levels throughout the day. Delivery of testosterone through transdermal patches was developed primarily to promote the therapeutic effects of testosterone therapy without the often painful side effects associated with testosterone injections. Transdermal patches, however, similar to estrogen patches, have a physical presence, can fall off and can result in skin irritation. Testosterone gel formulated products for men are designed to deliver testosterone without the pain of injections and the physical presence, skin irritation and discomfort associated with transdermal patches. BioSante is aware of four gel testosterone products for men currently on the market in the United States.

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

Table of Contents

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

Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories (now known as AbbVie Inc.), a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

The Pill-Plus. The Pill-Plus is based on three issued U.S. patents claiming triple component therapy via any route of administration (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone). The Pill-Plus adds a third component, an androgen, to the normal two component (estrogen and progestogen) oral contraceptive to prevent testosterone deficiency which can result from the estrogen and progestogen components and 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, arousability and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to avoid or to improve the symptoms of female sexual dysfunction in oral contraceptive users.

BioSante has a fully paid-up right and exclusive license from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center for the three issued U.S. patents for triple component contraception. The Pill-Plus is subject to a sublicense agreement with Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market the product. BioSante may receive certain development and regulatory milestones for the first product developed under the license. In addition, BioSante will receive royalty payments on any sales of the product in the U.S., if and when approved and marketed. If the product is sublicensed by Pantarhei to another company, BioSante will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. BioSante has retained all rights under its licensed patents to the transdermal delivery of triple component contraceptives.

Elestrin. Elestrin is BioSante s first FDA approved product. Elestrin is a once daily transdermal gel that delivers estrogen without the skin irritation associated with, and the physical presence of, transdermal patches, and to avoid the effects of oral estrogen. Elestrin contains estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen.

Elestrin is indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. Elestrin is administered using a metered dose applicator. Two doses of Elestrin were approved by the FDA.

8

Table of Contents

Meda is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur (which was acquired by Jazz Pharmaceuticals, Inc. which subsequently sold its women s health business to Meda) pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

Elestrin also is subject to an exclusive agreement with Valeant Pharmaceuticals International, Inc. (which acquired PharmaSwiss SA) for the marketing of Elestrin in Israel. Valeant Pharmaceuticals will be responsible for regulatory and marketing activities in Israel. Israeli authorities have approved Elestrin, but the product has not been launched.

Other Products. Marketing rights to BioSante s gel products in Canada are subject to an agreement with Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in BioSante, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments are required to be in the form of a series of equity investments by Paladin in BioSante common stock at a 10 percent premium to the market price of its stock at the time the equity investment is made. No recent investments have been made and none are expected in the foreseeable future.

Oncolytic Virus Technology. In November 2010, BioSante entered into an assignment and technology transfer agreement with Cold Genesys, Inc. pursuant to which BioSante sold to Cold Genesys exclusive, worldwide rights to develop and commercialize its oncolytic virus technology. The oncolytic virus technology uses replication-competent adenoviruses derived from Adenovirus type 5, a common cold virus that replicate in and selectively kill tumor cells. The replication of the virus is controlled by replacing the promoter of a gene required for replication with a promoter that is preferentially expressed only in tumor cells. Furthermore, the virus may optionally include a gene encoding a cytokine, which enhances immune stimulation to the tumor, thereby providing a dual mechanism of action for killing targeted cancer cells by direct cell lysis as well as via cellular and humoral immune responses to the tumor. The oncolytic virus technology includes CG0070, a replication-competent adenovirus that has completed a Phase I clinical trial for treatment of superficial bladder cancer. In exchange for the technology, BioSante received an initial 19.9 percent ownership position in Cold Genesys and a $95,000 upfront cash payment and is eligible to receive future milestone and royalty payments.

Sales and Marketing

BioSante currently has no sales and marketing personnel to sell any of its products on a commercial basis. Under BioSante s license agreements, its licensees have agreed to market the products covered by the agreements in certain countries. For example, under BioSante s license agreement with Meda, Meda has agreed to use commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States, and under BioSante s agreement with Teva, Teva has agreed to use commercially reasonable efforts to market its male testosterone gel in the United States. If and when BioSante is ready to launch commercially a product not covered by its license agreements, BioSante will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist BioSante with this function.

Research and Product Development

BioSante historically has spent a significant amount of its financial resources on product development activities, with the largest portion being spent on clinical studies for LibiGel. BioSante spent approximately $16.9 million in 2012, $44.2 million in 2011 and $39.7 million in 2010 on research and product development activities. BioSante anticipates that its research and development expenses for 2013 will consist primarily of

Table of Contents

expenses associated with the conclusion of the LibiGel Phase III cardiovascular events and breast cancer study and the planning for the two new LibiGel Phase III efficacy trials. If BioSante s pending merger with ANI is completed, BioSante anticipates that is research and development expense for 2013 also will consist of expenses associated with ANI s targeted areas of product development including narcotics, anti-cancers and hormones (potent compounds) and extended release niche generic prescription product opportunities.

Manufacturing

BioSante does not have any facilities suitable for manufacturing on a commercial scale basis any of its products nor does it have any experience in volume manufacturing. BioSante currently uses third-party current Good Manufacturing Practices (cGMP), manufacturers to manufacture its products in development in accordance with FDA and other appropriate regulations.

Patents, Licenses and Proprietary Rights

BioSante s success depends and will continue to depend in part upon its ability to maintain its exclusive licenses, to obtain and maintain patent protection for its products and processes, to preserve its proprietary information, trademarks and trade secrets and to operate without infringing the proprietary rights of third parties. BioSante s policy is to attempt to protect its technology by, among other things, filing patent applications or obtaining license rights for technology that BioSante considers important to the development of its business.

License Agreements. BioSante licensed the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. Under the agreement, Antares granted BioSante an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories, including the U.S., Canada, New Zealand, South Africa, Israel, Mexico, China (including Hong Kong) and Indonesia. BioSante is the exclusive licensee in certain territories for issued U.S. patents for these products and additional patent applications have been filed for this licensed technology in the U.S. and several foreign jurisdictions. Under the agreement, BioSante is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its sub-licensees sell incorporating the in-licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee.

BioSante and Antares may terminate the license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party or if the other party goes into liquidation or bankruptcy or makes an assignment for the benefit of creditors or a receiver is appointed. Antares may terminate the agreement with respect to certain products or territories if BioSante does not continue development, seeking regulatory approval or marketing of such products in the covered territories. BioSante may terminate the agreement with respect to certain products or territories if, for technical, scientific or regulatory reasons, it is not likely that the product will gain required regulatory approvals in a territory, if regulatory approvals in a territory are not obtained or if BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

The patents covering the formulations used in these gel products are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the method of use of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. In addition, BioSante has other patents pending, which, if issued, may expire later than 2028. BioSante s male testosterone gel was developed initially by

BioSante and not covered under the Antares license.

BioSante has a fully-paid up right and exclusive license to the technology underlying its triple component contraceptives, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center.

Table of Contents

Trademarks and Trademark Applications/Registrations. BioSante owns trademark registrations in the U.S. and/or in certain foreign jurisdictions for several marks, including BIOSANTE® and LIBIGEL®. In addition, BioSante has filed trademark applications for several other marks including ELESTRIN (pursuant to a license agreement regarding Elestrin, the Elestrin trademark in the U.S. is now owned by Meda). In addition, BioSante owns common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, THE PILL-PLUS and ELESTRIN . For those trademarks for which registration has been sought, registrations have issued for some of those trademarks in certain jurisdictions and others currently are in the application/prosecution phase.

Confidentiality and Assignment of Inventions Agreements. BioSante requires its employees, consultants and advisors having access to its confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with BioSante. These agreements generally provide that all confidential information BioSante develops or makes known to the individual during the course of the individual s employment or consulting relationship with BioSante must be kept confidential by the individual and not disclosed to any third parties. BioSante also requires all of its employees and consultants who perform research and development for BioSante to execute agreements that generally provide that all inventions and works-for-hire conceived by these individuals during their employment by BioSante will be BioSante s property.

Competition

There is intense competition in the biopharmaceutical industry. Potential competitors in the United States are numerous and include major pharmaceutical and specialized biotechnology companies, universities and other institutions. In general, competition in the pharmaceutical industry can be divided into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions. Many of BioSante s competitors have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than BioSante does, as well as substantially greater experience than BioSante in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. A significant amount of research is carried out at academic and government institutions. These institutions are aware of the commercial value of their findings and are aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

There are several firms currently marketing or developing products that may be competitive with BioSante s gel products. They include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc. (a subsidiary of Hisamitsu Pharmaceutical Co., Inc.), Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc. and AbbVie Inc. Competitor products include oral tablets, transdermal patches, a spray and gels. BioSante expects its FDA-approved products, Elestrin and its male testosterone gel, and its other products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position and potentially on cost. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market and may result in certain marketing exclusivity as per federal legislation. Acceptance by physicians and other health care providers, including managed care groups, also is critical to the success of a product versus competitor products.

Governmental Regulation

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies in countries in which they do business. Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA regulations in the United States and by comparable regulations in foreign

Table of Contents

countries. Any products developed by BioSante will require FDA approvals in the United States and comparable approvals in foreign markets before they can be marketed.

The U.S. Federal Food, Drug, and Cosmetic Act (FDCA) and other federal and state statutes and regulations govern or influence, among other things, the development, testing, manufacture, safety, labeling, storage, recordkeeping, approval, advertising, promotion, sale, import, export and distribution of pharmaceutical products in the United States. Pharmaceutical manufacturers also are subject to certain record-keeping and reporting requirements, establishment registration and product listing, and FDA inspections.

Manufacturers of controlled substances also must comply with the federal Controlled Substances Act of 1970 (CSA) and regulations promulgated by the U.S. Drug Enforcement Administration (DEA), as well as similar state and local regulatory requirements for manufacturing, distributing, testing, importing, exporting and handling controlled substances.

Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, and criminal prosecution.

Product development and approval within the FDA regulatory framework take a number of years, involve the expenditure of substantial resources, and are uncertain. Many products ultimately do not reach the market because they are not found to be safe or effective or cannot meet the FDA s other regulatory requirements. After a product is approved, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies or evidence of safety concerns. Further, the current regulatory framework may change and additional regulatory or approval requirements may arise at any stage of BioSante s product development that may affect approval, delay the submission or review of an application or require additional expenditures by BioSante. BioSante may not be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of its products under development. Delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on BioSante s business.

New Product Development and Approval. All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, product testing, manufacturing processes, manufacturing facilities, packaging, labeling, quality control, and evidence of safety and effectiveness for intended uses. For a generic drug product, instead of safety and effectiveness data, an application must demonstrate that the proposed product is the same as the branded drug in several key characteristics. There are two types of applications used for obtaining FDA approval of new non-biological drug products, other than a generic product:

- An NDA, sometimes referred to as a full NDA, generally is submitted when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. Full NDAs typically are submitted for newly developed branded products and, in certain instances, an applicant submits an NDA or NDA supplement for a change to one of its previously approved products, such as a new dosage form, a new delivery system or a new indication.

- Another form of an NDA is the 505(b)(2) NDA, which typically is used to seek FDA approval of products that share characteristics (often, the active ingredient(s)) with a previously approved product of another company, but contain modifications to, or differences from, the approved

Table of Contents

product that preclude submission of an abbreviated new drug application. A 505(b)(2) NDA is required where at least some of the information required for approval does not come from studies conducted by or for the applicant or for which the applicant has obtained a right of reference. Usually, this means the application relies on the FDA s previous approval of a similar product or reference listed drug, or published data in scientific literature that are not the applicant s.

The process by which a product, other than a generic product, is approved for marketing in the United States can take from three to more than 10 years, and generally involves the following:

- laboratory and preclinical tests;
- submission of an Investigational New Drug (IND) application, which must become effective before clinical studies may begin;
- adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;
- submission of a full NDA or 505(b)(2) NDA containing, to the extent required, the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;
- scale-up to commercial manufacturing;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and
- FDA approval of the application.

To the extent that a 505(b)(2) NDA applicant can rely on a previously approved application or published literature, it may not be required to conduct some or all laboratory and preclinical tests or human clinical studies.

Pre-Clinical Studies and Clinical Trials. Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a product s uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and

other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information. BioSante s submission of an IND, or those of its collaboration partners, may not result in FDA authorization to commence a clinical trial.

A separate submission to an existing IND also must be made for each successive clinical trial conducted during product development. Depending on its significance, the FDA also must approve changes to an existing IND. Further, an independent institutional review board (IRB) for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. Alternatively, a central IRB may be used instead of individual IRBs. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

Table of Contents

The sponsor of a drug product typically conducts human clinical trials in three sequential phases, but the phases may overlap or not all phases may be necessary. The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

Phase II trials are designed to evaluate the effectiveness of the product in the treatment of a given disease and involve people with the disease under study. These trials often are well controlled, closely monitored studies involving a relatively small number of subjects, usually no more than several hundred. The optimal routes, dosages and schedules of administration are determined in these studies. If Phase II trials are completed successfully, Phase III trials are often commenced, although Phase III trials are not always required.

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials are usually conducted with several hundred to several thousand subjects.

A clinical trial may combine the elements of more than one phase and typically two or more Phase III studies are required. A company s designation of a clinical trial as being of a particular phase is not necessarily indicative that the trial will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to complete Phase I, II and III studies with respect to a given product.

Success in early-stage clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval. Regulations require the posting of certain details about active clinical trials on government (i.e., www.clinicaltrials.gov) or independent websites, and subsequently a limited posting of the results of those trials. This helps prospective patients find out about trials they may wish to enroll in, but also provides some competitive intelligence to other companies working in the field. Failure to post the trial or its results in a timely manner can result in civil penalties and the rejection of the drug application.

New Drug Applications. The results of the product development, including preclinical studies, clinical studies, and product formulation and manufacturing information, are then submitted to the FDA as part of the NDA.

The FDA reviews each submitted application before accepting it for filing, and may refuse to file the application if it does not appear to meet the minimal standards for filing. If the FDA refuses to file an application and requests additional information, the application must be resubmitted with the requested information. Once the submission is accepted for filing, the FDA begins an in-depth review of the application to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate FDA-advisory committee of outside experts, typically a panel of clinicians, for review, evaluation and a recommendation. Under the policies agreed to by

Table of Contents

the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy, and there is no assurance that the FDA will ultimately approve an NDA.

Acceptance for filing of an application does not assure FDA approval for marketing. The FDA has substantial discretion in the approval process and may disagree with an applicant s interpretation of the submitted data, which could delay, limit, or prevent regulatory approval. If it concludes that the application does not satisfy the regulatory criteria for approval, the FDA typically issues a complete response letter communicating the agency s decision not to approve the application and outlining the deficiencies in the submission. The complete response letter may request additional information, including additional preclinical testing or clinical trials. Even if such information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If the FDA approves the application, the agency may require post-marketing studies, also known as Phase IV studies, as a condition to approval. These studies may involve continued testing of a product and development of data, including clinical data, about the product s effects in various populations and any side effects associated with long-term use. After approval, the FDA also may require post-marketing studies or clinical trials if new safety information develops.

The FDA also may conclude that as part of the NDA or the 505(b)(2) NDA, the sponsor must develop a risk evaluation and mitigation strategy (REMS) to ensure that the benefits of the drug outweigh the risks. A REMS may have different components, including a package insert directed to patients, a plan for communication with healthcare providers, restrictions on a drug s distribution, or a medication guide to provide better information to consumers about the drug s risks and benefits.

Special Protocol Assessments (SPA). The special protocol assessment process generally involves FDA evaluation of a proposed Phase III clinical trial protocol and a commitment from the FDA that the design and analysis of the trial are adequate to support approval of an NDA, if the trial is performed according to the SPA and meets its endpoints. The FDA s guidance on the SPA process indicates that SPAs are designed to evaluate individual clinical trial protocols primarily in response to specific questions posed by the sponsors. In practice, the sponsor of a product candidate may request an SPA for proposed Phase III trial objectives, designs, clinical endpoints and analyses. A request for an SPA is submitted in the form of a separate amendment to an IND, and the FDA s evaluation generally will be completed within a 45-day review period under applicable PDUFA goals, provided that the trials have been the subject of discussion at an end-of-Phase II and pre-Phase III meeting with the FDA, or in other limited cases.

If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. While the FDA s guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has the latitude to change its assessment if certain exceptions apply. Exceptions include identification of a substantial scientific issue essential to safety or efficacy testing that later comes to light, a sponsor s failure to follow the protocol agreed upon, or the FDA s reliance on data, assumptions or information that are determined to be wrong.

The Hatch-Waxman Act. The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act (Hatch-Waxman), established an abbreviated process for obtaining FDA approval for generic versions of approved branded drug products. In addition to establishing a shorter, less expensive pathway for approval of generic drugs, Hatch-Waxman provides incentives for the development of new branded products and innovations to approved products by means of marketing exclusivities and extension of patent rights. Under the

Hatch-Waxman Act, newly-approved drugs and new conditions of use

Table of Contents

may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five years of marketing exclusivity if the product s active ingredient is a new chemical entity not previously approved. The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs for, among other things, new indications, dosages or strengths of a drug containing a previously approved active ingredient, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. This three-year marketing exclusivity period protects against the approval of abbreviated new drug applications and 505(b)(2) NDAs for the innovation that required clinical data; it does not prohibit the FDA from accepting or approving abbreviated new drug application or 505(b)(2) applications for other products containing the same active ingredient. The five- and three-year marketing exclusivity periods apply equally to patented and non-patented drug products. It is under this provision that BioSante received three years marketing exclusivity for Elestrin. .

Orphan Drug Exclusivity. The Orphan Drug Act was enacted by Congress to provide financial incentives for the development of drugs for rare conditions (affecting less than 200,000 individuals per year) in the United States. The orphan designation is granted for a combination of a drug entity and an indication and therefore it can be granted for an existing drug with a new (orphan) indication. Applications are made to the Office of Orphan Products Development at the FDA and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs may be exempt from application fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50 percent of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment.

Other Regulatory Requirements. Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with current good manufacturing practice regulations, commonly referred to as cGMP regulations, which govern the production of pharmaceutical products. BioSante currently does not have any manufacturing capability.

The FDA regulates and monitors all promotion advertising and of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

U.S. Drug Enforcement Administration. The DEA regulates certain drug products containing controlled substances, such as testosterone, pursuant to the U.S. Controlled Substances Act. The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

16

Table of Contents

Foreign Regulation. Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European and other countries (i.e., Canada, Australia and Japan), the sales price of a product also must be approved. The pricing review period often begins after market approval is granted. BioSante intends to seek and utilize foreign partners to apply for foreign approvals of its products.

Employees

As of December 31, 2012, BioSante had 23 employees, including 12 in product development and 11 in management or administrative positions. As of February 28, 2013, BioSante had 12 employees, including three in product development and nine in management or administrative positions. None of BioSante s employees is covered by a collective bargaining agreement. BioSante also engages independent contractors from time to time on an as needed, project by project, basis.

Forward-Looking Statements

This annual report on Form 10-K contains or incorporates by reference 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, BioSante or others on its 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 its Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that BioSante expects, believes or anticipates will or may occur in the future are forward-looking statements including, in particular, the statements about BioSante s plans, objectives, strategies and prospects regarding, among other things, its financial condition, results of operations, business and proposed merger with ANI. BioSante has identified some of these forward-looking statements with words like believe, may, could, would, might, possible, potential, project, will, should, expect, intend, plan, pr approximate, contemplate and continue , the negative of these words, other words and terms of similar meaning and the use of future dates. These forward-looking statements may be contained in this section, the notes to BioSante s financial statements and elsewhere in this report, including under the heading Part II. Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements generally relate to:

- the timing and anticipated completion of the proposed merger between BioSante and ANI;

- the expected benefits of and potential value created by the proposed merger for the stockholders of BioSante and ANI;

- the likelihood of the satisfaction of certain conditions to completion of the merger and whether and when the merger will be completed;

- the amount of shares of BioSante common stock that BioSante expects to issue in the proposed merger and the post-capitalization of the combined company after the merger;

- the status of BioSante s LibiGel Phase III development program;

- BioSante s future operating expenses, anticipated burn rate and whether and how long its existing cash and cash equivalents will be sufficient to fund its operations;

Table of Contents

- the amount of cash and cash equivalents that will be available to fund the combined company s business after the merger and the length of time that the combined company anticipates such cash and cash equivalents will be available to fund the combined company s operating plan after the merger;

- the market size and market acceptance of BioSante s approved products and products in development;

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

- BioSante s substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to BioSante. Some of the factors known to BioSante that could cause its actual results to differ materially from what it has anticipated in its forward-looking statements are described under the heading Part I. Item 1A. Risk Factors below. BioSante cautions 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 risks and uncertainties described under the heading Part I. Item 1A. Risk Factors below, as well as others that BioSante may consider immaterial or does not anticipate at this time. Although BioSante believes that the expectations reflected in its forward-looking statements are reasonable, BioSante does not know whether its expectations will prove correct. BioSante s expectations reflected in its forward-looking statements can be affected by inaccurate assumptions BioSante might make or by known or unknown risks and uncertainties, including those described below under the heading Part I. Item 1A. Risk Factors. The risks and uncertainties described under the heading Item 1A. Risk Factors below are not exclusive and further information concerning BioSante and its business, including factors that potentially could materially affect its financial results or condition, may emerge from time to time. BioSante assumes no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. BioSante advises you, however, to consult any further disclosures BioSante makes on related subjects in its quarterly reports on Form 10-Q and current reports on Form 8-K that BioSante files with or furnishes to the Securities and Exchange Commission.

Available Information

BioSante is a Delaware corporation that was initially formed as a corporation organized under the laws of the Province of Ontario in August 1996. BioSante continued as a corporation under the laws of the State of Wyoming in December 1996 and reincorporated under the laws of the State of Delaware in June 2001. In October 2009, Cell Genesys, Inc. was merged with and into BioSante, and BioSante was the surviving corporation.

On October 3, 2012, BioSante entered into a merger agreement with ANI pursuant to which, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. Although the exact timing of completion of the merger cannot be predicted with certainty, each company has scheduled a special meeting of its stockholders for March 15, 2013 to consider and vote on certain matters in connection with the merger. If the merger is approved by BioSante s and ANI s stockholders and the other conditions to closing are satisfied, it is anticipated that the merger will be completed as soon as reasonably practicable after the special

meetings of stockholders. The proposed merger with ANI is described in more detail below under the heading BioSante s Proposed Merger with ANI and elsewhere in this report.

BioSante s principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Its telephone number is (847) 478-0500, and its Internet web site address is www.biosantepharma.com.

Table of Contents

The information contained on BioSante s web site or connected to its web site is not incorporated by reference into and should not be considered part of this annual report on Form 10-K.

BioSante makes available, free of charge and through its Internet web site, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after BioSante electronically files such material with, or furnish it to, the SEC. BioSante also makes available, free of charge and through its Internet web site, to any stockholder who requests, its corporate governance guidelines, the charters of its board committees and its Code of Conduct and Ethics. Requests for copies can be directed to Investor Relations at (847) 478-0500, extension 120.

ITEM 1A. RISK FACTORS

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

Risks Related to the Merger Between BioSante and ANI

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

Pursuant to the terms of the merger agreement, it is anticipated that BioSante will issue shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante s net cash is $18.0 million as of the determination date. After such issuance, the shares of BioSante common stock outstanding immediately prior to completion of the merger will represent approximately 47 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger. These ownership percentages may change depending upon the amount of BioSante s net cash as of a determination date prior to completion of the merger. Accordingly, the issuance of shares of BioSante common stock to ANI stockholders in connection with the merger will reduce significantly the relative voting power of each share of BioSante common stock held by current BioSante stockholders. Consequently, the BioSante stockholders as a group will have significantly less influence over the management and policies of the combined company after the merger than prior to the merger.

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

Subject to the terms and conditions of the merger agreement, at the effective time of and as a result of the merger, each share of ANI capital stock issued and outstanding immediately prior to the effective time of the merger will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of

ANI s certificate of incorporation. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of net cash of BioSante, as defined in the merger agreement and generally consisting of BioSante s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. If BioSante has more than $18.0 million of net cash as of the determination date, then the percentage ownership of the current BioSante stockholders will be increased on a pro rata basis by 0.6 percent for each $1.0 million of net cash excess, which would dilute further the ownership of the current ANI stockholders in the combined company. If BioSante has less than $18.0 million of net cash as of the determination date, then the percentage ownership of current BioSante stockholders will be decreased on a pro rata basis by 0.6 percent for each $1.0 million of net cash shortfall, which would dilute further the ownership of the current BioSante stockholders in the combined company. In

Table of Contents

no event, however, will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. In addition, one of the conditions to ANI s obligations to complete the merger is BioSante s net cash as of the closing date being no less than $17.0 million as calculated and as adjusted pursuant to the provisions of the merger agreement. The items that will constitute BioSante s net cash at the determination date set forth in the merger agreement are subject to a number of factors, some of which are outside the control of BioSante and many of which are outside the control of ANI.

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

As of December 31, 2012, BioSante had outstanding options to purchase an aggregate of approximately 1.1 million shares of BioSante common stock, warrants to purchase an aggregate of approximately 4.7 million shares of BioSante common stock, an aggregate of 65,211 shares of BioSante class C special stock that are convertible into 65,211 shares of BioSante common stock and an aggregate of $8.3 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 that are convertible into an aggregate of 370,871 shares of BioSante common stock. BioSante is not prohibited under the terms of the merger agreement from issuing additional equity securities under certain circumstances, including securities issued pursuant to the exercise of outstanding options or warrants or the conversion or exchange of outstanding convertible senior notes. It is possible that prior to completion of the merger BioSante may issue additional equity securities. The exchange ratios in the merger agreement, which are designed to result in the issuance by BioSante of shares of BioSante common stock to ANI stockholders representing approximately 53 percent of the outstanding shares of common stock of the combined company as of immediately following completion of the merger, assuming BioSante s net cash is $18.0 million as of the determination date, are not adjustable based on issuances by BioSante of additional shares of BioSante common stock. Therefore, any such issuances by BioSante would result in additional dilution to the BioSante stockholders.

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

While there have been no significant adverse effects to date, the announcement and pendency of the merger could disrupt BioSante s business in the following ways, among others:

- third parties may seek to terminate and/or renegotiate their relationships with BioSante as a result of the merger, whether pursuant to the terms of their existing agreements with BioSante or otherwise; and

- the attention of BioSante management may be directed toward completion of the merger and related matters and may be diverted from the day-to-day business operations, including from other opportunities that otherwise might be beneficial to BioSante.

Should they occur, any of these matters could adversely affect the trading price of BioSante common stock or harm the financial condition, results of operations or business prospects of BioSante and/or the combined company.

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

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

Table of Contents

- the current trading price of BioSante common stock may reflect a market assumption that the merger will occur, meaning that a failure to complete the merger could result in a decline in the trading price of BioSante common stock;

- certain executive officers and/or directors of BioSante may seek other employment opportunities, and the departure of any of BioSante s executive officers and the possibility that the company would be unable to recruit and hire an executive could impact negatively BioSante s business and operating results;

- the BioSante board of directors will need to reevaluate BioSante s strategic alternatives, which alternatives may include a sale of the company, liquidation of the company or other strategic transaction;

- BioSante may be required to reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances;

- BioSante has incurred and is expected to continue to incur substantial transaction costs in connection with the merger whether or not the merger is completed;

- BioSante would not realize any of the anticipated benefits of having completed the merger; and

- under the merger agreement, BioSante is subject to certain restrictions on the conduct of its business prior to completion of the merger, which restrictions could adversely affect its ability to realize certain of its business strategies or take advantage of certain business opportunities.

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

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

BioSante has incurred and will continue to incur significant transaction costs in connection with the merger. These costs are primarily associated with the fees of its attorneys, accountants and financial advisor. Most of these costs will be paid by BioSante even if the merger is not completed. In addition, if the merger agreement is terminated due to certain triggering events specified in the merger agreement, BioSante may be required to pay ANI a termination fee of $1.0 million. The merger agreement also provides that under specified circumstances, BioSante may be required to reimburse ANI up to $500,000 for its expenses in connection with the transaction. If the merger is completed, the combined

company will bear the transaction costs of both BioSante and ANI in connection with the merger, including financial advisor, legal and accounting fees and expenses.

Because the merger will be completed after the date of the BioSante special meeting of stockholders, it is possible under certain limited circumstances described below that at the time of the special meeting, BioSante stockholders will not know the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger.

Subject to the terms of the merger agreement, at the effective time of the merger, each share of ANI capital stock issued and outstanding immediately prior to the merger will be canceled, extinguished and automatically converted into the right to receive that number of shares of BioSante common stock as determined pursuant to the exchange ratios described in the merger agreement. The exchange ratios depend on the net cash of BioSante as of a determination date prior to completion of the merger. The determination date is defined as the date that is 14 days prior to the date of the special meeting of BioSante stockholders, subject

Table of Contents

to extension for adjournment of the special meeting and subject to a dispute resolution provisions in the event there is a dispute between BioSante and ANI as to the amount of net cash of BioSante as of the determination date. Under the merger agreement, BioSante s net cash is defined as generally consisting of BioSante s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger. In the event of a dispute regarding the amount of net cash of BioSante as of the determination date, it is possible that the exact number of shares of BioSante common stock that the ANI stockholders will receive upon completion of the merger may not be available at the time of the special meeting of BioSante stockholders.

Some of the directors and executive officers of BioSante have interests in the merger that are different from, or in addition to, those of the other BioSante stockholders.

When considering the recommendation by the BioSante board of directors that the BioSante stockholders vote for each of the proposals being submitted to the BioSante stockholders at the special meeting of BioSante stockholders, the BioSante stockholders should be aware that certain of the directors and executive officers of BioSante have arrangements that provide them with interests in the merger that are different from, or in addition to, those of the stockholders of BioSante. For instance, in connection with the merger, Fred Holubow and Ross Mangano, each a current member of the BioSante board of directors, will continue to serve as a director of the combined company following completion of the merger and will receive cash and equity compensation in consideration for such service. The employment of BioSante s three executive officers will terminate immediately following completion of the merger and they will be entitled to receive severance cash payments ranging from $526,400 to $1,490,100, and other severance benefits such as continuing health insurance, in connection with such termination. The directors and executive officers of BioSante also have certain rights to indemnification and to directors and officers liability insurance that will be provided by the combined company following completion of the merger. The board of directors of BioSante was aware of these potential interests and considered them in making its recommendations to approve the proposals being submitted to the BioSante stockholders at the special meeting of BioSante stockholders.

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

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

- the general prohibition on BioSante s soliciting or engaging in discussions or negotiations regarding any alternative acquisition proposal;

- the requirement that BioSante reimburse ANI for expenses of up to $500,000 or pay a termination fee of $1.0 million to ANI if the merger agreement is terminated by ANI or BioSante under certain circumstances; and

- the requirement that BioSante submit the merger-related proposals to a vote of the BioSante stockholders even if the BioSante board of directors changes its recommendations with respect to such proposals.

Pursuant to voting agreements entered into between (i) BioSante and certain stockholders of ANI and (ii) ANI and the directors, executive officers and certain stockholders of BioSante, each such director, executive officer and applicable stockholder has agreed not to take any actions that BioSante or ANI, as applicable, is prohibited from taking pursuant to the no-solicitation restrictions contained in the merger agreement. In addition, holders of shares representing approximately 85 percent of the shares of the outstanding ANI capital stock, calculated on an as-converted basis, and approximately 86 percent of the outstanding shares of the ANI series D preferred stock, as of October 3, 2012 are subject to a voting

Table of Contents

agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger, and ANI is required under the terms of the merger agreement to convene and hold the ANI special meeting regardless of any change in the recommendation of the ANI board of directors. Likewise, holders of shares representing approximately two percent of the outstanding capital stock of BioSante as of October 3, 2012 are subject to a voting agreement, pursuant to which the holders of such shares have agreed to vote in favor of the approval and adoption of the merger agreement and the transactions contemplated thereby, including the merger and the issuance of the shares of BioSante common stock, and the approval of the BioSante charter amendments, and BioSante is required under the terms of the merger agreement to convene and hold the BioSante special meeting regardless of any change in the recommendation of the BioSante board of directors. These provisions might discourage an otherwise interested third party from considering or proposing an acquisition of BioSante, even one that may be deemed of greater value than the merger to BioSante stockholders. Furthermore, even if a third party elects to propose an acquisition, the concept of a termination fee or payment of the other party s expenses may result in that third party offering a lower value to BioSante stockholders than such third party might otherwise have offered.

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

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

BioSante may not issue contingent value rights (CVRs) to holders of BioSante common stock prior to the merger and, even if issued, the CVRs will not be certificated or transferable and may not result in any cash payments to holders of CVRs.

Although BioSante currently plans to enter into the contingent value rights agreement and issue CVRs to holders of BioSante common stock as of March 15, 2013, there is no assurance that the CVRs will be issued at all or based on the terms currently set forth in the form of the contingent value rights agreement. BioSante currently has not entered into the contingent value rights agreement and the BioSante board of directors may determine in its sole discretion not to issue the CVRs based on, among other things, the anticipated tax impact of the distribution and issuance of the CVRs to the holders of BioSante common stock. Furthermore, if BioSante and ANI agree, the terms of the contingent value rights agreement as contemplated currently may be changed prior to BioSante entering into the contingent value rights agreement. Even if CVRs are issued, they will not be certificated or transferable and may not result in any cash payments to holders of CVRs. Under the contingent value rights agreement, the combined company will not have any obligation, other than an obligation to act in good faith to pursue, engage in, negotiate, enter into or consummate an actual or potential LibiGel transaction (as such term is defined in the contingent value rights agreement).

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

Certain conditions to BioSante s obligations to complete the merger may be waived, in whole or in part, to the extent legally allowed, either unilaterally or by agreement of BioSante and ANI. In the event of a waiver of a condition, the board of directors of BioSante will evaluate the materiality of any such waiver to determine whether amendment of the joint proxy statement/prospectus and resolicitation of proxies is necessary. In the event that the board of directors of BioSante determines any such waiver is not significant enough to require resolicitation of stockholders, it will have the discretion to complete the merger without

23

Table of Contents

seeking further stockholder approval. The conditions requiring the approval of each company s stockholders cannot, however, be waived.

Risks Related to the Combined Company if the Merger is Completed

The success of the merger will depend, in large part, on the ability of the combined company following completion of the merger to realize the anticipated benefits from combining the businesses of BioSante and ANI.

The merger involves the integration of two companies that previously have operated independently with principal offices in two distinct locations. Due to legal restrictions, BioSante and ANI are able to conduct only limited planning regarding the integration of the two companies prior to completion of the merger. Significant management attention and resources will be required to integrate the two companies after completion of the merger. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company s failure to achieve some or all of the anticipated benefits of the merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company s cash and other assets efficiently to develop the business of the combined company;
- appropriately managing the liabilities of the combined company;
- potential unknown or currently unquantifiable liabilities associated with the merger and the operations of the combined company;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the merger; and
- performance shortfalls at one or both of the companies as a result of the diversion of management s attention caused by completing the merger and integrating the companies operations.

Delays in the integration process could adversely affect the combined company s business, financial results, financial condition and stock price following the merger. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time.

The merger will result in changes to the BioSante board of directors and the combined company may pursue different strategies than BioSante may have pursued independently.

If BioSante and ANI complete the merger, the composition of the BioSante board of directors will change in accordance with the merger agreement. Following completion of the merger, the combined company s board of directors will consist of seven members, including two of the current directors of BioSante and five of the current directors of ANI. Currently, it is anticipated that the combined company will continue to advance the product development efforts and business strategies of ANI primarily. However, because the composition of the board of directors of the combined company will consist of directors from both BioSante and ANI, the combined company may determine to pursue certain business strategies that BioSante would not have pursued independently.

Table of Contents

Ownership of the combined company s common stock may be highly concentrated, and it may prevent the BioSante stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the combined company s stock price to decline.

Upon completion of the merger, ANI s directors and executive officers continuing with the combined company, together with their respective affiliates, are expected to beneficially own or control approximately 41 percent of the combined company. Accordingly, these directors, executive officers and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the combined company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the combined company s assets or any other significant corporate transaction. These stockholders also may exert influence in delaying or preventing a change in control of the combined company, even if such change in control would benefit the other stockholders of the combined company. In addition, the significant concentration of stock ownership may affect adversely the market value of the combined company s common stock due to investors perception that conflicts of interest may exist or arise.

Future results of the combined company may differ materially from the unaudited pro forma financial statements presented in the joint proxy statement/prospectus and the financial forecasts prepared by ANI in connection with discussions concerning the merger.

The future results of the combined company may be materially different from those shown in the unaudited pro forma condensed combined financial statements presented in the joint proxy statement/prospectus, which show only a combination of the historical results of BioSante and ANI, and the financial forecasts prepared by ANI in connection with discussions concerning the merger. BioSante and ANI expect to incur significant costs associated with completion of the merger and combining the operations of the two companies. The exact magnitude of these costs is not yet known, but is estimated to be approximately $3.1 million. Furthermore, these costs may decrease the capital that the combined company could use for continued development of the combined company s business in the future or may cause the combined company to seek to raise new capital sooner than expected.

The combined company s ability to utilize BioSante s or ANI s net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the merger.

Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an ownership change (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the historic business of BioSante is not treated as being continued by the combined entity for the two-year period beginning on the date of the merger (referred to as the continuity of business requirement), the pre-transaction net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. In 2009, an ownership change occurred with respect to BioSante, and it is expected that the merger with ANI will result in another ownership change of BioSante. Accordingly, the combined company s ability to utilize BioSante s net operating loss and tax credit carryforwards may be substantially limited. These limitations, in turn, could result in increased future tax payments for the combined company, which could have a material adverse effect on the business, financial condition or results of operations of the combined company.

Under Section 384 of the Code, available net operating loss carryovers of BioSante or ANI may not be available to offset certain gains arising after the merger from assets held by the other corporation at the effective time of the merger. This limitation will apply to the extent that the gain is attributable to an unrealized built-in-gain in the assets of BioSante or ANI existing at the effective time of the merger. To the extent that any such gains are recognized in the five year period after the merger upon the disposition of any

25

Table of Contents

such assets, the net operating loss carryovers of the other corporation will not be available to offset such gains (but the net operating loss carryovers of the corporation that owned such assets will not be limited by Section 384 although they may be subject to other limitations under Section 382 as described above).

The price of BioSante common stock after the merger is completed may be affected by factors different from those currently affecting the price of BioSante common stock.

The business of BioSante differs significantly from the business of ANI; and, accordingly, the results of operations of the combined company and the trading price of BioSante common stock following completion of the merger may be affected significantly by factors different from those currently affecting the independent results of operations of BioSante.

The NASDAQ Global Market considers the anticipated merger of BioSante and ANI to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante; and therefore, has required that BioSante submit a new initial listing application, which requires certain actions on the part of the combined company which may not be successful and, if unsuccessful, could make it more difficult for holders of shares of the combined company to sell their shares.

The NASDAQ Global Market considers the merger between BioSante and ANI to be a business combination with a non-NASDAQ entity, resulting in a change in control of BioSante and has required that BioSante submit a new initial listing application. The NASDAQ Global Market may not approve BioSante s new initial listing application for The NASDAQ Global Market on a timely basis, or at all. If this occurs and the merger is still completed, stockholders may have difficulty converting their investments into cash effectively. Additionally, as part of the new initial listing application, BioSante will be required to submit, among other things, a plan for the combined company to effect a reverse stock split. A reverse stock split likely would increase the per share trading price by an as yet undetermined multiple. The change in share price may affect the volatility and liquidity of the combined company s stock, as well as the marketplace s perception of the stock. As a result, the relative price of the combined company s stock may decline and/or fluctuate more than in the past, and stockholders may have trouble converting their investments in the combined company into cash effectively.

The combined company s management will be required to devote substantial time to comply with public company regulations.

As a public company, the combined company will incur significant legal, accounting and other expenses that ANI did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including those related to corporate governance practices. The combined company s management and other personnel will need to devote a substantial amount of time to these requirements. Certain members of ANI s management, which will continue as the management of the combined company, do not have significant experience in addressing these requirements. Moreover, these rules and regulations will increase the combined company s legal and financial compliance costs relative to those of ANI and will make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that the combined company maintain effective internal control for financial reporting and disclosure controls and procedures. In particular, the combined company must perform system and process evaluation and testing of its internal control over financial reporting to allow management and the combined company s independent registered public accounting firm to report on

the effectiveness of its internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The combined company s compliance with these requirements will require that it incur substantial accounting and related expenses and expend significant management efforts. The combined company will need to hire additional accounting and financial staff to satisfy the ongoing requirements of Section 404 of the Sarbanes-Oxley Act. The costs of hiring such staff may be material and there can be no

Table of Contents

assurance that such staff will be immediately available to the combined company. Moreover, if the combined company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if the combined company or its independent registered public accounting firm identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of the combined company s financial reports, the market price of the combined company s common stock could decline and the combined company could be subject to sanctions or investigations by The NASDAQ Global Market, the SEC or other regulatory authorities.

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

Acquisitions involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. After completion of the merger, the combined company will possess not only all of the assets, but also all of the liabilities of both BioSante and ANI. Although BioSante conducted a due diligence investigation of ANI and its known and potential liabilities and obligations, and ANI conducted a due diligence investigation of BioSante and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise after completion of the merger, which could have an adverse effect on the combined company s business, operating results and financial condition.

BioSante and ANI do not expect the combined company to pay cash dividends.

BioSante and ANI anticipate that the combined company will retain its earnings, if any, for future growth and therefore not pay any cash dividends in the foreseeable future. Investors seeking cash dividends should not invest in the combined company s common stock for that purpose.

Anti-takeover provisions in the combined company s charter and bylaws may prevent or frustrate attempts by stockholders to change the board of directors or management and could make a third-party acquisition of the combined company difficult.

The combined company s certificate of incorporation and bylaws, as amended, will contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could limit the price that investors might be willing to pay in the future for shares of the combined company s common stock.

The sale or availability for sale of a substantial number of shares of common stock of the combined company after the merger and after expiration of the lock-up period could adversely affect the market price of such shares after the merger.

Sales of a substantial number of shares of common stock of the combined company in the public market after the merger or after expiration of the lock-up period that will apply to certain of ANI s stockholders and executive officers, or the perception that these sales could occur, could

adversely affect the market price of such shares and could materially impair the combined company s ability to raise capital through equity offerings in the future. BioSante is unable to predict what effect, if any, market sales of securities held by significant stockholders, directors or officers of the combined company or the availability of these securities for future sale will have on the market price of the combined company s common stock after the merger.

Table of Contents

Risks Related to BioSante

Risks Related to BioSante s Financial Condition and Future Capital Requirements

BioSante has not generated significant revenues and does not expect to in the near future. BioSante has a history of operating losses, expects continuing losses and may never become profitable.

Substantially all of BioSante s revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. In order to generate new and significant revenues, BioSante must develop and commercialize successfully its own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully, or acquire additional new products that generate or have the potential to generate revenues. Because of the numerous risks and uncertainties associated with BioSante s and its strategic partners product development programs and BioSante s ability to acquire additional new products, BioSante is unable to predict when it will be able to generate significant revenue or become profitable, if at all. BioSante incurred a net loss of $27.7 million for the year ended December 31, 2012. As of December 31, 2012, BioSante s accumulated deficit was $245.0 million. BioSante expects to continue to incur substantial and continuing losses for the foreseeable future. These losses will increase if BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development. Even if BioSante s approved products, products in development or any additional new products BioSante may acquire or in-license are introduced commercially, BioSante may never achieve market acceptance and it may never generate sufficient revenues or receive sufficient license fees or royalties on its licensed products and technologies in order to achieve or sustain future profitability.

Because BioSante has no source of significant recurring revenue, BioSante must depend on financing or partnering to sustain its operations. BioSante likely will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and BioSante may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

Developing products requires substantial amounts of capital. BioSante estimates that the cost of the two new LibiGel Phase III efficacy trials will be approximately $15 to $18 million each, or a combined $30 to $36 million spread over 18 months. No assurance can be provided, however, that BioSante s cost estimates will be correct. It is possible that the two new LibiGel Phase III efficacy trials will cost more than BioSante anticipates. If BioSante decides to pursue the two new LibiGel Phase III efficacy trials or in-license additional new products that require further development, BioSante will need to raise substantial additional capital or enter into strategic partnering agreements to fund its operations and it may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

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

- the progress, timing, cost and results of its clinical development programs, including the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them and if BioSante in-licenses additional new products that require further development;

- the cost, timing and outcome of regulatory actions with respect to BioSante s products;

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

- BioSante s ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;

Table of Contents

- BioSante s ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;

- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;

- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;

- the emergence of competing products and technologies, and other adverse market developments;

- the perceived, potential and actual commercial success of BioSante s products;

- the outstanding principal amount of BioSante s 3.125% convertible senior notes due May 1, 2013 (convertible senior notes) that are scheduled to mature and become due and payable on May 1, 2013 and BioSante s ability to avoid a fundamental change or an event of default under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;

- BioSante s operating expenses; and

- the resolution of BioSante s pending purported class action and shareholder derivative litigation and any amount it may be required to pay in excess of its directors and officers liability insurance.

BioSante s future capital requirements and projected expenditures are based upon numerous assumptions and subject to many uncertainties, and actual requirements and expenditures may differ significantly from its projections. To date, BioSante has relied primarily upon proceeds from sales of its equity securities to finance its business and operations. BioSante likely will need to raise additional capital to fund its operations. As of December 31, 2012, BioSante had $34.8 million of cash and cash equivalents. BioSante does not have any existing credit facilities under which it may borrow funds. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations, including in particular the two new LibiGel Phase III efficacy trials if BioSante decides to pursue them. As of December 31, 2012, BioSante has $8.3 million in principal amount of convertible senior notes outstanding that mature on May 1, 2013. Assuming the merger is completed during the first quarter of 2013 and BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash equivalents as of December 31, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the closing condition under the merger agreement to have at least $17.0 million of net cash, as defined in the merger agreement, available upon the closing of the merger. If the merger is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing to operate its business as an independent, stand-alone company, a sale of the company, liquidation of the company or other strategic transaction. BioSante s liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides

not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of December 31, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier in order to create a cash cushion and take advantage of favorable financing conditions.

The December 2011 announcement of the results of BioSante s prior completed LibiGel Phase III efficacy trials has significantly depressed the trading price of BioSante common stock and harmed BioSante s ability to raise additional capital. BioSante can provide no assurance that additional financing, if needed, will

Table of Contents

be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in BioSante s LibiGel Phase III development program, the future value of the company and/or if economic and market conditions deteriorate. BioSante has on file effective shelf registration statements that allow it to raise up to an aggregate of $102.4 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, under applicable SEC rules, if BioSante has a public float of less than $75.0 million, it can only offer to sell under the registration statement up to one-third of its public float during any 12-month period. BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to it, or at all. If adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to make changes to its operations to reduce costs. As an alternative to raising additional financing, BioSante may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights BioSante has under its existing license agreements or decide or be forced to explore other strategic alternatives, such as selling or merging the company or winding down its operations and liquidating the company. In such case, the BioSante stockholders could lose some or all of their investment.

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

If BioSante raises additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of its stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of its existing stockholders. In addition, the issuance of any equity securities could be at a discount to the market price.

If BioSante incurs additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for its business activities, and BioSante could be subject to covenants that restrict its ability to operate its business and make distributions to its stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of BioSante s assets, as well as prohibitions on the ability of BioSante to create liens, pay dividends, redeem its stock or make investments. There is no assurance that any equity or debt financing transaction will be available on terms acceptable to BioSante, or at all.

As an alternative to raising additional financing by issuing additional equity or debt securities, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under BioSante s existing license agreements or enter into other business collaborations or combinations, including a possible sale or merger of its company. If BioSante raises additional funds through licensing arrangements, BioSante may be required to relinquish greater or all rights to BioSante s products at an earlier stage of development or on less favorable terms than BioSante otherwise would choose.

BioSante has substantial indebtedness, in the form of convertible senior notes, which notes BioSante may not be able to pay when they become due and payable on May 1, 2013, or earlier if BioSante experiences a fundamental change or an event of default under the indenture governing such notes.

As of December 31, 2012, BioSante had $8.3 million in aggregate principal amount of convertible senior notes outstanding. The annual interest payment on these notes is approximately $259,000. At maturity, on May 1, 2013, the entire then remaining aggregate outstanding principal amount of the convertible senior notes will become due and payable. In addition, upon the occurrence of a fundamental change , holders of the convertible senior notes may require BioSante to purchase their notes prior to the May 1, 2013 maturity date. A fundamental change includes a

significant change in BioSante s ownership; the first day the majority of its board of directors does not consist of continuing directors; the consummation of certain recapitalizations,

Table of Contents

reclassifications, or changes of common stock, share exchanges or consolidations or mergers; or the termination of trading of BioSante common stock (which will be deemed to have occurred if BioSante common stock is neither listed for trading on a United States national securities exchange nor any United States system of automated dissemination of quotations of securities prices or traded in over-the-counter securities markets). The proposed merger between BioSante and ANI will not amount to a fundamental change under the indenture. Additionally, the aggregate principal amount of the outstanding convertible senior notes will become due and payable upon an uncured or unwaived event of default. Although BioSante believes it will be able to pay the aggregate outstanding principal amount of its convertible senior notes plus accrued interest when the notes mature on May 1, 2013, it is possible that BioSante may not have sufficient funds to pay the aggregate principal amount of its then outstanding convertible senior notes when they mature on May 1, 2013, or become due and payable earlier if BioSante were to experience a fundamental change or an event of default under the indenture governing such notes.

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

The indenture governing BioSante s convertible senior notes contains covenants, such as the requirement to pay accrued interest on May 1 and November 1 of each year, the requirement to repurchase the notes upon a fundamental change, as defined in the indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If BioSante does not comply with the covenants in the indenture, an event of default could occur and all amounts due under the notes could become immediately due and payable. Upon the occurrence of an event of default under the indenture, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Although it is possible BioSante could negotiate a waiver with the trustee and the holders of the notes, such a waiver likely would involve significant costs. It also is possible that BioSante could refinance or restructure its obligations under the notes; however, such a refinancing or restructuring also likely would involve significant costs and likely would result in higher interest rates than the current 3.125% annual interest rate on the notes.

Future purchases, exchanges or restructurings of BioSante s outstanding convertible senior notes could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of BioSante s existing stockholders and/or decrease its cash balance.

In February 2012, BioSante entered into privately-negotiated securities exchange agreements with one of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,868,055 shares of its common stock, as adjusted to reflect its one-for-six reverse stock split effected on June 1, 2012, to the note holder in exchange for the cancellation of an aggregate of $9.0 million principal amount of BioSante s convertible senior notes, including accrued and unpaid interest of $79,024. In July 2012, BioSante entered into a privately-negotiated securities exchange agreement with two of the holders of its convertible senior notes pursuant to which BioSante issued an aggregate of 1,784,070 shares of its common stock to the note holder in exchange for the cancellation of an aggregate of $3.5 million principal amount of BioSante s convertible senior notes and accrued and unpaid interest of $20,686. An aggregate of $8.3 million principal amount of the convertible senior notes remained outstanding as of September 30, 2012. From time-to-time, BioSante again may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of its company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante s available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante s cash balance. A significant decrease in

Table of Contents

BioSante s cash balance may impair its ability to execute strategic alternatives, including the proposed merger with ANI, or leave BioSante without sufficient cash remaining for operations.

BioSante is subject to pending purported securities class action and shareholder derivative litigation, which could divert management s attention, harm its business and/or reputation and result in significant liabilities, as well as harm its ability to raise additional financing and execute certain strategic alternatives.

BioSante is subject to pending purported securities class action and shareholder derivative litigation.

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of BioSante s disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante s securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante s securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. On December 28, 2012, BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint. Briefing on the motion to dismiss is ongoing and is expected to be completed during the first quarter of 2013.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption *Weinstein v. BioSante Pharmaceuticals, Inc. et al.*, naming BioSante s directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante s corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss the amended complaint in the action pending in District Court, and on January 18, 2013, the defendants filed a motion to dismiss the amended complaint in the action pending in Illinois state court. Briefing on these motions is ongoing and is expected to be completed during the first quarter of 2013.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante s operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante s operations, including its financial condition, results of operations, or cash flows.

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of

Table of Contents

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.

Risks Related to BioSante s Business

BioSante s two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that the two new LibiGel Phase III efficacy trials, if BioSante decides to pursue them, will not meet the co-primary and secondary endpoints, which could harm BioSante s business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.

BioSante s lead near term product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved product. In June 2012, BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials. This decision was based on an extensive analysis of previous efficacy data, consultation with key opinion leaders in FSD, testosterone therapy and placebo effects, as well as a meeting with the FDA. The protocol for the two new efficacy trials is in development. BioSante intends to apply for an FDA Special Protocol Assessment (SPA) agreement prior to initiating the two new efficacy trials. Currently, it is expected that the efficacy trials will include the same FDA-required efficacy endpoints as prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire.

The initiation of the two new LibiGel Phase III efficacy trials involves risk, especially since BioSante s prior LibiGel Phase III efficacy trials failed to meet the co-primary or secondary endpoints. Although the results indicated that LibiGel performed as predicted based on previous experience with testosterone products for female sexual dysfunction, the placebo response in the two efficacy trials was greater than expected; and therefore, LibiGel s results were not shown to be statistically different from placebo. No assurance can be provided that BioSante will be able to design the two new LibiGel Phase III efficacy trials to minimize sufficiently the placebo effect and meet the co-primary and secondary endpoints for the trials. In addition, BioSante can provide no assurance that it will be able to obtain an FDA SPA agreement for such trials or that BioSante will initiate or complete the trials on a timely basis, or ever. Any of these possible results could harm BioSante s business and further disappoint BioSante stockholders and cause the trading price of BioSante common stock to decrease.

Although BioSante s male testosterone gel is approved by the FDA, BioSante is uncertain as to when Teva will begin to market and sell the male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales in light of Teva s settlement agreement with AbbVie Inc.

BioSante s male testosterone gel was developed initially by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted a New Drug Application, which NDA was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, AbbVie Inc., a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/AbbVie patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

Table of Contents

Several of BioSante s products are in the clinical development stages and, depending on the product, likely will not be approved by regulatory authorities or introduced commercially for at least several years and likely more, if at all.

Several of BioSante s products are in the clinical development stages and will require further development, preclinical and clinical testing and investment prior to obtaining required regulatory approvals and commercialization in the United States and abroad. Other than Elestrin and BioSante s male testosterone gel, none of BioSante s products have been approved by the FDA or other regulatory authorities; and accordingly, none of BioSante s products have been introduced commercially and most are not expected to be for several years and likely more, if at all. BioSante cannot assure you that any of its products in clinical development will:

- be developed successfully;
- prove to be safe and effective in clinical studies;
- meet applicable regulatory standards or obtain required regulatory approvals;
- demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- be capable of being produced in commercial quantities at reasonable costs;
- obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or
- be marketed successfully or achieve market acceptance by physicians and patients.

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

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

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

To obtain regulatory approval to market many of BioSante s products, costly and lengthy human clinical trials are required, and the results of the studies and trials are highly uncertain. As part of the FDA approval process, BioSante must conduct, at its own expense or the expense of current or potential licensees or other entities, clinical trials in human subjects on each of BioSante s products. BioSante expects the number of human clinical trials that the FDA will require will vary depending on the product, the disease or condition

Table of Contents

the product is being developed to address and regulations applicable to the particular product. Depending on the stage of development, BioSante may need to perform multiple pre-clinical studies using various doses and formulations before BioSante can begin human clinical trials, which could result in delays in BioSante s ability to market its products. Furthermore, even if BioSante obtains favorable results in pre-clinical studies on animals, the results in humans may be different.

In order to receive regulatory approval for commercial sale, BioSante must demonstrate that its products are safe and effective for use in the target human population. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. BioSante faces the risk that the results of its clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. As an example, BioSante s prior two pivotal LibiGel Phase III efficacy trials did not meet the co-primary endpoints of an increase in satisfying sexual events and an increase in desire and the secondary endpoint of a decrease in distress compared to placebo even though treatment with LibiGel in BioSante s Phase II clinical trial significantly increased satisfying sexual events compared to placebo. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent BioSante from submitting for regulatory approval of its products.

Additional factors that can cause delay or termination of BioSante s human clinical trials include:

- slow subject enrollment;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- longer treatment time required to demonstrate efficacy or safety;
- new or additional trials or studies that are designed differently in order to increase the chances of demonstrating efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and
- lack of funding.

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

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

BioSante s products in development will require the submission and approval of an NDA in order to obtain required approval by the FDA to commercially market the product. The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

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

Table of Contents

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

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

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

BioSante may not achieve projected goals and objectives in the time periods that BioSante anticipates or announce publicly, which could have an adverse effect on its business and could cause the price of BioSante common stock to decline.

BioSante sets goals and objectives for, and makes public statements regarding, the timing of certain accomplishments and milestones regarding its business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the submission of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in BioSante s current clinical studies, the amount of time, effort and resources committed to its programs by BioSante and its current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving BioSante s products in development will advance or be completed in the time periods that BioSante or its strategic partners announce or expect, that BioSante or its current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that BioSante or its current and potential future strategic partners will be able to adhere to its current schedule for the achievement of key milestones under any of its development programs. If BioSante or any of its strategic partners fail to achieve one or more of these milestones as planned, BioSante s business could be affected adversely and materially and the trading price of BioSante common stock could decline. BioSante also discloses from time-to-time projected financial information, including its cash position and anticipated cash burn rate and other expenditures, for future periods. These financial projections are based on management s current expectations and may not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

If the market opportunities for BioSante s products are smaller than BioSante anticipates, then its future revenues and business may be affected adversely.

From time-to-time, BioSante discloses estimated market opportunity data for its products and products in development. Although BioSante believes it has a reasonable basis for its market opportunity estimates, BioSante estimates may prove to be incorrect. If the market opportunities for BioSante s products are smaller than BioSante anticipates, its anticipated revenues from the sales or licensure of such products will be lower than BioSante anticipates.

36

Table of Contents

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

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

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

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

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

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

Table of Contents

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

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

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

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

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which BioSante s clinical studies are conducted all have the power to stop or recommend stopping its clinical studies prior to completion. BioSante s clinical studies for its products in development may not begin as planned, may need to be amended, suspended or terminated and may not be completed on schedule, if at all. This is particularly true if BioSante no longer believes it can obtain regulatory approval for a particular product or if BioSante no longer has the financial resources to dedicate to a clinical development program for a particular product.

BioSante relies on third parties to assist it in certain aspects of its clinical studies. If these third parties do not perform as required contractually or expected, BioSante s clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.

BioSante relies on third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist it in certain aspect of its clinical studies. BioSante is responsible for confirming that BioSante s studies are conducted in accordance with applicable regulations and that each of its clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires BioSante to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. BioSante s reliance on these few third parties does not relieve it of these responsibilities. If the third parties assisting BioSante with certain aspects of its clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA s good clinical practice regulations, do not adhere to BioSante s protocols or otherwise fail to generate reliable clinical data, BioSante may need to enter into new arrangements with alternative third parties and its clinical studies may be extended, delayed or terminated or may need to be repeated, and BioSante may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, BioSante s ability to collect damages may be limited contractually.

BioSante s products will remain subject to ongoing regulatory review even if BioSante receives marketing approval. If BioSante fails to comply with continuing regulations, BioSante could lose these approvals, and the sale of any future products could be suspended.

Even if BioSante receives regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of BioSante s approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy (REMS). If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug s risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, result in more restrictive labeling than originally

Table of Contents

approved, force BioSante to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay BioSante s ability to obtain regulatory approvals in additional countries. In addition, BioSante will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

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

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

BioSante may enter into additional strategic relationships with third parties to help develop and commercialize its products in development. If BioSante does not enter into such relationships, BioSante will need to undertake development and commercialization efforts on its own, which would be costly and could delay BioSante s ability to obtain required approvals for and commercialize its future products.

A key element of BioSante s business strategy is BioSante s intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of its products. For example, BioSante has a strategic relationship with Meda with respect to Elestrin, with Teva with respect to BioSante s male testosterone gel and with Pantarhei Science with respect to The Pill Plus. BioSante currently does not have a strategic partner for LibiGel.

BioSante may enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, its products in development, including LibiGel, and any additional new products BioSante may acquire or in-license. BioSante faces significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. BioSante may not be able to negotiate additional strategic relationships on acceptable terms, or at all. BioSante is unable to predict when, if ever, it will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If BioSante is unable to negotiate additional strategic relationships for its products, BioSante may be forced to curtail the development of a particular product, reduce, delay or terminate its development program or one or more of its other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at BioSante s own expense. In

Table of Contents

addition, BioSante would then bear all the risk related to the development and commercialization of that product. If BioSante elects to increase its expenditures to fund development or commercialization activities on its own, BioSante may need to obtain additional capital, which may not be available to BioSante on acceptable terms, or at all. If BioSante does not have sufficient funds, BioSante will not be able to bring its products in development and any additional new products BioSante may acquire or in-license if they receive regulatory approvals to market and generate product revenue.

If BioSante is unable to partner with a third party and obtain assistance for the potential commercialization of its products, if approved for commercial sale, BioSante would need to establish its own sales and marketing capabilities, which involves risk.

BioSante does not have an internal sales and marketing organization and has limited experience in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing BioSante s own sales capabilities and increasing its marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if BioSante enters into arrangements with third parties to perform sales, marketing and distribution services, revenues from sales of the product or the profitability of these product revenues are likely to be lower than if BioSante markets and sells any products that BioSante develops itself.

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

- BioSante s inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put BioSante at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

BioSante s current strategic relationships and any future additional strategic relationships it may enter into involve risks with respect to the development and commercialization of its products.

A key element of BioSante s business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of BioSante s products. For example, BioSante has strategic relationships with Meda with

Table of Contents

respect to Elestrin, with Teva with respect to its male testosterone gel and with Pantarhei Science with respect to The Pill Plus.

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

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

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

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

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

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

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

- strategic partners may experience financial difficulties;

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

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

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

Although BioSante maintains the right to receive sales-based milestones of up to $140 million, its ability to receive these milestones is dependent upon Meda s ability to market and sell Elestrin, and based on Elestrin sales to date, BioSante believes it is unlikely that it will receive any sales-based milestone payments from Meda in the foreseeable future, or at all.

Meda (which acquired Jazz Pharmaceuticals, Inc. s women s health business, and which in turn had acquired BioSante s original licensee, Azur Pharma International II Limited (Azur)), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante continues to recognize certain royalty revenue from sales of

Table of Contents

Elestrin; however, such revenue is offset by its corresponding obligation to pay royalties to Antares, from whom BioSante licensed the technology underlying its Elestrin product. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda if Elestrin reaches certain predefined sales per calendar year. BioSante can provide no assurance that Meda will be successful in marketing Elestrin, Elestrin will be accepted widely in the marketplace or that Meda will remain focused on the commercialization of Elestrin, especially if Meda does not experience significant Elestrin sales. Based on current sales of Elestrin, BioSante believes it is unlikely that BioSante will receive any sales-based milestone payments from Meda in the near term, if at all.

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

The commercial success of BioSante s products in development, if BioSante receives the required FDA or other regulatory approvals, and the commercial success of its male testosterone gel, which is FDA approved, but not yet commercially launched, are dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products, if approved for commercial sale with respect to BioSante s products in development, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials with respect to BioSante s products in development;
- the existence, prevalence and severity of any side effects;
- the availability of competitive or alternative treatments and potential or perceived advantages or disadvantages compared to competitive or alternative treatments;
- the timing of market entry relative to competitive treatments;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of BioSante s products by third-party payors and governmental and other payors; and

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

Some of these factors are not within BioSante s control, especially if BioSante has transferred all of the marketing rights associated with the product, as BioSante has with the U.S. marketing rights to Elestrin to Meda, and the U.S. development and marketing rights to its male testosterone gel to Teva. BioSante s products may not achieve expected levels of market acceptance.

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

Table of Contents

Even if BioSante or its strategic partners successfully develop, obtain required regulatory approvals and commercialize any of its products under development, BioSante faces uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could affect adversely the commercial success of BioSante s products.

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

- private health insurers;
- health maintenance organizations;
- pharmacy benefit management companies;
- government health administration authorities; and
- other healthcare-related organizations.

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

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

of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for BioSante s products, if approved, is substantially less that BioSante expects in the future, its business could be affected materially and adversely.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent BioSante from maintaining prices for its products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that BioSante s approved products are marketed outside of the

Table of Contents

United States, foreign government pricing controls and other regulations may prevent BioSante from maintaining prices for such products that are sufficient for BioSante to realize profits and may otherwise significantly harm its business, financial condition and operating results.

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

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

To the extent that BioSante or its licensees enter into manufacturing arrangements with third parties, BioSante and such licensees will depend upon these third parties to perform its obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond BioSante s control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for BioSante.

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

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

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

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

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

Table of Contents

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

If BioSante reallocates its resources to other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante may not be successful in developing such products and technologies and BioSante will be subject to all the risks and uncertainties associated with research and development of products and technologies.

BioSante has explored the possibility of reallocating its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license. It BioSante decides to reallocate its resources towards other products and technologies in its current product portfolio or any additional new products and technologies that BioSante may acquire or in-license, BioSante cannot guarantee that any such allocation would result in the identification and successful development of one or more approved and commercially viable products. The development of products and technologies is subject to a number of risks and uncertainties, including:

- the time, costs and uncertainty associated with the clinical testing required to demonstrate the safety and effectiveness of BioSante s products and obtain regulatory approvals;
- the ability to raise sufficient funds to fund the research and development of BioSante s products;
- the ability to find third party strategic partners to assist or share in the costs of product development, and potential dependence on such strategic partners, to the extent BioSante relies on them for future sales, marketing or distribution;
- the ability to protect the intellectual property rights associated with BioSante s products;
- litigation;
- competition;
- ability to comply with ongoing regulatory requirements;
- government restrictions on the pricing and profitability of products in the United States and elsewhere; and

- the extent to which third-party payers, including government agencies, private health care insurers and other health care payers, such as health maintenance organizations, and self-insured employee plans, will cover and pay for newly approved therapies.

BioSante has very limited staffing and is dependent upon key employees and the limited use of independent contractors, the loss of some of which could affect adversely its operations.

BioSante s success is dependent upon the efforts of a relatively small management team and staff. BioSante also has engaged independent contractors from time-to-time on an as needed, project by project, basis. During 2012, in order to reduce BioSante s operating expenses, BioSante terminated all of its independent contractor arrangements and reduced its total employee headcount. Such reductions in force, combined with BioSante s future business prospects and financial condition, put BioSante at risk of losing key personnel who BioSante will need going forward to implement its business strategies. BioSante has no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. BioSante has employment arrangements in place with its executive and other officers, but none of these executive and other officers is bound legally to remain employed with BioSante for any specific term. BioSante does not have key man life insurance policies covering its executive and other officers or any of its

Table of Contents

other employees. If key individuals leave BioSante, its business could be affected adversely if suitable replacement personnel are not recruited quickly. There is competition for qualified personnel in the biotechnology and biopharmaceutical industry in the suburban Chicago, Illinois area in all functional areas, which makes it difficult to retain and attract the qualified personnel necessary for the development and growth of BioSante s business. BioSante s financial condition and recent reductions in force and expense reductions may make it difficult for BioSante to retain current personnel and attract qualified employees and independent contractors in the future.

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

BioSante faces an inherent risk of product liability as a result of the clinical testing of its products in development and the commercial sale of its products that have been or will be approved for commercial sale. BioSante may be held liable if any product it develops causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for BioSante s products, injury to its reputation, withdrawal of clinical studies, costs to defend litigation, substantial monetary awards to clinical study participants or patients, loss of revenue and the inability to commercialize any products that BioSante develops.

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires BioSante s management to assess the effectiveness of its internal control over financial reporting and to provide a report by its registered independent public accounting firm addressing the effectiveness of BioSante s internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If BioSante is unable to assert that its internal control over financial reporting is effective or if BioSante s registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or identifies one or more material weaknesses in BioSante s internal control over financial reporting, BioSante could lose investor

confidence in the accuracy and completeness of its financial reports, which in turn could have an adverse effect

Table of Contents

on the trading price of BioSante common stock. If BioSante fails to maintain the adequacy of its internal controls, BioSante may not be able to ensure that it can conclude on an ongoing basis that BioSante has effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal control over financial reporting could have an adverse effect on the trading price of BioSante common stock.

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

BioSante is subject to changing rules and regulations of federal and state governments as well as the stock exchange on which BioSante common stock is listed. These entities, including the SEC and The NASDAQ Stock Market, continue to issue new requirements and regulations in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC and The NASDAQ Stock Market to adopt additional rules and regulations in these areas. BioSante s efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management s time from its other business activities.

BioSante s operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

BioSante s principal executive office and its only business location is in Lincolnshire, Illinois, which is a suburb of Chicago. Natural disasters or other catastrophic events could disrupt BioSante s operations or those of its strategic partners, contractors and vendors. Even though BioSante believes it carries commercially reasonable business interruption and liability insurance, and its contractors may carry liability insurance that protect BioSante in certain events, BioSante might suffer losses as a result of business interruptions that exceed the coverage available under its and its contractors insurance policies or for which it or its contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on BioSante s operations and financial results, and could delay its efforts to identify and execute any strategic opportunities.

Risks Related to BioSante s Industry

Because BioSante s industry is very competitive, BioSante may not succeed in bringing certain of its products to market and any products BioSante or its strategic partners introduce commercially may not be successful.

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

47

Table of Contents

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

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

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

Despite BioSante s efforts at compliance, there is no guarantee that BioSante may not be deemed to be deficient in some manner in the future. If BioSante was deemed to be deficient in any significant way, its business, financial position and results of operations could be materially affected and the trading price of BioSante common stock could decline.

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

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

Risks Related to BioSante s Intellectual Property

BioSante licenses rights to the technology underlying LibiGel and many of its other products and technologies from third parties. The loss of these rights, including in particular, BioSante s rights underlying LibiGel, could have an adverse effect on its business and future prospects and could cause the trading price of BioSante common stock to decline.

BioSante licenses rights to certain technology underlying its gel products, including LibiGel, but not its male testosterone gel, from Antares Pharma, Inc. and The Pill Plus from Wake Forest University Health Sciences. BioSante may lose its rights to these technologies if BioSante breaches its obligations under the

Table of Contents

license agreements. Although BioSante intends to use commercially reasonable efforts to meet these obligations and to cause its sublicensees to meet these obligations, if BioSante violates or fails to perform any term or covenant of the license agreements, the other party to these agreements under certain circumstances may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve BioSante of its obligation to pay any royalty or license fees owed at the time of termination. In addition, it is possible that the licensors of the technology licensed by BioSante will not continue to maintain certain patents and other intellectual property rights, breach the agreements or take actions inconsistent with BioSante s license rights, which could harm BioSante s business.

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

BioSante has licensed some of its products to third parties, including Meda, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and Valeant Pharmaceuticals. All of these parties, except for Meda, have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products, except for Valeant Pharmaceuticals, which has not agreed to be responsible for manufacturing the products. In addition, in the future BioSante may enter into additional similar license agreements. BioSante s products that it has licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. BioSante s current and future licensees may have different and, sometimes, competing priorities. BioSante cannot assure you that its strategic partners or any future third party to whom it may license its products will remain focused on the development and commercialization of its partnered products or will not otherwise breach the terms of its agreements with them, especially since these third parties also may compete with BioSante with respect to some of its products. Any breach of BioSante s agreements by its strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered products in these agreements if BioSante is unable to license the products to another party on substantially the same or better terms or continue the development and future commercialization of the products itself. As an example, BioSante s male testosterone gel was developed initially by BioSante, and then licensed to Teva for late stage clinical development and commercialization. Teva submitted an NDA for BioSante s male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva s NDA submission, in April 2011, AbbVie Inc., a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/AbbVie patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. In light of the settlement agreement, BioSante is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if BioSante would begin to receive royalties from such sales.

If BioSante is unable to protect its proprietary technology, it may not be able to compete as effectively.

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

Table of Contents

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

- BioSante does not know whether its licensor s patent applications will result in issued patents.

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

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

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

- BioSante also may support and collaborate in research conducted by government organizations or universities. BioSante cannot guarantee that it will be able to acquire any rights to technology or products derived from these collaborations. If BioSante does not obtain required licenses or rights, it could encounter delays in product development while it attempts to design around other patents or it may be prohibited from developing, manufacturing or selling products requiring these licenses. There also is a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

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

Table of Contents

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

The patents for BioSante s commercialized products and products in development have varying expiration dates and, when these patents expire, BioSante may be subject to increased competition and it may not be able to recover its development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which BioSante licenses from Antares Pharma are scheduled to expire in June 2022 and the U.S. patent covering the method of use of LibiGel for treating FSD and HSDD will expire in December 2028. Although BioSante has filed additional U.S. patent applications covering LibiGel, it can provide no assurance that such applications will be granted and that the patent applications will issue. In addition to patents, BioSante may receive three years of marketing exclusivity in the United States for LibiGel under the Hatch-Waxman Act and an additional six months of pediatric exclusivity, if BioSante decides to pursue regulatory approval for LibiGel. Depending upon if and when BioSante receives regulatory approval for LibiGel and its other products in development and the then expiration dates of the patents underlying LibiGel and such other products, BioSante may not have sufficient time to recover its development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

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

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

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

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt BioSante s potential gross margins. In addition, BioSante cannot be sure that the necessary licenses would be available to BioSante on satisfactory terms, or that it could redesign its products or processes to avoid patent infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent BioSante from developing, manufacturing and selling some of its products, which could harm its business, financial condition and operating results. With respect to products which BioSante has licensed to others, BioSante s licensees may be responsible for the defense of any patent infringement claims, which would result in its dependence upon them to defend its intellectual property rights.

Table of Contents

Risks Related to BioSante Common Stock

The trading price of BioSante common stock has been volatile, and your investment in BioSante common stock or convertible senior notes could decline in value.

The price of BioSante common stock has fluctuated in the past and it is likely that the price of BioSante common stock will continue to fluctuate in the future. Since January 1, 2011 through December 31, 2012, the sale price of BioSante common stock ranged from $1.08 per share to $24.12 per share. These prices reflect the one-for-six reverse stock split of BioSante common stock that was effective at the close of business on June 1, 2012. The securities of small capitalization, biopharmaceutical companies, including BioSante, from time-to- time experience significant price fluctuations, often unrelated to the operating performance of these companies. In addition, as BioSante s convertible senior notes are convertible into shares of BioSante common stock, volatility or depressed prices of BioSante common stock could have a similar effect on the trading price of the notes. Interest rate fluctuations also can affect the price of BioSante s convertible senior notes. In particular, the market price of BioSante common stock and its convertible senior notes may fluctuate significantly due to a variety of factors, including:

- general stock market and general economic conditions in the United States and abroad, not directly related to BioSante or its business;

- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to BioSante s products in development or its competitors products;

- actual or anticipated results of BioSante s clinical studies or those of its competitors;

- changes in anticipated or actual timing of BioSante s development programs, including delays or cancellations of clinical studies for its products;

- announcements of technological innovations or new products by BioSante or its competitors;

- announcements by licensors or licensees of BioSante s technology;

- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;

- developments concerning BioSante s efforts to identify and implement strategic opportunities and the terms and timing of any resulting transactions;

- public concern as to the safety or efficacy of or market acceptance of products developed by BioSante or its competitors;

- BioSante s cash and cash equivalents and its need and ability to obtain additional financing;

- equity sales by BioSante to fund its operations or restructure its outstanding convertible senior notes;

- changes in laws or regulations applicable to BioSante s products;

- the resolution of BioSante s pending purported class action and shareholder derivative litigation;

- developments or disputes concerning patents or other proprietary rights;

Table of Contents

- period-to-period fluctuations in BioSante s financial results, including its cash and cash equivalents, operating expenses, cash burn rate or revenues;

- loss of key management;

- common stock sales and purchases in the public market by one or more of BioSante s larger stockholders, officers or directors;

- reports issued by securities analysts regarding BioSante common stock and articles published regarding its business and/or products;

- changes in the market valuations of other life science or biotechnology companies; and

- other financial announcements, including delisting of BioSante common stock from The NASDAQ Global Market, review of any of its filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in its filings with the SEC or its failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this report or in subsequent reports BioSante files with or submits to the SEC from time to time could have a material and adverse impact on the market price of BioSante common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. BioSante currently is subject to such litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management s attention and resources, which could harm BioSante s business and financial condition, as well as the market price of BioSante common stock.

Provisions in BioSante s charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to BioSante stockholders.

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

- authorizing the issuance of blank check preferred shares that could be issued by the BioSante board of directors to increase the number of outstanding shares and thwart a takeover attempt;

- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

- advance notice provisions in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by BioSante stockholders to bring business to be considered by its stockholders at a meeting or replace its board of directors.

BioSante does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in BioSante common stock must come from increases in the fair market value and trading price of BioSante common stock.

BioSante does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in BioSante common stock must come from increases in the fair market value and trading price of BioSante common stock.

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

BioSante s principal executive office is located in a leased facility in Lincolnshire, Illinois, where BioSante leases approximately 20,000 square feet of office space for approximately $21,000 per month. BioSante s lease for this space expires in February 2014. Management of BioSante considers its leased properties suitable and adequate for its current and foreseeable needs.

ITEM 3. LEGAL PROCEEDINGS

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming BioSante and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of BioSante s disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of BioSante s securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased BioSante s securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. BioSante believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. On December 28, 2012, BioSante and Mr. Simes filed motions to dismiss the consolidated amended complaint. Briefing on the motion to dismiss is ongoing and is expected to be completed during the first quarter of 2013.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption *Weinstein v. BioSante Pharmaceuticals, Inc. et al*., naming BioSante s directors as defendants and BioSante as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in BioSante s corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012, the plaintiffs filed their consolidated amended complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 11, 2013, the defendants filed a motion to dismiss the amended complaint in the action pending in District Court, and on January 18, 2013, the defendants filed a motion to dismiss the amended complaint in the action pending in Illinois state court. Briefing on these motions is ongoing and is expected to be completed during the first quarter of 2013.

The lawsuits are in their early stages; and, therefore, BioSante is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on BioSante s operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on BioSante s operations, including its financial condition, results of operations, or cash flows.

Table of Contents

BioSante is not involved in any other legal actions, however, from time to time may be subject to various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of its business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Price

BioSante common stock is listed for trading on The NASDAQ Global Market, under the symbol BPAX. The following table sets forth the high and low daily sale prices for BioSante common stock, as reported by The NASDAQ Global Market, for each calendar quarter during 2012 and 2011.

2012	**High**	**Low**
First Quarter	$ 7.38	$ 2.64
Second Quarter	$ 4.56	$ 2.00
Third Quarter	$ 2.62	$ 1.21
Fourth Quarter	$ 1.97	$ 1.08

2011	**High**	**Low**
First Quarter	$ 15.24	$ 9.72
Second Quarter	$ 19.20	$ 11.58
Third Quarter	$ 24.12	$ 12.12
Fourth Quarter	$ 16.56	$ 2.28

Number of Record Holders; Dividends

As of February 15, 2013, there were 453 record holders of BioSante common stock and six record holders of BioSante class C stock. To date, BioSante has not declared or paid any cash dividends on BioSante common stock and BioSante class C stock is not eligible to receive dividends.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2012, BioSante did not issue or sell any equity securities without registration under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

BioSante did not purchase any shares of its common stock or other equity securities of BioSante during the fourth quarter ended December 31, 2012. The Board of Directors has not authorized any repurchase plan or program for the purchase of shares of BioSante common stock or other securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

Table of Contents

Stock Performance Graph

The following graph compares the annual cumulative total stockholder return on BioSante common stock from December 31, 2007 until December 31, 2012, with the annual cumulative total return over the same period of The NASDAQ Stock Market (U.S.) Index and Russell 3000 Index.

The comparison assumes the investment of $100 in each of BioSante common stock, The NASDAQ Stock Market (U.S.) Index and Russell 3000 Index on December 31, 2007, and the reinvestment of all dividends.

The foregoing Stock Performance Graph shall not be deemed to be filed with the Securities and Exchange Commission or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended. Notwithstanding anything to the contrary set forth in any of BioSante s previous filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate future filings, including this annual report on Form 10-K, in whole or in part, the foregoing Stock Performance Graph shall not be incorporated by reference into any such filings.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial information has been derived from BioSante s audited financial statements. The information below is not necessarily indicative of results of future operations, and should be read together with Part II. Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements and related notes included in Part II. Item 8. Financial Statements and Supplementary Data of this report in order to fully understand factors that may affect the comparability of the information presented below:

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 2,301	$ 435	$ 2,474	$ 1,258	$ 3,781
Expenses					
Research and development	16,889	44,182	39,706	13,681	15,790
General and administration	8,230	6,982	5,940	5,374	5,125
Acquired in-process research and development				9,000	
Excess consideration paid over fair value				20,192	
Licensing expense	95	50	269	300	836
Depreciation and amortization	259	148	168	137	43
Total expenses	25,473	51,362	46,083	48,684	21,794
Other (expense) income Convertible note fair value adjustment	(4,328)	(23)	(1,871)	33	
Other expense Investment impairment charge			(286)		
Other interest (expense) income	(340)	(674)	(675)	(135)	588
Other income		15	245		
Income tax benefit	122				
Net loss	$ (27,718)	$ (51,609)	$ (46,196)	$ (47,528)	$ (17,425)
Basic and diluted net loss per common share(1)	$ (1.27)	$ (3.15)	$ (4.21)	$ (8.40)	$ (3.83)
Weighted average number of common shares and common equivalent shares outstanding(1)	21,758	16,398	10,985	5,659	4,551

	As of December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 34,794	$ 57,225	$ 38,155	$ 29,858	$ 14,787
Total assets	38,769	62,380	44,767	36,437	17,679
Total current liabilities (includes short-term convertible senior notes in 2010 and 2012)	10,594	7,228	8,183	3,930	3,853
Convertible senior notes, total long-term		17,337	17,436	16,676	
Stockholders equity	28,176	37,815	19,147	15,830	13,826

(1) All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Table of Contents

ITEM 7. 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 BioSante s financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings Part I. Item 1. Business Forward-Looking Statements and Part I. Item 1A. Risk Factors of this report. The following discussion of BioSante s results of operations and financial condition should be read in conjunction with BioSante s financial statements and the related notes thereto included elsewhere in this report. This Management s Discussion and Analysis is organized in the following major sections:

- **Business Overview**. This section provides a brief overview description of BioSante s business, focusing in particular on developments during the most recent fiscal year.

- **Summary of 2012 Financial Results and Outlook for 2013**. This section provides a brief summary of BioSante s financial results and financial condition for 2012 and BioSante s outlook for 2013.

- **Critical Accounting Policies and Estimates**. This section discusses the accounting estimates that are considered important to BioSante s financial condition and results of operations and require BioSante to exercise subjective or complex judgments in their application. All of BioSante s significant accounting policies, including BioSante s critical accounting estimates, are summarized in Note 2 to BioSante s financial statements.

- **Results of Operations**. This section provides BioSante s analysis of the significant line items in BioSante s statements of operations.

- **Liquidity and Capital Resources**. This section provides an analysis of BioSante s liquidity and cash flows and a discussion of BioSante s outstanding indebtedness and commitments.

- **Recent Accounting Pronouncements**. This section discusses recently issued accounting pronouncements that have had or may affect BioSante s results of operations and financial condition.

Overview

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. BioSante s corporate strategy is to develop high value medically-needed pharmaceutical products. As a part of its corporate

strategy, BioSante seeks to implement strategic alternatives with respect to its products and 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, BioSante may engage in discussions with third parties regarding the licensure, sale or acquisition of its products and technologies or a merger or sale of BioSante, with the goal of maximizing stockholder value.

On October 3, 2012, BioSante entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. BioSante believes that the merger of the two companies will be able to create more value than BioSante could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. Although the exact timing of completion of the merger cannot be predicted with certainty, each company has scheduled a

Table of Contents

special meeting of its stockholders for March 15, 2013 to consider and vote on certain matters in connection with the merger. If the merger is approved by BioSante s and ANI s stockholders and the other conditions to closing are satisfied, it is anticipated that the merger will be completed as soon as reasonably practicable after the special meetings of stockholders. The proposed merger with ANI is described in more detail below under the heading Proposed Merger with ANI and elsewhere in this report.

BioSante s products, either approved or in clinical development, include:

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

- Male testosterone gel once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva).

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

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of hot flashes associated with menopause and marketed in the U.S. by Meda, BioSante s licensee.

Proposed Merger with ANI

Agreement and Plan of Merger

On October 3, 2012, BioSante entered into an agreement and plan of merger with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The merger agreement provides that, subject to the terms and conditions set forth in the merger agreement, ANI will merge with and into BioSante, with BioSante continuing as the surviving company. BioSante believes that the merger of the two companies will be able to create more value than BioSante could achieve individually. The combined company that will result from the merger will be a fully integrated specialty branded and generic pharmaceutical company focused on developing, manufacturing and marketing branded and generic prescription pharmaceuticals. Although the exact timing of completion of the merger cannot be predicted with certainty, each company has scheduled a special meeting of its stockholders for March 15, 2013 to consider and vote on certain matters in connection with the merger. If the merger is approved by BioSante s and ANI s stockholders and the other conditions to closing are satisfied, it is anticipated that the merger will be completed as soon as reasonably practicable after the special meetings of stockholders.

At the effective time of the merger, each outstanding share of capital stock of ANI will be converted into the right to receive that number of shares of BioSante common stock, if any, as determined pursuant to the exchange ratios described in the merger agreement and the provisions of ANI s certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the combined company after the merger. No fractional shares of BioSante common stock will be issued in connection with the merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following completion of the transactions contemplated by the merger agreement, the current ANI stockholders are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current BioSante stockholders are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming BioSante s net cash as of the determination date is $18.0 million. The exchange ratios are subject to potential adjustment as described in the merger agreement depending upon the amount of BioSante s net cash, as defined in and as calculated pursuant to the merger agreement and

Table of Contents

generally consisting of BioSante s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current BioSante stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

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

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

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

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

Table of Contents

Voting Agreements

Concurrently and in connection with the execution of the merger agreement, certain ANI stockholders, who collectively held approximately 90 percent of the outstanding shares of ANI common stock on an as-converted basis and approximately 86 percent of the outstanding shares of ANI series D preferred stock as of October 3, 2012, entered into voting agreements with BioSante, pursuant to which each ANI stockholder agreed to vote its shares of ANI capital stock in favor of the merger, the merger agreement and the transactions contemplated by the merger agreement and against certain transactions or certain actions that would delay, prevent or nullify the merger or the transaction contemplated by the merger agreement. In addition, one of the ANI stockholders, who held approximately 57 percent of the outstanding shares of ANI capital stock as of October 3, 2012, has agreed to vote in favor of the election of the two directors designated by BioSante at the first annual meeting of BioSante stockholders following completion of the merger.

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

Lock-Up Agreements

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

Contingent Value Rights Agreement

BioSante has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to holders of BioSante common stock as of immediately prior to completion of the merger. BioSante expects that one CVR will be issued for each share of BioSante common stock outstanding as of the record date, which has been set as March 15, 2013. However, the CVRs will not be certificated and will not be attached to the shares of BioSante common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event BioSante receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to BioSante s LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between BioSante and its transfer agent, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to BioSante s LibiGel program, as determined pursuant to the CVR agreement, and will not exceed $40 million in the aggregate.

Business Overview

BioSante s lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, BioSante has focused its efforts on two Phase III LibiGel efficacy trials and its LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, BioSante announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and

Table of Contents

decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel s results were not shown to be statistically different from the placebo.

Beginning in December 2011, BioSante analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 BioSante announced a plan to initiate two new LibiGel Phase III efficacy trials.

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

BioSante is continuing to develop a protocol for the two new LibiGel efficacy trials and plans to seek an FDA SPA agreement covering aspects of the two new efficacy trials.

Elestrin was BioSante s first FDA approved product and now is one of BioSante s two FDA approved products. Meda (which acquired Jazz Pharmaceuticals, Inc. s women s health business and which in turn had acquired Azur Pharma International II Limited (Azur), BioSante s prior licensee), is marketing Elestrin in the U.S. In December 2009, BioSante entered into an amendment to its original licensing agreement with Azur pursuant to which BioSante received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to BioSante related to sales of Elestrin. BioSante maintains the right to receive up to $140 million in sales-based milestone payments from Meda if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

BioSante s male testosterone gel is its second FDA approved product. This product was developed initially by BioSante, and then licensed by BioSante to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, AbbVie Inc., a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been disclosed publicly. No launch date for this product has been announced by Teva.

Under BioSante s development and license agreement with Teva, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, which was paid to BioSante in December 2002, and an obligation by Teva to pay BioSante certain milestones and royalties on sales of the product in exchange for rights to develop and market the product, as described in more

detail below. Teva is entitled to deduct the amount of any legal expenses

Table of Contents

incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product. The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. BioSante may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

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

BioSante licenses the technology underlying certain of its gel products, including LibiGel and Elestrin, but not the male testosterone gel, from Antares Pharma, Inc. The patents covering the formulations used in the gel products covered under the license agreement are expected to expire in 2022, although with respect to LibiGel, a new U.S. patent covering the method of use of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. BioSante s license agreement with Antares requires BioSante to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products BioSante or its licensees sell incorporating the licensed technology. Specifically, BioSante is obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by BioSante or a licensee. Since entering into the agreement and through December 31, 2012, BioSante has paid Antares an upfront payment of $1.0 million, an aggregate of $5.1 million in milestone payments and an aggregate of $100,000 in royalties. Aggregate potential milestone payments to be paid by BioSante to Antares under the agreement include 25 percent of the potential $140 million in sales-based milestone payments, or $35 million from Meda if Elestrin reaches certain predefined sales per calendar year; although, based on current sales levels, BioSante believes its receipt of such payments unlikely in the near term, if at all.

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

Table of Contents

BioSante determines that it is not economically viable to continue development or marketing of a product in a territory.

On January 31, 2013, BioSante entered into an asset purchase agreement with Aduro BioTech, Inc. pursuant to which BioSante sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

Summary of 2012 Financial Results and Outlook for 2013

Substantially all of BioSante s revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. BioSante s business operations to date have consisted primarily of licensing and research and development activities and if BioSante does not complete its proposed merger with ANI, BioSante would expect this to continue for the immediate future. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, Inc., to fund its ongoing business operations and short-term liquidity needs.

As of December 31, 2012, BioSante had $34.8 million of cash and cash equivalents and had outstanding $8.3 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed, BioSante expects its cash and cash equivalents as of December 31, 2012 to meet its liquidity requirements through at least its anticipated closing of the merger, including the requirement under the merger agreement to have at least $17 million of net cash, as defined in and as calculated under the merger agreement, available upon the closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone business, a sale of the company, liquidation of the company or other strategic transaction. BioSante s liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash equivalents as of December 31, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

BioSante incurred expenses of $16.9 million on research and development activities during the year ended December 31, 2012, which is a 62 percent decrease compared to 2011, primarily as a result of the conclusion of the two LibiGel Phase III efficacy trials at the end of 2011. BioSante anticipates that its research and development expenses for 2013 will be approximately $2.5 million and will consist primarily of expenses associated with the conclusion of the safety study. This estimate assumes no further development of LibiGel and completion of the merger with ANI, but does not include research and development expenses to be incurred by the combined company after completion of the merger.

General and administrative expenses for the year ended December 31, 2012 increased 18 percent compared to 2011 due primarily to an increase in professional fees and other administrative expenses. BioSante s general and administrative expenses generally fluctuate from year-to-year and quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

BioSante recognized an income tax benefit based on the receipt of an income tax credit for the year ended December 31, 2012 of $121,791 compared to the recognition of no income tax benefit or expense for the year ended December 31, 2011. The income tax benefit was a result of an election to accelerate research and

Table of Contents

development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended.

BioSante recognized a net loss for the year ended December 31, 2012 of $27.7 million compared to a net loss of $51.6 million for the year ended December 31, 2011. This decrease was primarily a result of the conclusion of the prior two LibiGel Phase III efficacy trials at the end of 2011 and in September 2012 the conclusion of the LibiGel Phase III safety study, and was offset in part by an increase in the non-cash fair value adjustment relating to the cancellation of $12.5 million in aggregate principal amount of BioSante s convertible senior notes. BioSante recognized a net loss per share for the year ended December 31, 2012 of $1.27 compared to a net loss per share of $3.15 for the year ended December 31, 2011. This decrease in net loss per share was the result of the significantly higher weighted average number of shares outstanding, partially offset by the lower net loss described above.

Critical Accounting Policies and Estimates

BioSante s significant accounting policies are described in Note 2 to BioSante s financial statements included under the heading Part II. Item 8. Financial Statements and Supplementary Data of this report. The discussion and analysis of BioSante s financial statements and results of operations are based upon BioSante s financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The discussion and analysis of BioSante s financial statements and results of operations are based upon BioSante s financial statements, which have been prepared in accordance with GAAP. The preparation of BioSante s 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 SEC 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 BioSante to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, BioSante has identified the critical accounting policy described below. Although BioSante believes that its estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

Accounting for Convertible Senior Notes Assumed in Connection with the Cell Genesys Acquisition

On October 14, 2009, BioSante completed a legal merger with Cell Genesys, as a result of which BioSante acquired all of the assets and liabilities of Cell Genesys. Concurrently with the merger, the common stock of Cell Genesys was converted into common stock of BioSante, and Cell Genesys ceased to exist. The primary reason BioSante merged with Cell Genesys was BioSante s need at that time for additional funding to continue its then Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for BioSante to access capital prior to and at the time the merger agreement was entered into by BioSante and Cell Genesys in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been BioSante s primary method for raising additional financing. BioSante has accounted for this transaction with Cell Genesys under GAAP as an acquisition of the net assets of Cell Genesys, whereby BioSante has recorded the individual assets and liabilities of Cell Genesys as of the completion of the merger based on their estimated fair values. As Cell Genesys had ceased operations, the acquisition was not considered to be a business combination, and the allocation of the purchase price did not result in recognition of goodwill. As a result of this treatment, during the fourth quarter of 2009, BioSante recognized a non-cash expense of approximately $20.2 million representing the excess of the consideration and costs of the transaction over the fair value of assets and liabilities received.

BioSante assumed $22.0 million in aggregate principal amount of convertible senior notes in connection with the Cell Genesys acquisition, including $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011, which were repaid prior to the November 1, 2011 maturity date, and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013,

Table of Contents

$8.3 million in aggregate principal amount of which were outstanding as of December 31, 2012. As of December 31, 2012, $8.3 million in aggregate principal amount of convertible senior notes remained outstanding.

BioSante elected to apply the fair value option to the debt at the time of the acquisition, with recognition of subsequent changes in the fair value of the convertible senior notes recognized in BioSante s statements of operations immediately. As a result of this election, BioSante periodically must estimate the fair value of its convertible senior notes, which requires BioSante to make certain judgments and estimates about appropriate discount rates, BioSante s creditworthiness, and assumptions regarding potential conversion of the notes. BioSante believes that its estimates and assumptions are reasonable; however, changes in these estimates and assumptions could result in significant differences in the carrying value of the convertible senior notes. The most sensitive of these assumptions is the discount rate used in the fair value estimate, which was 19.4 percent at December 31, 2012, and is based on the median yield to maturity of Ca and Caa3 rated debt instruments as of December 31, 2012. A one percentage point increase or decrease in the discount rate would cause the recorded value of the convertible senior notes to decrease or increase by approximately $22,000.

Results of Operations

The following table sets forth, for the periods indicated, BioSante s results of operations.

	Year Ended December 31,		
	2012	**2011**	**2010**
Revenue	$ 2,300,736	$ 435,160	$ 2,474,237
Expenses			
Research and development	16,888,849	44,182,260	39,705,502
General and administrative	8,229,523	6,981,490	5,940,360
Licensing expense	95,000	50,000	268,750
Total expenses	25,472,318	51,361,990	46,082,598
Other (expense) income Convertible note fair value adjustment	(4,328,468)	(23,427)	(1,870,916)
Other expense Investment impairment charge			(286,000)
Other expense Interest expense	(348,019)	(681,573)	(688,083)
Other income		15,000	244,479
Other income Interest income	8,539	8,326	12,665
Income tax benefit	121,791		
Net loss	$ (27,717,739)	$ (51,608,504)	$ (46,196,216)
Net loss per common share (basic and diluted)	$ (1.27)	$ (3.15)	$ (4.21)
Weighted average number of common shares and common equivalent shares outstanding	21,757,906	16,397,618	10,985,291

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenue recognized during 2012 consisted primarily of licensing revenue from Teva under the terms of the license agreement amendment executed in October 2012 pursuant to which Teva made a $1.0 million payment to BioSante upon signing of the amendment in October 2012 and a $750,000 milestone payment in December 2012. Additionally, BioSante recognized royalty revenue from Meda for Elestrin sales, which royalty revenue is offset by BioSante s corresponding obligation to pay Antares royalties representing the same amount. BioSante s corresponding obligation to pay Antares a portion of the royalties received, which equaled $550,736 during 2012 and $335,160 during 2011, is

recorded within general and administrative expenses in BioSante s statements of operations. In addition, during 2011, BioSante recognized $100,000 in revenue from its receipt of an upfront non-refundable licensing fee from The John P. Hussman Foundation associated with BioSante s former GVAX cancer vaccine portfolio.

Table of Contents

Research and development expenses for 2012 decreased 62 percent compared to 2011 primarily as a result of the completion of BioSante s two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012.

General and administrative expenses for 2012 increased 18 percent compared to 2011 primarily as a result of an increase in professional fees and other administrative expenses primarily due to BioSante s efforts to seek strategic alternatives, including in particular expenses incurred in connection with BioSante s pending merger with ANI.

The fair value adjustment on BioSante s convertible senior notes for 2012 was $4.3 million compared to $23,427 for 2011. The increase in the expense for 2012 was primarily as a result of $3.2 million non-cash fair value adjustment (expense) recorded upon cancellation of $12.5 million in aggregate principal amount of BioSante s convertible senior notes in February and July 2012 in exchange for the issuance of 3,652,125 shares of BioSante common stock. The convertible fair value adjustment for 2011 increased the recorded liability and corresponding expense by $23,427 and included BioSante s 3.125% convertible senior notes due November 1, 2011 and 3.125% convertible senior notes due May 1, 2013.

Interest expense was $348,019 and $681,573 for 2012 and 2011, respectively, as a result of BioSante s convertible senior notes. Interest expense decreased during 2012 as a result of the repayment of BioSante s 3.125% convertible senior notes due November 1, 2011 during the fourth quarter of 2011 and the cancellation of $12.5 million in aggregate principal amount of BioSante s 3.125% convertible senior notes due May 1, 2013, including accrued and unpaid interest, during the first and third quarters of 2012 in exchange for the issuance of 3,652,125 shares of BioSante common stock.

Interest income increased $213 for 2012 compared to 2011 as a result of higher average interest rates despite lower average cash balances during 2012.

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

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenue decreased $2.0 million, or 82.4 percent in 2011 compared to 2010, primarily as a result of the recognition of royalty revenue during 2010 resulting primarily from the receipt of $2.3 million in non-refundable upfront payments from Azur, partially offset by BioSante s receipt during 2011 of $100,000 in a non-refundable upfront licensing fee from The John P. Hussman Foundation relating to an exclusive worldwide license of BioSante s former melanoma vaccine. The $2.3 million payment from Azur in 2010 was in exchange for the elimination of all remaining future royalty payments that BioSante is not required to pay Antares under a separate agreement and certain future milestone payments due BioSante under the terms of the original license, as permitted by the amendment to BioSante s license agreement signed in December 2009. The only other revenue recognized during 2011 consisted of royalty revenue from Jazz Pharmaceuticals for Elestrin sales, which royalty revenue is offset by BioSante s corresponding obligation to pay Antares royalties representing the same amount.

Research and development expenses for 2011 increased 11.3 percent compared to 2010 primarily as a result of the conduct of the three LibiGel Phase III clinical studies, particularly the safety study.

General and administrative expenses for 2011 increased 17.5 percent compared to 2010 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses during 2011.

Table of Contents

The fair value adjustment on BioSante s convertible senior notes for 2011 was $23,427 compared to $1.9 million for 2010 as the fair value of the debt did not change significantly between December 31, 2010 and 2011.

Interest expense for 2011 was $681,573 compared to $688,083 for 2010.

During 2010, BioSante recorded an investment impairment loss of $286,000 based on BioSante s determination that an other-than-temporary loss had occurred with respect to BioSante s investment in Ceregene, Inc. based on a third-party investment in Ceregene in 2010.

Liquidity and Capital Resources

The following table highlights several items from BioSante s balance sheets:

Balance Sheet Data	December 31, 2012	December 31, 2011
Cash and cash equivalents	$ 34,794,341	$ 57,225,234
Total current assets	35,173,144	58,026,381
Investments	3,413,762	3,405,807
Total assets	38,769,170	62,379,755
Total current liabilities	10,593,665	7,227,703
Convertible senior notes due May 1, 2013, non-current	0	17,336,760
Total liabilities	10,593,665	24,564,463
Total stockholders equity	28,175,505	37,815,292

Working Capital

Since its inception, BioSante has incurred significant operating losses resulting in an accumulated deficit of $245.0 million as of December 31, 2012. To date, BioSante has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs.

As of December 31, 2012, BioSante had $34.8 million of cash and cash equivalents and $8.3 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013 outstanding. Absent the receipt of any additional licensing income or financing, BioSante expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the proposed merger between BioSante and ANI is completed during the first quarter of 2013, BioSante expects its cash and cash equivalents as of December 31, 2012 to meet its liquidity requirements through at least the anticipated closing of the merger, including the requirement under the merger agreement to have at least $17 million of net cash as defined in and as calculated pursuant to the merger agreement available upon closing of the merger. If the proposed merger between BioSante and ANI is not completed, BioSante will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone company, a sale of the company, liquidation of the company or other strategic transaction. BioSante s liquidity position will be dependent upon the strategic alternative selected; however, assuming BioSante does not enter into another strategic transaction, and assuming BioSante decides not to commence the two new efficacy trials for LibiGel, BioSante expects its cash and cash

equivalents as of December 31, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Substantial additional financing would be required should BioSante decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or BioSante, nonetheless, may choose to raise additional financing earlier.

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

- the timing, cost and successful completion of the proposed merger between BioSante and ANI;

Table of Contents

- the progress, timing, cost and results of BioSante s clinical development programs, including in particular the conclusion of the LibiGel Phase III safety study, and if BioSante has not completed the proposed merger between BioSante and ANI, beginning in mid-2013, the two new LibiGel Phase III efficacy trials if BioSante decides to commence such trials, and if BioSante in-licenses additional new products that require further development;

- the cost, timing and outcome of regulatory actions with respect to BioSante s products;

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

- BioSante s ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;

- BioSante s ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;

- the timing and amount of any royalties, milestone or other payments BioSante may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;

- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;

- the emergence of competing products and technologies, and other adverse market developments;

- the perceived, potential and actual commercial success of BioSante s products;

- the outstanding principal amount of BioSante s 3.125% convertible senior notes due May 1, 2013 that are scheduled to mature and become due and payable on May 1, 2013 and BioSante s ability to avoid a fundamental change or an event of default under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;

- BioSante s operating expenses; and

- the resolution of BioSante s pending purported class action and shareholder derivative litigation and any amount BioSante may be required to pay in excess of its directors and officers liability insurance.

BioSante does not have any existing credit facilities under which it could borrow funds. In the event that BioSante would require additional working capital to fund future operations, it could seek to acquire such funds through additional equity or debt financing arrangements. If BioSante raises additional funds by issuing equity securities, its stockholders may experience dilution. Debt financing, if available, may involve covenants restricting BioSante s operations or its ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to BioSante, or at all. As an alternative to raising additional financing, BioSante may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, or sell certain assets or rights under its existing license agreements. In addition, from time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through

Table of Contents

cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. In February 2012, BioSante issued an aggregate of 1,868,055 shares of its common stock to one of the holders of its convertible senior notes in exchange for the cancellation of $9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest of $79,024, and in July 2012, BioSante issued an aggregate of 1,784,070 shares of its common stock to two of the holders of BioSante s convertible senior notes in exchange for the cancellation of $3.5 million in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of BioSante common stock, the willingness of the note holders to sell, exchange or restructure their notes, BioSante s available cash and cash equivalents, its liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of existing BioSante stockholders and/or decrease BioSante s cash balance. A significant decrease in BioSante s cash balance, together with an inability to raise additional financing when needed, may impair BioSante s ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante is subject to pending purported class action and shareholder derivative litigation, which litigation is described elsewhere in this report. Such litigation could divert management s attention, harm BioSante s business and/or reputation and result in significant liabilities, as well as harm BioSante s ability to raise additional financing and execute certain strategic alternatives.

BioSante can provide no assurance that additional financing, if needed, will be available on terms favorable to BioSante, or at all. This is particularly true if investors are not confident in the success of the proposed merger between BioSante and ANI, BioSante s LibiGel development program, the future value of BioSante and/or economic and market conditions deteriorate. If BioSante does not complete the proposed merger between BioSante and ANI and if adequate funds are not available or are not available on acceptable terms when BioSante needs them, BioSante may need to reduce its operating costs further or it may be forced to explore other strategic alternatives, such as other business combination transactions or winding down its operations and liquidating the company. In such case, BioSante stockholders could lose some or all of their investment.

Uses of Cash and Cash Flow

Years Ended December 31, 2012, 2011 and 2010

Net cash used in operating activities was $25.3 million for the year ended December 31, 2012 compared to $47.9 million for the year ended December 31, 2011 and $40.1 million for the year ended December 31, 2010. Net cash used in operating activities for 2012 was primarily the result of the net loss for that period which was lower compared to the prior year period due to lower clinical trial related expenses primarily as a result of the completion of BioSante s two LibiGel Phase III efficacy trials at the end of 2011 and the conclusion of the safety study in September 2012. Net cash used in operating activities for 2011 was primarily the result of the net loss for that period which was higher compared to 2010 due to higher LibiGel Phase III clinical study related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities and the non-cash mark-to-market expense for BioSante s convertible senior notes. Net cash used in operating activities for 2010 was primarily the result of the net loss for that period, which was slightly higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets.

Net cash used in investing activities was $619,148 for the year ended December 31, 2012 compared to net cash used in investing activities of $719,925 for the year ended December 31, 2011 and net cash used in investing activities of $60,366 for the year ended December 31, 2010. Net

cash used in investing activities for

Table of Contents

2012 was due primarily to the purchase of fixed assets. The increase in net cash used in investing activities for 2011 compared to 2010 was due to a significant increase in the purchase of fixed assets, including in particular machinery, computers and furniture. The machinery purchased during 2011 related to BioSante-owned machinery for LibiGel product manufacturing at its contract manufacturer and the increased amounts spent on computers and furniture during 2011 was due primarily to its increased number of personnel in 2011 compared to 2010.

Net cash provided by financing activities was $3.5 million for the year ended December 31, 2012 compared to $67.7 million for the year ended December 31, 2011 and $48.5 million for the year ended December 31, 2010. Net cash provided by financing activities in 2012 was the result of BioSante s August 2012 registered direct offering, which resulted in net proceeds of $3.3 million, after deduction of placement agent fees and offering expenses. Net cash provided by financing activities in 2011 resulted from the net proceeds to BioSante, after deducting placement agent fees, underwriters discounts, commissions and other offering expenses, from the completion of BioSante s March 2011 registered direct offering and August 2011 underwritten public offering, partially offset by the repayment of the 3.125% convertible senior notes due November 1, 2011 of $1.2 million. Net cash provided by financing activities in 2010 resulted from the net proceeds to BioSante, after deducting placement agent fees and offering expenses, from the completion of BioSante s March, June and December 2010 registered direct offerings.

3.125% Convertible Senior Notes Due May 1, 2013

As a result of BioSante s merger with Cell Genesys in 2009, BioSante assumed $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 issued by Cell Genesys. Prior to the November 1, 2011 maturity date, BioSante repaid in its entirety the outstanding aggregate principal amount of the 3.125% convertible senior notes due November 1, 2011 and all accrued and unpaid interest thereon through such date. During the year ended December 31, 2012, BioSante issued an aggregate of approximately 3.7 million shares of BioSante common stock to holders of the 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of $12.5 million in aggregate principal amount of such notes, including accrued and unpaid interest.

Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the remaining convertible senior notes is approximately $259,000.

The remaining outstanding convertible senior notes are convertible into an aggregate of approximately 370,871 shares of BioSante common stock at a conversion price of $22.32 per share, subject to adjustments for stock dividends, stock splits and other similar events. The convertible senior notes are general, unsecured obligations of BioSante, ranking equally with all of BioSante s existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of BioSante s existing and future secured indebtedness to the extent of the value of the related collateral, and structurally subordinated to all existing and future liabilities and other indebtedness of any subsidiaries of BioSante. The convertible senior notes are subject to repurchase by BioSante at each holder s option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the convertible senior notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by BioSante, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of BioSante common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of December 31, 2012, the convertible senior notes were not eligible for redemption. The indenture governing the convertible senior notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict BioSante from paying dividends, incurring additional debt or issuing or repurchasing other securities of BioSante. In

Table of Contents

addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the convertible senior notes in the event of a highly leveraged transaction or a fundamental change of BioSante except in certain circumstances specified in the indenture.

From time to time, BioSante may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of BioSante, in open market purchases, privately negotiated transactions and/or a tender offer. The amounts involved may be material. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, BioSante s available cash and cash equivalents, its liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the BioSante stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the existing BioSante stockholders and/or decrease BioSante s cash balance. A significant decrease in BioSante s cash balance may impair its ability to execute strategic alternatives or leave it without sufficient cash remaining for operations.

BioSante has elected to record the convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, BioSante has adjusted the carrying value of the convertible senior notes to their fair value as of December 31, 2012, with changes in the fair value of the convertible senior notes occurring since December 31, 2011 reflected in convertible note fair value adjustment in BioSante s statement of operations for the year ended December 31, 2012. The fair value of the convertible senior notes are based on Level 2 inputs according to the fair value hierarchy required under GAAP, which means fair value of the convertible senior notes is based on observable prices that are based on inputs not quoted on active markets, but corroborated by market data. The aggregate recorded fair value of the convertible senior notes of $7.9 million as of December 31, 2012 differs from their total stated principal amount of $8.3 million as of such date by $0.4 million. The aggregate recorded fair value of the convertible senior notes of $17.3 million as of December 31, 2011 differs from their total stated principal amount of $20.8 million as of such date by $3.5 million.

Commitments and Contractual Obligations

The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2012:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible senior notes	$ 8,277,850	$ 8,277,850	$ 0	$ 0	$ 0
Interest payment obligations related to convertible senior notes	129,500	129,500	0	0	0
Operating lease	290,350	248,632	41,718	0	0
Commitment under license agreement with Wake Forest	300,000	300,000	0	0	0
Total contractual cash obligations	$ 8,997,700	$ 8,955,982	$ 41,718	$ 0	$ 0

On January 31, 2013, BioSante entered into an asset purchase agreement with Aduro pursuant to which BioSante sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments. As a result of such agreement, Aduro is responsible for future contractual obligations relating to the GVAX cancer vaccine portfolio. As such, all future contractual obligations related to the GVAX cancer vaccine portfolio of BioSante as of December 31, 2012 have been omitted from the above table. In February 2013, the Wake Forest University commitment was paid in full.

Table of Contents

Off-Balance Sheet Arrangements

BioSante does not have any off-balance sheet arrangements that have or reasonably are likely to have a material effect on BioSante s financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, BioSante is not exposed materially to any financing, liquidity, market or credit risk that could arise if BioSante had engaged in these arrangements.

Recent Accounting Pronouncements

BioSante does not expect the adoption of any recent accounting pronouncements to have a material effect on its financial position, results of operations or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

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

Interest Rate Sensitivity

Principal Amount by Expected Maturity and Average Interest Rate

As of December 31, 2012	2012	2013	Total	Fair Value December 31, 2012
Total cash equivalents	$ 34,210,555			$ 34,210,555
Average interest rate	0.01%			
Fixed interest rate convertible senior notes		$ 8,277,850	$ 8,277,850	$ 7,883,886
Average interest rate	3.125%	3.125%	3.125%	

As of December 31, 2011	2012	2013	Total	Fair Value December 31, 2011
Total cash equivalents	$ 55,465,507			$ 55,465,507
Average interest rate	0.02%			
Fixed interest rate convertible senior notes		$ 20,782,000	$ 20,782,000	$ 17,336,760
Average interest rate	3.125%	3.125%	3.125%	

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Description	Page
Management s Report on Internal Control Over Financial Reporting	76
Report of Independent Registered Public Accounting Firm	77
Report of Independent Registered Public Accounting Firm	78
Balance Sheets as of December 31, 2012 and 2011	79
Statements of Operations for the years ended December 31, 2012, 2011 and 2010	80
Statements of Stockholders Equity for the years ended December 31, 2012, 2011 and 2010	81
Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010	82
Notes to the Financial Statements for the years ended December 31, 2012, 2011 and 2010	83-106

Table of Contents

MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

As management of BioSante Pharmaceuticals, Inc., we are responsible for establishing and maintaining an adequate system of internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, for BioSante Pharmaceuticals, Inc. This system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

BioSante s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of BioSante; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of BioSante are being made only in accordance with authorizations of management and directors of BioSante; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of BioSante s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and even when determined to be effective, can only provide reasonable assurance with respect to financial statement preparation and presentation. Also, projection of any evaluation of the effectiveness of internal control over financial reporting to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With our participation, management evaluated the effectiveness of BioSante s internal control over financial reporting as of December 31, 2012. In making this evaluation, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. Based on this assessment, management concluded that BioSante s internal control over financial reporting was effective as of December 31, 2012.

/s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary

February 28, 2013

Further discussion of BioSante s internal controls and procedures is included under the heading Part II. Item 9A. Controls and Procedures of this report.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

BioSante Pharmaceuticals, Inc.

Lincolnshire, Illinois

We have audited the internal control over financial reporting of BioSante Pharmaceuticals, Inc. (the Company) as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2012 of the Company and our report dated February 28, 2013 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
February 28, 2013

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

BioSante Pharmaceuticals, Inc.

Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (the Company) as of December 31, 2012 and 2011, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of BioSante Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2013 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
February 28, 2013

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Balance Sheets

December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 34,794,341	$ 57,225,234
Prepaid expenses and other assets	378,803	801,147
	35,173,144	58,026,381
PROPERTY AND EQUIPMENT, NET	166,386	861,364
OTHER ASSETS		
Investments	3,413,762	3,405,807
Deposits	15,878	86,203
	$ 38,769,170	$ 62,379,755
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 1,128,644	$ 3,150,677
Accrued compensation	1,078,683	1,597,329
Other accrued expenses	502,452	2,479,697
Current portion of Convertible Senior Notes	7,883,886	
	10,593,665	7,227,703
Long-term Convertible Senior Notes		17,336,760
TOTAL LIABILITIES	10,593,665	24,564,463
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2012 - 65,211; 2011 - 65,214 Class C special stock	391	391
2012 - 24,422,240; 2011 - 18,269,754 Common stock	273,132,001	255,054,049
	273,132,392	255,054,440
Accumulated deficit	(244,956,887)	(217,239,148)
	28,175,505	37,815,292
	$ 38,769,170	$ 62,379,755

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Operations

Years ended December 31, 2012, 2011 and 2010

	Year Ended December 31,		
	2012	2011	2010
REVENUE			
Licensing revenue	$ 1,750,000	$ 100,000	$ 115,807
Grant revenue			51,870
Royalty revenue	550,736	335,160	2,306,560
	2,300,736	435,160	2,474,237
EXPENSES			
Research and development	16,888,849	44,182,260	39,705,502
General and administration	8,229,523	6,981,490	5,940,360
Licensing expense	95,000	50,000	268,750
Depreciation and amortization	258,946	148,240	167,986
	25,472,318	51,361,990	46,082,598
OTHER			
Convertible note fair value adjustment	(4,328,468)	(23,427)	(1,870,916)
Investment impairment charge			(286,000)
Interest expense	(348,019)	(681,573)	(688,083)
Other income		15,000	244,479
Interest income	8,539	8,326	12,665
LOSS BEFORE INCOME TAX BENEFIT	(27,839,530)	(51,608,504)	(46,196,216)
Income tax benefit	121,791		
NET LOSS	$ (27,717,739)	$ (51,608,504)	$ (46,196,216)
Loss per common share:			
Basic	$ (1.27)	$ (3.15)	$ (4.21)
Diluted	$ (1.27)	$ (3.15)	$ (4.21)
Weighted average number of common and common equivalent shares outstanding:			
Basic	21,757,906	16,397,618	10,985,291
Diluted	21,757,906	16,397,618	10,985,291

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Stockholders Equity

Years ended December 31, 2012, 2011 and 2010

	Class C Special Shares		Common Stock		Accumulated	
	Shares	Amount	Shares	Amount	Deficit	Total
Balance, January 1, 2010	**65,214**	**$ 391**	**8,877,094**	**$ 135,264,431**	**$ (119,434,428)**	**$ 15,830,394**
Issuance of common shares						
Stock option exercise			222	2,014		2,014
Stock option expense				992,757		992,757
Stock warrant expense				65,529		65,529
Registered direct offerings of common shares and warrants, net			4,687,871	48,452,644		48,452,644
June 1, 2012 fractional share adjustment			1			
Net loss					(46,196,216)	(46,196,216)
Balance, December 31, 2010	**65,214**	**$ 391**	**13,565,188**	**$ 184,777,375**	**$ (165,630,644)**	**$ 19,147,122**
Issuance of common shares						
Stock option exercise			3,194	32,442		32,442
Warrant exercises - various			1,458	24,062		24,062
Stock option expense				1,177,683		1,177,683
Stock warrant expense				204,980		204,980
Underwritten offering of common shares, net			2,666,666	44,961,137		44,961,137
Registered direct offering of common shares and warrants, net			2,033,247	23,876,370		23,876,370
June 1, 2012 fractional share adjustment			1			
Net loss					(51,608,504)	(51,608,504)
Balance, December 31, 2011	**65,214**	**$ 391**	**18,269,754**	**$ 255,054,049**	**$ (217,239,148)**	**$ 37,815,292**
Issuance of common shares						
Shares issued in exchange for convertible senior notes and accrued interest			**3,652,125**	**13,881,052**		**13,881,052**
Warrant exercises - various			**140,712**	**211,068**		**211,068**
Stock option expense				**725,625**		**725,625**
Registered direct offering of common shares and warrants, net			**2,359,932**	**3,260,865**		**3,260,865**
			(283)	**(658)**		**(658)**

June 1, 2012 fractional share adjustment							
Share redesignation	**(3)**						
Net loss						**(27,717,739)**	**(27,717,739)**
Balance, December 31, 2012	**65,211**	**$ 391**	**24,422,240**	**$ 273,132,001**	**$**	**(244,956,887)**	**$ 28,175,505**

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Cash Flows

Years ended December 31, 2012, 2011 and 2010

	Year Ended December 31,		
	2012	2011	2010
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (27,717,739)	$ (51,608,504)	$ (46,196,216)
Adjustments to reconcile net loss to net cash (used in) operating activities			
Depreciation and amortization	258,946	148,240	167,986
Employee and director stock-based compensation	725,625	1,177,683	992,757
Stock warrant expense - noncash		204,980	65,529
Loss on disposal or impairment of equipment	1,047,225	367,502	4,583
Investment impairment charge			286,000
Other non-cash items			(65,807)
Convertible note fair value adjustment	4,328,468	23,427	1,870,916
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	492,670	1,682,466	(365,332)
Accounts payable and accrued liabilities	(4,418,215)	134,103	3,142,078
Net cash used in operating activities	(25,283,020)	(47,870,103)	(40,097,506)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of investments	(7,955)		
Proceeds from sale of fixed assets			3,075
Purchase of fixed assets	(611,193)	(719,925)	(63,441)
Net cash used in investing activities	(619,148)	(719,925)	(60,366)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Fractional share payout	(658)		
Cash paid for convertible note repayment		(1,234,000)	
Proceeds from common stock option exercises		32,442	2,014
Proceeds from common stock warrant exercises	211,068	24,062	
Proceeds from issuance of common stock by underwritten offering		44,961,137	
Proceeds from issuance of common stock by registered direct offering	3,260,865	23,876,370	48,452,644
Net cash provided by financing activities	3,471,275	67,660,011	48,454,658
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(22,430,893)	19,069,983	8,296,786
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	57,225,234	38,155,251	29,858,465
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 34,794,341	$ 57,225,234	$ 38,155,251
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Interest paid, including acquired accrued interest	$ 313,435	$ 688,000	$ 688,000
Noncash Investing and Financing Activities:			
Investment - non-cash	$	$	$ 65,807
Shares issued for convertible senior notes and accrued interest	$ 13,881,052	$	$

Purchase of fixed assets on account, non-cash investing activity	**$**	**$** **21,405**	**$**

See accompanying notes to the financial statements.

Table of Contents

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. The Company s products, either approved or in human clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva); (3) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (4) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Meda, the Company s licensee.

The Company s lead product in development is LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. For the past several years, the Company focused its efforts on two Phase III LibiGel efficacy trials and a LibiGel Phase III cardiovascular and breast cancer safety study. In December 2011, the Company announced results from its two Phase III LibiGel efficacy trials, which showed that the trials did not meet the co-primary or secondary endpoints. Although LibiGel performed as predicted, increasing satisfying sexual events and sexual desire and decreasing distress associated with low desire, the placebo response in the two efficacy trials was greater than expected, and LibiGel s results were not shown to be statistically different from the placebo.

Beginning in December 2011, the Company analyzed the data from its Phase III LibiGel efficacy trials, consulted with key opinion leaders in female sexual dysfunction, testosterone therapy and placebo effects, and met with representatives of the FDA. As a result of this process, in June 2012 the Company announced a plan to initiate two new LibiGel Phase III efficacy trials. The Company subsequently began the process of developing a protocol for the two new efficacy trials and applying for an FDA Special Protocol Assessment (SPA) agreement covering aspects of the two new efficacy trials.

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

Table of Contents

1. DESCRIPTION OF BUSINESS (continued)

The Company is continuing to develop a protocol for the two new LibiGel efficacy trials and intends to seek an FDA SPA agreement covering aspects of the two new efficacy trials.

On October 3, 2012, the Company entered into an agreement and plan of merger (the Merger Agreement) with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (ANI). The Merger Agreement provides that, subject to the terms and conditions set forth in the Merger Agreement, ANI will merge with and into the Company, with the Company continuing as the surviving company (the Merger). Following completion of the Merger, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of the Company are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming the Company s net cash as defined in the Merger Agreement and generally consisting of the Company s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Merger, is $18.0 million. The exchange ratios in the Merger are subject to potential adjustment as described in the Merger Agreement depending upon the amount of the Company s net cash as of a determination date prior to the closing date of the Merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current Company stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The pending Merger with ANI is more fully described in Note 3, Pending Merger with ANI.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These financial statements are expressed in U.S. dollars. The Company is organized into one operating and one reporting segment.

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (generally accepted accounting principles). The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The Company does not have items of other comprehensive income for the years ended December 31, 2012, 2011 or 2010; and therefore, has not presented comprehensive income.

On June 1, 2012, the Company effected a one-for-six reverse split of its outstanding common stock and class C special stock. All share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Cash and Cash Equivalents

The Company generally considers all instruments with original maturities of three months or less to be cash equivalents. Interest income on invested cash balances is recognized on the accrual basis as earned.

The Company s policy is to manage its cash and cash equivalents in order to ensure maximum safety of principal. As of December 31, 2012, all of the Company s cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account or a U.S. Treasury money market fund. As of December 31, 2011, all of the Company s cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account.

Fair Value of Financial Instruments

The carrying value of certain of the Company s financial instruments, including cash equivalents, accounts receivable and accounts payable, approximate fair value due to their short maturities. Other information about the Company s assets and liabilities recorded at fair value is included in Note 14, Fair Value Measurements.

Property and Equipment

Property and equipment that currently is being used in the Company s operations is stated at cost less accumulated depreciation and amortization. Depreciation is computed primarily on a straight line basis over the estimated useful lives of the respective assets, typically five and seven years for software and computer equipment and 10 years for non-computer equipment.

Long-Lived Assets

Long-lived assets are reviewed for possible impairment whenever events indicate that the carrying amount of such assets may not be recoverable. If such a review indicates an impairment, the carrying amount of such assets is reduced to estimated recoverable value.

Convertible Senior Notes

The Company has outstanding 3.125% convertible senior note obligations, which contain certain redemption, repurchase and conversion adjustment features. The Company assumed the convertible senior notes in connection with its merger with Cell Genesys, Inc. (Cell Genesys) in October 2009. The Company made an irrevocable election to account for these convertible senior notes at fair value commencing from the date of the merger with Cell Genesys, resulting in recognition of a single liability for the convertible senior notes which are reported at fair value at each reporting date. Subsequent changes in the carrying value of the convertible senior notes are reflected in fair value adjustment in the accompanying statements of operations.

Research and Development

Research and development costs are charged to expense as incurred. Direct government grants are recorded as an offset to the related research and development costs when the Company has complied with the conditions attached to the grant and there is reasonable assurance that the funds will be received.

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Legal Costs

For ongoing matters, legal costs are charged to expense as incurred.

Basic and Diluted Net Loss Per Share

The basic and diluted net loss per share is computed based on the weighted average number of the shares of common stock and class C special stock outstanding, all being considered as equivalent of one another. Basic loss per share is computed by dividing loss available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted loss per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The computation of diluted loss per share does not include the Company s stock options, warrants or convertible debt as such securities have an antidilutive effect on loss per share.

Stock-Based Compensation

The Company recognizes stock-based compensation expense granted to employees generally on a straight-line basis over the estimated service period of the award, or when certain performance-based vesting provisions occur, for awards that contain these features. The Company also has granted options to non-employees in exchange for services. Expense related to such grants is recognized within the Company s statements of operations in accordance with the nature of the service received by the Company.

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue and are re-measured until the counterparty s performance under the arrangement is complete.

Revenue Recognition

The Company has entered into various licensing agreements that have generated license revenue or other upfront fees and which also may involve subsequent milestone payments earned upon completion of development milestones by the Company, upon the occurrence of certain regulatory actions, such as the filing of a regulatory application or the receipt of a regulatory approval, or upon the achievement of certain sales-based milestones. Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Non-refundable license fees that meet these criteria and are due to the Company upon execution of an agreement are recognized as revenue immediately.

Milestones, in the form of additional license fees, typically represent non-refundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as completion of specified clinical development activities and/or regulatory submissions and/or approvals, or as sales-based milestone payments. Revenues from milestone payments that meet the criteria in the preceding paragraph are recognized when the milestone is achieved.

Additionally, royalty revenue based upon sales of products under license is recorded when such royalties are earned and are deemed collectible, which is generally in the quarter when the related products are sold.

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Income Taxes

Deferred tax assets or liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates. A valuation allowance is provided against deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is not more likely than not. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2012 and 2011.

Investments

The investments balance of $3,413,762 and $3,405,807 as of December 31, 2012 and 2011 consists of the Company s investments that are recorded using the cost method, and substantially represents the Company s investment in Ceregene, Inc., a privately held biotechnology company (Ceregene). As a result of the Company s merger with Cell Genesys, the Company acquired a minority investment in Ceregene. The Company has recorded its investment using the cost method, as no active market exists for this investment, and the Company does not possess significant influence over operating and financial policies of Ceregene, although the Company by virtue of its stock ownership of Ceregene has the right to designate one member on the Ceregene board of directors. During 2010, the Company recorded a $286,000 impairment on this investment. Such impairment was based on a third-party investment in Ceregene in 2010.

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

Recent Accounting Pronouncements

The Company does not expect the adoption of any recent accounting pronouncements to have a material effect on the Company s financial position, results of operations or cash flows.

3. PENDING MERGER WITH ANI

Agreement and Plan of Merger

On October 3, 2012, the Company entered into the Merger Agreement with ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. The Merger Agreement provides that, upon the terms and subject to the conditions set forth in the Merger Agreement, ANI will merge with and into the Company, with the Company continuing as the surviving company. At the effective time of the Merger, each outstanding share of capital stock of ANI will be converted into the right to receive a number of shares of the Company s common stock, if any, as determined pursuant to the exchange ratios described in the Merger Agreement and the provisions of ANI s certificate of incorporation. All options, warrants or other rights to purchase shares of capital stock of ANI, will be canceled at the effective time of the Merger without any consideration in exchange, except for certain warrants which although not cancelled will not represent the right to acquire any equity or other interest in the

Table of Contents

3. PENDING MERGER WITH ANI (continued)

combined company after the Merger. No fractional shares of the Company s common stock will be issued in connection with the Merger, and holders of ANI capital stock will be entitled to receive cash in lieu thereof. Following completion of the Merger, the current stockholders of ANI are expected to own approximately 53 percent of the outstanding shares of common stock of the combined company, and current stockholders of the Company are expected to own approximately 47 percent of the outstanding shares of common stock of the combined company, assuming the Company s net cash as of the determination date is $18.0 million. The exchange ratios are subject to potential adjustment as described in the Merger Agreement depending upon the amount of the Company s net cash , as defined in the Merger Agreement and generally consisting of the Company s cash and cash equivalents less certain expenses and liabilities, as of a determination date prior to the closing date of the Merger, but in no event will the current ANI stockholders own less than 50.1 percent (or the current Company stockholders own more than 49.9 percent) of the outstanding shares of common stock of the combined company. The Merger is intended to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code of 1986, as amended.

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

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

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

Table of Contents

3. PENDING MERGER WITH ANI (continued)

the charter amendments, subject to certain exceptions. Each of the Company and ANI also has agreed not to solicit proposals relating to alternative business combination transactions or enter into discussions or an agreement concerning any proposals for alternative business combination transactions, subject to exceptions for the Company in the event of the Company s receipt of a superior proposal.

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

Voting Agreements

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

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

Lock-Up Agreements

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

Contingent Value Rights Agreement

The Company has the right in its sole discretion to issue contingent value rights (each, a CVR and collectively, the CVRs) to its existing stockholders immediately prior to the completion of the Merger.

Table of Contents

3. PENDING MERGER WITH ANI (continued)

The Company expects that one CVR will be issued for each share of the Company s common stock outstanding as of the record date, which is March 15, 2013. However, the CVRs will not be certificated and will not be attached to the shares of the Company s common stock. Each CVR will be a non-transferable (subject to certain limited exceptions) right to potentially receive certain cash payments in the event the Company receives net cash payments during the ten-year period after the distribution of the rights as a result of the sale, transfer, license or similar transaction relating to the Company s LibiGel program, upon the terms and subject to the conditions set forth in a contingent value rights agreement to be entered into between the Company and an as of yet unidentified third party, as rights agent. The aggregate cash payments to be distributed to the holders of the CVRs, if any, will be equal to 66 percent of the net cash payments received by the combined company as a result of the sale, transfer, license or similar transaction relating to the Company s LibiGel program, as determined pursuant to the CVR agreement, and will not exceed $40 million in the aggregate.

4. LIQUIDITY AND CAPITAL RESOURCES

Substantially all of the Company revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. The Company s business operations to date have consisted primarily of licensing and research and development activities and if the Company does not complete its proposed merger with ANI, the Company would expect this to continue for the immediate future. To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its 2009 merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs.

During 2012, the Company raised approximately $3.3 million in net proceeds, after deducting placement agent fees and other offering expenses, through the sale of common stock and warrants in a registered direct offering, as more fully described in Note 9, Stockholders Equity.

As of December 31, 2012, the Company had $34.8 million of cash and cash equivalents and had outstanding $8.3 million in aggregate principal amount of its 3.125% convertible senior notes due May 1, 2013. Absent the receipt of any additional licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as it continues to use cash to fund its operations. Assuming the Merger between the Company and ANI is completed, the Company expects its cash and cash equivalents as of December 31, 2012 to meet its liquidity requirements through at least its anticipated closing of the Merger, including the requirement under the Merger Agreement to have at least $17 million of net cash, as defined in and as calculated pursuant to the Merger Agreement, available upon the closing of the Merger. If the Merger between the Company and ANI is not completed, the Company will need to reevaluate its strategic alternatives, which may include continuing as an independent, stand-alone business, a sale of the Company, liquidation of the Company or other strategic transaction. The Company s liquidity position will be dependent upon the strategic alternative selected; however, assuming the Company does not enter into another strategic transaction, and assuming the Company decides not to commence the two new efficacy trials for LibiGel, the Company expects its cash and cash equivalents as of December 31, 2012 will be sufficient to meet its liquidity requirements for at least the next three to five years. Additional financing would be required should the Company decide to commence the two new efficacy trials for LibiGel. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

Table of Contents

4. LIQUIDITY AND CAPITAL RESOURCES (continued)

The Company s future capital requirements will depend upon numerous factors, including:

- the timing, cost and successful completion of the Company s Merger with ANI;

- the progress, timing, cost and results of the Company s clinical development programs, including in particular the conclusion of the LibiGel Phase III safety study, and if the Company has not completed its merger with ANI, beginning in mid-2013, the two new LibiGel Phase III efficacy trials if the Company decides to commence such trials, and if the Company in-licenses additional new products that require further development;

- the cost, timing and outcome of regulatory actions with respect to the Company s products;

- the success, progress, timing and costs of the Company s business development efforts to implement business collaborations, licenses and other business combinations or transactions, and the Company s efforts to evaluate various strategic alternatives available with respect to the Company s products and the Company;

- the Company s ability to obtain value from its current products and technologies and its ability to out-license its products and technologies to third parties for development and commercialization and the terms of such out-licenses;

- the Company s ability to acquire or in-license additional new products and technologies and the costs and expenses of such acquisitions or licenses;

- the timing and amount of any royalties, milestone or other payments the Company may receive from or be obligated to pay to current and potential licensors, licensees and other third parties;

- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights;

- the emergence of competing products and technologies, and other adverse market developments;

- the perceived, potential and actual commercial success of the Company s products;

- the outstanding principal amount of the Company s 3.125% convertible senior notes due May 1, 2013 (convertible senior notes) that are scheduled to mature and become due and payable on May 1, 2013 and the Company s ability to avoid a fundamental change or an event of default under the indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;

- the Company s operating expenses; and

- the resolution of the Company s pending purported class action and shareholder derivative litigation and any amount the Company may be required to pay in excess of its directors and officers liability insurance.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing

Table of Contents

4. LIQUIDITY AND CAPITAL RESOURCES (continued)

arrangements. If the Company raises additional funds by issuing equity securities, the Company s stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company s operations or its ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to license one or more of the Company s products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, or sell certain assets or rights under the Company s existing license agreements. In addition, from time to time, the Company may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of the Company s common stock, the willingness of the note holders to sell, exchange or restructure their notes, the Company s available cash and cash equivalents, the Company s liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company s stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company s existing stockholders and/or decrease the Company s cash balance. A significant decrease in the Company s cash balance, together with an inability to raise additional financing when needed, may impair the Company s ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

The Company is subject to pending purported class action and shareholder derivative litigation, which litigation is described in more detail in Note 13, Commitments and Contingencies to the Company s financial statements. Such litigation could divert management s attention, harm the Company s business and/or reputation and result in significant liabilities, as well as harm the Company s ability to raise additional financing and execute certain strategic alternatives.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the success of the Company s pending merger with ANI, the Company s LibiGel clinical development program, the future value of the Company and/or economic and market conditions deteriorate. If the Company does not complete its pending merger with ANI and if adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to reduce its operating costs further or the Company may be forced to explore other strategic alternatives, such as other business combination transactions or winding down the Company s operations and liquidating the Company. In such case, the Company s stockholders could lose some or all of their investment.

5. LICENSE AGREEMENTS

LibiGel and Elestrin

The Company licensed the technology underlying LibiGel and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). Under the agreement, Antares granted the Company an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories. Under the agreement, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology. The patents covering the formulations used in these gel products are expected to expire in 2022 and 2028.

Table of Contents

5. LICENSE AGREEMENTS (continued)

Male Testosterone Gel

The Company s male testosterone gel was developed initially by the Company, and then licensed by the Company to Teva for late stage clinical development. Teva submitted an NDA to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. No launch date for this product has been announced by Teva.

Under the Company s development and license agreement with Teva, Teva has agreed to market the male testosterone gel for the U.S. market and is responsible for any and all manufacturing and marketing associated with the product. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, which was paid to the Company in December 2002, and an obligation by Teva to pay the Company certain milestones and royalties on sales of the product in exchange for rights to develop and market the product. Teva is entitled to deduct the amount of any legal expenses incurred by Teva in connection with associated patent litigation against Teva from the net sales of the product.

The term of the development and license agreement will expire 10 years from the date on which Teva makes its first commercial sale of the male testosterone gel to an unrelated third party in an arms-length transaction in the United States. The parties may terminate the development and license agreement upon the occurrence of certain events, including a material breach of the agreement by the other party. The Company may terminate the agreement if Teva files a petition in bankruptcy, enters into an arrangement with its creditors or makes an assignment for the benefit of creditors or a receiver or trustee is appointed or if Teva suffers or permits the entry of an order adjudicating it to be bankrupt or insolvent. Teva may terminate the agreement if Teva determines that the continued development and/or marketing of the male testosterone gel is no longer commercially viable.

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

The Pill Plus

The Company has a fully paid-up right and exclusive license to the technology underlying its triple component contraceptive, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The Company received this fully paid-up right and exclusive

license in December 2012 when it entered into an amendment to the license agreement to eliminate all regulatory milestone payments, maintenance payments and royalty payments. The patents covering the technology underlying The Pill Plus are expected to expire in 2016.

Table of Contents

5. LICENSE AGREEMENTS (continued)

Other License Agreements

The Company has entered into several other license agreements in which the Company has out-licensed certain of the rights and technologies the Company has licensed. Under these agreements, the Company typically is entitled to receive royalty payments on any sales of the products and, in some cases, may be entitled to receive certain development and regulatory milestones.

6. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2012 and 2011 consists of the following:

	2012	2011
Computer equipment	**$ 176,500**	$ 520,647
Office equipment	**381,448**	388,659
Equipment	**0**	378,147
	557,948	1,287,453
Accumulated depreciation and amortization	**(391,562)**	(426,089)
	$ 166,386	$ 861,364

There was no construction in progress as of December 31, 2012 or December 31, 2011.

Based upon the conclusion of the LibiGel safety study, the merger agreement with ANI and discussions with prospective purchasers of the Company s gel filling machine, none of which resulted in a sale of the machine, the Company has determined that the value of the Company s gel filling machine and components was impaired; and therefore, recorded a write-down of the asset to zero. The write-down of $929,431 is classified within research and development expense in the Company s statement of operations for the year ended December 31, 2012.

7. CONVERTIBLE SENIOR NOTES

The Company assumed liabilities related to two series of convertible senior notes of Cell Genesys as a part of its 2009 merger with Cell Genesys - $1,234,000 aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 (the 2011 Notes) and $20,782,000 aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes and collectively with the 2011 Notes, the Notes).

Immediately prior to November 1, 2011, the Company repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued interest thereon through such date. As of December 31, 2012, an aggregate of $8,277,850 in principal amount of the 2013 Notes remained outstanding. The remaining 2013 Notes are exchangeable at the option of the holder or upon certain specified events into an aggregate of approximately 0.4 million shares of the Company s common stock at a conversion price of $22.32 per share.

The 2013 Notes are general, unsecured obligations of the Company, ranking equally with all of the Company s existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of the Company s 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 the Company s

Table of Contents

7. CONVERTIBLE SENIOR NOTES (continued)

subsidiaries. The 2013 Notes are subject to repurchase by the Company at each holder s option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by the Company, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of the Company s common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of December 31, 2012, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company s other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

From time to time, the Company may purchase, exchange or restructure its outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the trading price and volume of the Company s common stock, the willingness of the note holders to sell, exchange or restructure their notes, the Company s available cash and cash equivalents, the Company s liquidity requirements, regulatory limitations, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company s stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company s existing stockholders and/or decrease the Company s cash balance. A significant decrease in the Company s cash balance may impair the Company s ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

In February 2012, the Company issued an aggregate of 1.9 million shares of its common stock to one of the holders of the 2013 Notes in exchange for the cancellation of $9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest of $79,024, and in July 2012, the Company issued an aggregate of 1.8 million shares of its common stock to two of the holders of the 2013 Notes in exchange for the cancellation of $3.5 million in aggregate principal amount of such notes and accrued and unpaid interest of $20,686. Non-cash fair value adjustment of $(3,157,150) was recorded as a result of the cancellation of such notes. The fair value adjustment recorded upon the cancellation of the 2013 Notes is primarily attributable to the time value effect of settling these obligations at a date prior to the stated maturity of the 2013 Notes.

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of December 31, 2012, with changes in the fair value of the Notes occurring since December 31, 2011, reflected in fair value adjustment in the statements of operations. The fair value of the Notes is based on Level 2 inputs. The recorded fair value of the Notes of an aggregate of $7,883,886 as of December 31, 2012 differs from their total stated principal amount of $8,277,850 by $393,964.

Table of Contents

7. CONVERTIBLE SENIOR NOTES (continued)

The recorded value of the Notes of an aggregate of $17,336,760 as of December 31, 2011 differs from their total stated principal amount of $20,782,000 by $3,445,240. The Company recorded fair value adjustments of $(1,171,318) and $(23,427) related to the Notes for the years ended December 31, 2012 and 2011, respectively, to increase its recorded liability and corresponding expense in 2012 and 2011. There was an immaterial change in the fair value of the convertible senior notes due to a change in instrument specific credit risk for the years ended December 31, 2012, 2011 and 2010.

The Company establishes the value the convertible senior notes based upon contractual terms of the notes, as well as certain key assumptions. The assumptions as of December 31, 2012 were:

	2013 Notes
Average risk-free rate	0.08%
Volatility of BioSante common stock	79.9%
Discount rate for principal payments in cash	19.4%

The assumptions as of December 31, 2011 were:

	2013 Notes
Average risk-free rate	0.19%
Volatility of BioSante common stock	77.4%
Discount rate for principal payments in cash	18.5%

The discount rate is based on observed yields as of the measurement date for debt securities of entities having a Ca and Caa3 rating for long-term corporate obligations as assigned by Moody s Investors Service. Volatility is based on the historical fluctuations in the Company s stock price for a period of time equal to the remaining time until the debt maturity. The risk-free rate is based on observed yields as of the measurement date of one-year, two-year and three-year U.S. Treasury Bonds.

8. INCOME TAXES

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company s U.S. and state tax returns remain subject to examination for the year ended 1998 and all subsequent periods due to the availability of tax loss and credit carryforwards. The Company determined there are no uncertain tax positions existing as of December 31, 2012 or 2011.

The components of the Company s net deferred tax asset at December 31, 2012 and 2011 were as follows:

	2012	2011
Net operating loss carryforwards	**$ 72,756,414**	$ 63,969,813
Tax basis in intangible assets	**3,868,769**	4,095,269
Deferred financing costs for tax	**8,644,459**	7,010,462
Research and development credits	**9,142,943**	8,266,610
Stock option expense	**3,028,904**	2,754,981
Other	**46,506**	448,140
	97,487,995	86,545,275
Valuation allowance	(**97,487,995**)	(86,545,275)
	$	$

Table of Contents

8. INCOME TAXES (continued)

The Company recognized an income tax benefit based on the receipt of an income tax credit for 2012 of $121,791 compared to the recognition of no income tax benefit or expense for 2011 or 2010. The income tax benefit was a result of an election to accelerate research and development credits in lieu of receiving bonus depreciation on certain property under Section 168(k)(4) of the Internal Revenue Code of 1986, as amended. The Company s current and accumulated losses result in net operating loss carryforwards. At December 31, 2012, the Company had approximately $192,732,223 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2018-2032 and their utilization in future years may be limited as prescribed by Section 382 of the United States Internal Revenue Code; however, the Company has not performed an analysis to determine the amount of any such limitation. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, and other items have generated deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, which is the amount management believes is more likely than not to be realized. Additionally, the Company has provided a full valuation allowance against approximately $9,142,943 of research and development credits, which are available to reduce future income taxes, if any in the future. The research and development credits expire in the years 2018-2032.

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate of 34.5% to pre-tax income as follows:

	2012	2011	2010
Tax at U.S. federal statutory rate	**$ (9,562,620)**	$ (17,804,934)	$ (15,937,695)
State taxes, net of federal benefit	**(900,827)**	(1,677,276)	(1,501,377)
Research and development credits	**(667,308)**	(1,537,863)	(966,941)
Other, net	**66,244**	132,491	133,932
Change in valuation allowance	**10,942,720**	20,887,582	18,272,081
	$ (121,791)	$	$

9. STOCKHOLDERS EQUITY

Authorized and Outstanding Capital Stock

The Company is authorized to issue 200,000,000 shares of common stock, $0.0001 par value per share, 4,687,684 shares of class C special stock, $0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.0001 par value per share.

No shares of preferred stock were outstanding as of December 31, 2012 or 2011.

There were 65,211 and 65,214 shares of class C special stock issued and outstanding as of December 31, 2012 and 2011. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one

share of the Company s common stock, at an exchange price of $15.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of the Company s assets upon any liquidation, dissolution or winding-up of the Company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

There were 24,422,240 and 18,269,754 shares of common stock issued and outstanding as of December 31, 2012 and 2011, respectively. The Company has presented the par values of its common stock and the related additional paid in capital on a combined basis for all periods presented.

Table of Contents

9. STOCKHOLDERS EQUITY (continued)

Reverse Stock Split

On May 30, 2012, the Company s stockholders approved an amendment to the Company s Restated Certificate of Incorporation to effect a reverse split of the Company s outstanding shares of common stock and class C special stock in the discretion of the Company s Board of Directors at an exchange ratio of not less than one-for-two and not more than one-for-ten. On June 1, 2012, the Board of Directors of the Company effected a one-for-six reverse split of the Company s outstanding shares of common stock and class C special stock. No fractional shares were issued as a result of the reverse stock split, and stockholders who otherwise would have been entitled to a fractional share received, in lieu thereof, a cash payment based on the closing sale price of the Company s common stock on June 1, 2012. The total cash payment for fractional shares was $658. The reverse stock split did not change the number of authorized shares of the Company s common stock or class C special stock or the par value of the Company s common stock or class C special stock, but because the number of authorized shares of the Company s common stock and class C special stock was not affected, the effect of the reverse stock split was to increase the number of authorized but unissued shares of the Company s common stock and class C special stock. The primary purpose of the reverse stock split was to increase the Company s ability to maintain the listing of its common stock on The NASDAQ Global Market.

Equity Offerings

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

On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 2.7 million shares of its common stock at a purchase price of $18.00 per share, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses.

On March 8, 2011, the Company completed a registered direct offering of 2,033,247 shares of its common stock and warrants to purchase an aggregate of 670,966 shares of its common stock at a purchase price of $12.3678 per share to institutional investors for gross proceeds of $25.1 million. The offering resulted in net proceeds to the Company of $23.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of $13.50 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 40,663 shares of the Company s common stock at an exercise price of $15.48 per share, which warrants were exercisable immediately and will expire on June 9, 2014.

Table of Contents

9. STOCKHOLDERS EQUITY (continued)

On March 8, 2010, the Company completed a registered direct offering of an aggregate of 1,734,104 shares of its common stock and warrants to an aggregate of 867,048 shares of its common stock, at a purchase price of $10.38 per share to funds affiliated with two institutional investors resulting in net proceeds to the Company of approximately $17.5 million, after deducting placement agent fees and other offering expenses. The warrants are exercisable beginning on September 9, 2010, have an exercise price of $12.48 per share and will expire on September 8, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 34,681 shares of the Company s common stock at an exercise price of $12.96 per share, which warrants were exercisable beginning on September 8, 2010 and will expire on June 9, 2014.

On June 23, 2010, the Company completed a registered direct offering of 1,189,061 shares of its common stock and warrants to purchase an aggregate of 594,525 shares of its common stock at a purchase price of $12.615 per share to funds affiliated with certain institutional investors for gross proceeds of $15.0 million. The offering resulted in net proceeds to the Company of approximately $14.1 million, after deducting placement agent fees and offering expenses. The warrants were exercisable immediately, have an exercise price of $14.70 per share and will expire on June 23, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 35,671 shares of the Company s common stock at an exercise price of $15.78 per share, which warrants were exercisable immediately and will expire on June 9, 2015.

On December 31, 2010, the Company completed a registered direct offering of 1,764,706 shares of its common stock and warrants to purchase an aggregate of 882,348 shares of its common stock at a purchase price of $10.20 per share to funds affiliated with certain institutional investors for gross proceeds of $18.0 million. The offering resulted in net proceeds to the Company of approximately $16.9 million, after deducting placement agent fees and offering expenses. The warrants were exercisable immediately, have an exercise price of $12.00 per share and expire on December 30, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 52,939 shares of the Company s common stock at an exercise price of $12.75, which warrants were exercisable immediately and will expire on June 9, 2015.

Convertible Senior Notes

See Note 7, Convertible Senior Notes for information regarding the Company s convertible senior notes.

Table of Contents

9. STOCKHOLDERS EQUITY (continued)

Warrants

Warrants to purchase an aggregate of 4,738,093 shares of the Company s common stock were outstanding and exercisable as of December 31, 2012:

Issue Date	Number of Underlying Shares Of Common Stock		Per Share Exercise Price	Expiration Date
December 15, 2008	50,000	$	24.00	June 14, 2014
August 13, 2009	399,998	$	15.00	August 12, 2014
August 13, 2009	40,000	$	15.00	June 9, 2014
March 8, 2010	867,048	$	12.48	September 8, 2015
March 8, 2010	34,681	$	12.96	June 9, 2014
June 23, 2010	594,525	$	14.70	June 23, 2015
June 23, 2010	35,671	$	15.78	June 9, 2015
November 22, 2010	30,000	$	12.00	November 21, 2013
December 30, 2010	882,348	$	12.00	December 30, 2015
December 30, 2010	52,939	$	12.75	June 9, 2015
March 8, 2011	670,966	$	13.50	March 8, 2014
March 8, 2011	40,663	$	15.48	June 9, 2014
August 20, 2012	1,039,254	$	1.50	August 16, 2017

During 2012, the Company issued warrants to purchase an aggregate of 1,179,966 shares of the Company s common stock in connection with the August 2012 registered direct offering as described above. During 2012, warrants to purchase an aggregate of 140,712 shares of common stock were exercised and warrants to purchase an aggregate of 95,874 shares of the Company s common stock expired unexercised.

During 2011, the Company issued warrants to purchase an aggregate of 711,629 shares of the Company s common stock in connection with the March 2011 registered direct offering as described above. During 2011, warrants to purchase an aggregate of 1,458 shares of common stock were exercised and warrants to purchase an aggregate of 151,868 shares of the Company s common stock expired unexercised.

During 2010, the Company issued warrants to purchase an aggregate of 2,467,212 shares of the Company s common stock in connection with registered direct offerings as described above, and warrants to purchase 30,000 shares of the Company s common stock as compensation for investor relations services as described below. During 2010, no warrants were exercised and warrants to purchase an aggregate of 127,291 shares of the Company s common stock expired unexercised.

In 2010, the Company issued warrants to purchase 30,000 shares of the Company s common stock in consideration for various investor relations services. The warrants became exercisable on a ratable basis over a twelve-month period from the date of grant. The Company uses the

Black-Scholes pricing model to value these types of warrants and remeasures the awards each quarter until the measurement date is established. For the years ended December 31, 2012, 2011 and 2010, the Company recorded $0, $204,980 and $65,529, respectively, in non-cash general and administrative expense pertaining to consultant warrants.

Table of Contents

10. STOCK-BASED COMPENSATION

The Company has two stockholder-approved equity-based compensation plans under which stock options have been granted the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan except with respect to options outstanding under the 1998 Plan. As of December 31, 2012, the number of shares of the Company s common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan, was 1,833,333 plus the number of shares subject to options outstanding under the 1998 Plan as of the effective date of the 2008 Plan but only to the extent that such outstanding options are forfeited, expire or otherwise terminate without the issuance of such shares. Of such authorized shares, 3,416 shares had been issued and 860,828 shares were subject to outstanding stock options as of December 31, 2012.

Outstanding employee stock options generally vest over a period of three or four years and have 10-year contractual terms. Upon exercise of an option, the Company issues new shares of its common stock. From time to time, the Company grants employee stock options that have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. No performance-based options were outstanding as of December 31, 2012. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan and the 2008 Plan was $725,625, $1,177,683 and $992,757 for the years ended December 31, 2012, 2011 and 2010, 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 weighted average fair value of the options at the date of grant for options granted during 2012, 2011 and 2010 was $4.08, $7.32 and $6.66 per share, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2012	2011	2010
Expected option life (years)	**5.5 6.25**	5.5 6.25	6.00
Risk-free interest rate	**0.775% - 1.105%**	1.175% - 2.57%	2.42%
Expected stock price volatility	**92.97% - 97.20%**	69.07% - 72.16%	76.05%
Dividend yield			

The Company uses the simplified method to estimate the life of options. The risk-free interest 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 calculated a volatility rate based on the closing price for its common stock at the end of each calendar month as reported by The NASDAQ Global Market. The Company has not in the past issued a cash dividend nor does it have any current plans to do so in the future; and therefore, an expected dividend yield of zero was used. Forfeitures are estimated at the time of grant and revised through a cumulative catch-up in the period of change if actual forfeitures differ from those estimates. The Company reduced its workforce during the fourth quarter of 2012 and the termination of employment of these employees resulted in a reversal of previously recognized non-cash stock-based compensation expense related to the forfeiture of non-vested options.

Table of Contents

10. STOCK-BASED COMPENSATION (continued)

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

	2012	2011	2010
Research and development	**$ 53,812**	$ 423,925	$ 325,208
General and administrative	**671,813**	753,758	667,549
Total stock-based compensation expense	**$ 725,625**	$ 1,177,683	$ 992,757

A summary of activity under the Plans during the year ended December 31, 2012 is presented below:

Options	Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value
Outstanding December 31, 2011	906,860	$ 18.36	6.97	$ 0
Granted	358,582	$ 4.08		
Exercised				
Forfeited or expired	160,583	$ 12.90		
Outstanding December 31, 2012	1,104,859	$ 14.51	6.45	$ 0
Exercisable at December 31, 2012	614,425	$ 20.77	4.73	$ 0
Vested or expected to vest at December 31, 2012	1,069,890	$ 14.69	6.39	$ 0

There is no aggregate intrinsic value of the Company s outstanding and exercisable options as of December 31, 2012.

As of December 31, 2012, there was $1,108,898 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 weighted-average period of 1.96 years, however, if the Company s proposed merger with ANI is completed, the cost would then be expected to be recognized in 2013.

The intrinsic value of options exercised during the year ended December 31, 2011 and 2010 was $22,106 and $974, respectively. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position. The total fair value of shares vested during the years ended December 31, 2012, 2011 and 2010 was $701,481, $667,171 and $764,921, respectively.

11. RETIREMENT PLAN

The Company offers a discretionary 401(k) Plan to all of its employees. Under the 401(k) Plan, employees may defer income on a tax-exempt basis, subject to limitations under the Internal Revenue Code of 1986, as amended. Under the 401(k) Plan, the Company may make discretionary matching contributions. Company contributions expensed in 2012, 2011 and 2010 totaled $122,059, $211,494 and $179,349, respectively.

12. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space which expires in 2014. The future minimum lease payments during 2013 and 2014 are $248,632 and $41,718, respectively.

Rent expense amounted to $423,522, $424,294 and $338,588 for the years ended December 31, 2012, 2011 and 2010, respectively.

Table of Contents

13. COMMITMENTS AND CONTINGENCIES

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. In 2012, 2011 and 2010, the Company paid or accrued $550,736, $335,160 and $152,228, respectively, to Antares as a result of royalties generated by Elestrin revenues.

Wake Forest License

In April 2002, the Company exclusively in-licensed from Wake Forest University Health Sciences and Cedars-Sinai Medical Center three issued U.S. patents claiming triple component therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and obtained an option to license the patents for triple component contraception. The financial terms of the license included an upfront payment by the Company in exchange for exclusive rights to the license and regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed. In July 2005, the Company exercised the option for an exclusive license for the three U.S. patents for triple component contraception. The financial terms of this license included an upfront payment, regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed. In December 2012, the Company and Wake Forest University Health Sciences and Cedars-Sinai Medical Center entered into an amendment to the license agreement pursuant to which the Company received a fully paid-up right and exclusive license to the licensed technology in exchange for a $300,000 payment.

The Company has agreed to indemnify, hold harmless and defend Wake Forest University Health Sciences and Cedars-Sinai Medical Center against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation as no events occurred that would require indemnification.

Employee Reduction Implications

As a result of the conclusion of the Company s LibiGel Phase III cardiovascular events and breast cancer safety study, as announced by the Company in September 2012, and in light of the Company s proposed merger with ANI, the Company plans to reduce its workforce during the first quarter of 2013 effective upon completion of the merger. In connection with the announced reduction, the Company will pay $215,979 to non-executive officers in aggregate severance costs during 2013. If the proposed merger with ANI is completed, the employment of the Company s three executive officers will terminate immediately following the completion of the merger and they will be entitled to receive severance cash payments ranging from $526,400 to $1,490,100 and other severance benefits such as continuing health insurance, in connection with such termination.

Pending Litigation

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming the Company and its President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company s disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company s securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (the Exchange Act), Rule 10b-5 and Section 20(a)

Table of Contents

13. COMMITMENTS AND CONTINGENCIES (continued)

of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff seeks to represent a class of persons who purchased the Company s securities between February 12, 2010 and December 15, 2011, and seeks unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. The Company believes the action is without merit and intends to defend the action vigorously. On November 6, 2012, the plaintiff filed a consolidated amended complaint. The Company and Mr. Simes filed motions to dismiss the consolidated amended complaint on December 28, 2012. Briefing on the motion to dismiss is ongoing and is expected to be completed during the first quarter of 2013.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption *Weinstein v. BioSante Pharmaceuticals, Inc. et al*., naming the Company s directors as defendants and the Company as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in the Company s corporate governance and internal control procedures. On September 24, 2012, the District Court consolidated the two cases before it and on November 20, 2012 plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss this complaint. On November 27, 2012, the plaintiff in the action pending in Illinois state court filed an amended complaint. On January 18, 2013, the individual defendants filed a motion to dismiss this complaint. Briefing on these motions is ongoing and is expected to be completed during the first quarter of 2013.

The lawsuits are in their early stages; and, therefore, the Company is unable to predict the outcome of the lawsuits and the possible loss or range of loss, if any, associated with their resolution or any potential effect the lawsuits may have on the Company s operations. Depending on the outcome or resolution of these lawsuits, they could have a material effect on the Company s operations, including its financial condition, results of operations, or cash flows. No amounts have been accrued related to these lawsuits as of December 31, 2012.

14. FAIR VALUE MEASUREMENTS

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

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

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

104

Table of Contents

14. FAIR VALUE MEASUREMENTS (continued)

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

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

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

Description	December 31, 2012 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 34,210,555		$ 34,210,555	
Total assets	$ 34,210,555		$ 34,210,555	
Liabilities:				
2013 Notes	$ 7,883,886		$ 7,883,886	
Total liabilities	$ 7,883,886		$ 7,883,886	

Description	December 31, 2011 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund	$ 55,465,507		$ 55,465,507	
Total assets	$ 55,465,507		$ 55,465,507	
Liabilities:				
2013 Notes	17,336,760		17,336,760	
Total liabilities	$ 17,336,760		$ 17,336,760	

The Company made an election to record the values of the 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earning immediately pursuant to ASC 825. The fair values of the 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company s stock, and the current borrowing rates for similar companies. See Note 7, Convertible Senior Notes for more information and disclosures regarding key assumptions used in this fair value determination.

15. SUBSEQUENT EVENT

On January 31, 2013, the Company entered into an asset purchase agreement with Aduro BioTech, Inc., a clinical-stage immunotherapy company, pursuant to which the Company sold all of its assets related to its GVAX cancer vaccine portfolio in exchange for a $1.0 million up front cash payment plus the potential for future royalty, milestone and sublicense payments.

In January 2013, the Company funded a rabbi trust with approximately $2.3 million of cash for the purpose of providing a funding mechanism to make severance payments to certain executive officers who become entitled to such payments six months after the closing of the proposed merger with ANI. Cash held in the rabbi trust is considered restricted cash based on the terms of the rabbi trust.

Table of Contents

16. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2012 and 2011 is as follows:

	2012			
	First	Second	Third	Fourth
Revenue	$ 114,000	$ 108,780	$ 110,383	$ 1,967,573
Research and development expenses	5,153,217	5,398,305	3,822,736	2,514,591
General and administrative expenses	1,831,852	1,948,995	1,546,864	2,901,812
Licensing expense	30,000	0	50,000	15,000
Operating loss	(6,931,935)	(7,269,453)	(5,334,966)	(3,635,228)
Net loss	(10,264,477)	(7,344,116)	(6,121,815)	(3,987,331)
Loss per share:				
Basic and diluted	$ (0.53)	$ (0.36)	$ (0.27)	$ (0.16)

	2011			
	First	Second	Third	Fourth
Revenue	$ 57,000	$ 81,003	$ 182,784	$ 114,373
Research and development expenses	14,864,420	11,116,323	11,500,053	6,701,465
General and administrative expenses	1,593,557	1,989,103	1,675,268	1,723,562
Licensing expense	0	0	50,000	0
Operating loss	(16,442,921)	(13,064,942)	(13,028,207)	(8,340,710)
Net loss	(17,250,676)	(14,975,231)	(12,733,691)	(6,648,906)
Loss per share:				
Basic and diluted	$ (1.22)	$ (0.96)	$ (0.73)	$ (0.36)

Table of Contents

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

BioSante maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to provide reasonable assurance that the information required to be disclosed by BioSante in the reports it files or submits 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 BioSante s management, including BioSante s 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 BioSante s disclosure controls and procedures, BioSante recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and BioSante is required to apply its judgment in evaluating the cost-benefit relationship of possible internal controls. BioSante s management evaluated, with the participation of BioSante s Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of BioSante s disclosure controls and procedures as of the end of the period covered in this annual report on Form 10-K. Based on that evaluation, BioSante s Chief Executive Officer and Chief Financial Officer concluded that BioSante s disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in BioSante s 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 BioSante is made known to management, including BioSante s Chief Executive Officer and Chief Financial Officer, particularly during the period when BioSante s periodic reports are being prepared.

Management s Report on Internal Control Over Financial Reporting

BioSante s management report on internal control over financial reporting is included in this report in Part II. Item 8, under the heading Management s Report on Internal Control over Financial Reporting.

The report of Deloitte & Touche LLP, BioSante s independent registered public accounting firm, regarding the effectiveness of BioSante s internal control over financial reporting is included in this report in Part II. Item 8, under the heading Report of Independent Registered Public Accounting Firm.

Change in Internal Control Over Financial Reporting

There was no change in BioSante s internal control over financial reporting that occurred during BioSante s fourth quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, BioSante s internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On February 25, 2013, BioSante s Board of Directors, upon recommendation of the Compensation Committee, and after reviewing recent accomplishments of BioSante s management team not relating to BioSante s pending merger with ANI, including in particular the sale of the GVAX cancer vaccines to Aduro BioTech, the amendment to the license and development agreement with Teva and other developments with respect to LibiGel, awarded annual cash bonuses to BioSante s executive and other officers. The amount of the bonuses ranged from $25,000 to $200,000 and, in the case of each executive, amounted to less than, and in

Table of Contents

some cases, substantially less than, target bonuses under BioSante s performance incentive plan. The bonuses to be paid to BioSante s executive officers named in the Summary Compensation Table are found later in this report under the heading Item 11. Executive Compensation Executive Compensation Summary of Cash and Other Compensation and are incorporated herein by reference. The payment of these bonuses will have no effect on the severance payments anticipated to be paid to these individuals upon termination of their employment in connection with the pending merger with ANI. These bonuses will not be paid until March 15, 2013 at the earliest and no earlier than immediately prior to the effective time of the pending merger with ANI. The bonuses will be paid only in the event that the minimum net cash condition under the merger agreement is satisfied. Until payment of these bonuses, the Compensation Committee has the power and authority to revoke, reduce or delay their payment.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

The table below sets forth certain information as of February 15, 2013 that has been furnished to BioSante by each director of BioSante.

Name	Age	Principal Occupation	Director Since
Louis W. Sullivan, M.D.(1)(2)(3)	79	President Emeritus of the Morehouse School of Medicine and Chairman of the Board of Directors of BioSante	1996
Stephen M. Simes	61	Vice Chairman, President and Chief Executive Officer of BioSante	1998
Fred Holubow(1)(3)	74	Principal of Petard Risk Analysis and a General Partner of Starbow Partners	1999
Ross Mangano(1)(2)(3)	67	President of Oliver Estate, Inc.	1999
John T. Potts, Jr., M.D.	81	Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School	2009
Edward C. Rosenow III, M.D.(2)	78	Master Fellow of the American College of Physicians and the American College of Chest Physicians	1997
Stephen A. Sherwin, M.D.(2)(3)	64	Chairman of the Board and Co-Founder of Ceregene, Inc. and Clinical Professor of Medicine at the University of California, San Francisco	2009

(1) Member of the Audit and Finance Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

The paragraphs below provide information about each director of BioSante, including all positions he holds, his principal occupation and business experience for the past five years, and the names of other publicly-held companies of which he currently serves as a director or served as a director during the past five years. BioSante believes that all of its directors display personal and professional integrity; satisfactory levels of education and/or business experience; broad-based business acumen; an appropriate level of understanding of its business and its industry and other industries relevant to its business; the ability and willingness to devote adequate time to the work of the Board of Directors and its

committees; a fit of skills and personality with those of its other directors that helps build a board of directors that is effective, collegial and responsive to the needs of its company; strategic thinking and a willingness to share ideas; a diversity of experiences, expertise and background; and the ability to represent the interests of all of the BioSante stockholders. The information presented below regarding each director also sets forth specific experience, qualifications, attributes and skills that led the Board of Directors to the conclusion that he should serve as a director in light of BioSante s business and structure.

Table of Contents

The Honorable Louis W. Sullivan, M.D. has been BioSante s Chairman of the Board since 1998 and has been a director of BioSante since its formation. Dr. Sullivan served as Secretary of Health and Human Services in the cabinet of President George H.W. Bush from 1989 to 1993. Since retiring from the Bush Administration, Dr. Sullivan has been associated with the Morehouse School of Medicine in Atlanta, Georgia. Currently, he serves as President Emeritus and he previously served as President and Dean of the School from 1981 to 1985 and as President from 1985 to 1989 and from 1993 to 2002. Dr. Sullivan serves on the board of directors of Henry Schein Inc., United Therapeutics Corporation and Emergent BioSolutions Inc. Dr. Sullivan also serves as chairman of the National Health Museum in Atlanta, Georgia and as chairman of the Sullivan Alliance to Increase Diversity in the Health Profession. Dr. Sullivan previously served on the boards of directors of Inhibitex, Inc., 3M Corp., Bristol-Myers Squibb Company, Cigna Corporation and Georgia Pacific Corp.

Dr. Sullivan is an experienced public company director having served as a member of the boards of directors of several large and small public companies. As such, Dr. Sullivan contributes an enhanced knowledge of public company requirements and issues to BioSante s Board of Directors, including corporate governance matters, which are specifically relevant to his role as BioSante s Chairman of the Board and as a member of BioSante s Nominating and Corporate Governance Committee, and executive compensation matters, which are relevant to his role as Chair of BioSante s Compensation Committee. As BioSante s longest serving director having served as a director of BioSante for over 15 years, Dr. Sullivan has a deep and meaningful knowledge of BioSante, business and industry, all of which BioSante believes is helpful and gives important perspective to BioSante s Board of Directors. Finally, Dr. Sullivan is a medical doctor and thus adds medical expertise to BioSante s Board of Directors.

Stephen M. Simes has served as BioSante s Vice Chairman, President and Chief Executive Officer and a director of BioSante since 1998. From 1994 to 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of AbbVie Inc.), a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes s career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.). Mr. Simes currently serves as BioSante s designee on the board of directors of Ceregene, Inc., a privately-held biotechnology company focused on the treatment of major neurodegenerative disorders.

BioSante believes Mr. Simes s qualifications to serve as a member of the Board of Directors include his extensive depth of knowledge of BioSante and its business, management and employees and its day-to-day operations which he has gained through his position as President and Chief Executive Officer of BioSante for over 15 years. As both a member of BioSante s executive team and Board of Directors, Mr. Simes provides a critical link between management and BioSante s Board of Directors, enabling BioSante s Board of Directors to perform its oversight function with the benefits of management s perspectives on the business. In addition, Mr. Simes s extensive experience and knowledge of the pharmaceutical industry as a result of his previous executive positions with other pharmaceutical companies, as well as BioSante, and his involvement with the pharmaceutical industry for over 35 years add tremendous value to BioSante s Board of Directors. Mr. Simes has substantial FDA regulatory and licensing experience which he has gained through his prior positions with other pharmaceutical companies and experience with BioSante, and which has been particularly important to BioSante and his service on BioSante s Board of Directors.

Fred Holubow has been a director of BioSante since 1999. Mr. Holubow is the Principal of Petard Risk Analysis and a General Partner of Starbow Partners, an investor in early stage healthcare ventures. From 2001 to December 2011, Mr. Holubow served as a Managing Director of William Harris Investors, Inc., a registered investment advisory firm. From 1982 to 2001, Mr. Holubow served as Vice President of Pegasus Associates, a registered investment advisory firm he co-founded. He specializes in analyzing and investing in

Table of Contents

pharmaceutical and biotechnology companies. Mr. Holubow previously served on the boards of directors of Micrus Endovascular Corporation, ThermoRetec Corporation, Savient Pharmaceuticals, Inc. (formerly Bio-Technology General Corp.), Gynex Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc.

BioSante believes Mr. Holubow s qualifications to serve as a member of BioSante s Board of Directors include his significant experience of analyzing and investing in pharmaceutical and biotechnology companies both in his current position as a Principal of Petard Risk Analysis and a General Partner of Starbow Partners and in his prior positions as a Managing Director of William Harris Investors and Vice President of Pegasus Associates. In addition, through his experience of serving on the boards of directors and more specifically the audit committees of several other public companies, Mr. Holubow has developed a substantial financial and accounting expertise with pharmaceutical and biotechnology companies, which he contributes to BioSante s Board of Directors and more specifically to BioSante s Audit and Finance Committee in his role as Chair of BioSante s Audit and Finance Committee.

Ross Mangano has been a director of BioSante since 1999. Mr. Mangano has been the President and a director of Oliver Estate, Inc., a management company specializing in investments in public and private companies, since 1971. Mr. Mangano in the past has served on the boards of directors of Cerprobe Corporation, Tower Federal Savings & Loan, Cypress Communications, Inc. and Mego Financial Corp.

BioSante believes Mr. Mangano s qualifications to serve as a member of BioSante s Board of Directors include his significant general business experience as President of Oliver Estate, Inc. and his significant experience analyzing and investing in public and private companies. In addition, BioSante believes Mr. Mangano provides BioSante s Board of Directors valuable business, leadership and management experience and insights into many aspects of BioSante s business. Mr. Mangano is President of JO & Co., which is a significant stockholder of BioSante, and controls all voting and investment power with respect to shares of BioSante common stock held by JO & Co., which BioSante believes gives him and the Board of Directors the perspective of a significant stockholder in making decisions.

John T. Potts, Jr., M.D. has been a director of BioSante since October 2009 when he was elected to the Board of Directors in connection with BioSante s merger with Cell Genesys, Inc. His career spans more than 40 years of service in science and medicine. Dr. Potts is currently the Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School. After medical training at the University of Pennsylvania, he did his internship and residency at Massachusetts General Hospital (MGH) from 1957 to 1959, then went to the National Institutes of Health (NIH) to work with Nobel laureate Christian Anfinsen in protein chemistry. Dr. Potts remained at the NIH from 1959 to 1968, when he returned to the MGH as chief of endocrinology. He served as chairman of the Department of Medicine and physician-in-chief from 1981 to 1996. In his role as director of research from 1995 to 2004, Dr. Potts was responsible for developing strategies for preserving and strengthening the extensive scientific research effort at MGH, an endeavor which he continues to the present. The author or co-author of more than 500 scientific publications, he is a member of the National Academy of Sciences, the Institute of Medicine, and the American Academy of Arts and Sciences. Dr. Potts is a director of Zeltiq Aesthetics, a founder of Radius Health, Inc., and a member of the Scientific Advisory Boards of Radius Health, Inc. and MPM Capital. During the past five years, Dr. Potts previously served on the boards of directors of Cell Genesys, Inc. and Celltaxsys.

BioSante believes Dr. Potts s qualifications to serve as a member of BioSante s Board of Directors include his prior experience as a director of Cell Genesys, Inc. and his familiarity with BioSante s GVAX cancer vaccines and the other technologies BioSante acquired as a result of its merger with Cell Genesys. Dr. Potts is a well accomplished endocrinologist and thus has significant experience and interest in the industry in which BioSante participates.

Edward C. Rosenow, III, M.D. has been a director of BioSante since 1997. Dr. Rosenow is a Master Fellow of the American College of Physicians as well as Master Fellow of the American College of Chest Physicians. Dr. Rosenow was the Arthur M. and Gladys D. Gray Professor of Medicine at the Mayo Clinic

Table of Contents

from 1988 until his retirement in 1996. Beginning with his residency in 1960, Dr. Rosenow has worked at the Mayo Clinic in many professional capacities including as a Consultant in Internal Medicine (Thoracic Diseases) from 1966 to 1996, an Assistant Professor, Associate Professor and Professor of Medicine at the Mayo Clinic Medical School, President of the Mayo Clinic Staff in 1986, and Chair of the Division of Pulmonary and Critical Care Medicine from 1987 to 1994. In 1994, Dr. Rosenow received the Mayo Distinguished Clinician Award. Dr. Rosenow also has served as a consultant to NASA, space station FREEDOM at the Johnson Space Center in Houston, Texas from 1989 to 1990 and as the President of the American College of Chest Physicians from 1989 to 1990. In 1998, he received the Mayo Distinguished Alumnus Award. In 2007, Dr. Rosenow was awarded a named professorship, the Edward C. Rosenow III, M.D. Professorship in the Art of Medicine at the Mayo Clinic School of Medicine, given by Bruce, Martha and Zylpha Clinton. In 2009, he received the Plummer Society Award for Excellence in Medicine.

BioSante believes Dr. Rosenow s qualifications to serve as a member of BioSante s Board of Directors include his significant prior experience as a medical doctor and his interest in the industry in which BioSante participates. As BioSante s second longest serving director having served as a director of BioSante for over 14 years, Dr. Rosenow has a deep and meaningful knowledge of BioSante and its business and industry, all of which BioSante believes is helpful to its Board of Directors.

Stephen A. Sherwin, M.D. has been a director of BioSante since October 2009 when he was elected to the Board of Directors in connection with BioSante s merger with Cell Genesys, Inc. Dr. Sherwin is currently chairman of the board of directors of Ceregene, Inc., a company which he co-founded in 2001 and a Clinical Professor of Medicine at the University of California, San Francisco. Dr. Sherwin served as chief executive officer and a director of Cell Genesys, Inc. from the beginning of company operations in 1990 to October 2009 and as chairman of the board from 1994 to October 2009. From 1983 to 1990, Dr. Sherwin held various positions at Genentech, Inc., most recently as vice president of clinical research. Prior to 1983, Dr. Sherwin was on the staff of the National Cancer Institute. Dr. Sherwin also was a co-founder of Abgenix, Inc., an antibody company, which was acquired by Amgen in 2006. He also is a director of Biogen Idec, Inc., Neurocrine Biosciences, Inc. and Rigel Pharmaceuticals, Inc. and currently chairman emeritus of the Biotechnology Industry Organization (BIO). Dr. Sherwin holds a B.A. in biology from Yale University, an M.D. from Harvard Medical School and is board-certified in internal medicine and medical oncology. During the past five years, Dr. Sherwin previously served on the board of directors of Cell Genesys, Inc.

BioSante believes Dr. Sherwin s qualifications to serve as a member of BioSante s Board of Directors include his prior experience as chief executive officer of Cell Genesys, Inc. and his familiarity with BioSante s GVAX cancer vaccines and other technologies BioSante acquired from Cell Genesys. Dr. Sherwin has extensive knowledge of the life sciences industry and brings to BioSante s Board of Directors more than 25 years of experience in senior leadership positions at large and small publicly traded life sciences companies and as chairman emeritus of BIO. Dr. Sherwin s medical expertise in internal medicine provides a unique contribution to BioSante s Board of Directors. As an experienced public company director and executive, Dr. Sherwin contributes an enhanced knowledge of public company requirements and issues, including corporate governance matters, which are specifically relevant to his role as Chair of BioSante s Nominating and Corporate Governance Committee, and executive compensation matters, which are relevant to his service as a member of BioSante s Compensation Committee.

Table of Contents

Executive Officers

BioSante s executive officers, their ages and the offices held, as of February 15, 2013, are as follows:

Name	Age	Title
Stephen M. Simes	61	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	52	Senior Vice President of Finance, Chief Financial Officer and Secretary
Michael C. Snabes, M.D., Ph.D.	64	Senior Vice President, Medical Affairs

Each of BioSante s executive officers serves at the discretion of BioSante s Board of Directors and holds office until his successor is elected and qualified or until his earlier resignation or removal. There are no family relationships among any of BioSante s directors or executive officers. Information regarding the business experience of BioSante s executive officers is set forth below.

Stephen M. Simes has served as BioSante s Vice Chairman, President and Chief Executive Officer and a director of BioSante since 1998. From 1994 to 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., (currently a wholly owned subsidiary of AbbVie Inc.) a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes s career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.). Mr. Simes currently serves as BioSante s designee on the board of directors of Ceregene, Inc., a privately-held biotechnology company focused on the treatment of major neurodegenerative disorders.

Phillip B. Donenberg, CPA, has served as BioSante s Senior Vice President of Finance since August 2010 and Chief Financial Officer and Secretary since 1998. Before joining BioSante, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of AbbVie Inc.) from 1995 to 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc. (currently Savient Pharmaceuticals, Inc.), Applied NeuroSolutions, Inc. (formerly Molecular Geriatrics Corporation) and Xtramedics, Inc.

Michael C. Snabes, M.D., Ph.D., has served as BioSante s Senior Vice President, Medical Affairs since August 2010. Dr. Snabes also served as BioSante s Vice President of Clinical Development from April 2008 to August 2010. Prior to this, Dr. Snabes served as a medical consultant to BioSante on clinical and regulatory matters since 2005. Before joining BioSante, Dr. Snabes was an Associate Professor in the Section of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at The University of Chicago Pritzker School of Medicine. From 2003 to 2004, Dr. Snabes served as Medical Advisor in Clinical Research and Development in Inflammation, Arthritis, and Pain at Pfizer, Inc., a pharmaceutical company, and from 1999 to 2003 in the same position at Pharmacia, Inc., a pharmaceutical company acquired by Pfizer, where he worked on the successful development of the COX-2 inhibitors, Celebrex and Bextra. From 1997 to 1999, Dr. Snabes served as Associate Director in Clinical Research in Women s Health at Searle/Monsanto. Dr. Snabes is an elected Fellow of the American College of Obstetrics and Gynecology, the American College of Surgeons and the American College of Endocrinology. Dr. Snabes is the author of more than 135 publications and abstracts.

113

Table of Contents

Board Committees

The Board of Directors has three standing committees: Audit and Finance Committee, Compensation Committee and Nominating and Corporate Governance Committee. Each of these committees has the composition and responsibilities described below. The Board of Directors from time to time may establish other committees to facilitate the management of BioSante and may change the composition and the responsibilities of its existing committees. For example, the Board of Directors has established a special Transaction Committee comprised of Mr. Simes, Mr. Holubow and Mr. Mangano to assist the Board in approving certain securities offerings and certain other special transactions. Each of BioSante s three standing committees has a charter which can be found on the Investors Corporate Governance Board Committees section of BioSante s corporate website at *www.biosantepharma.com*.

The table below summarizes the current membership of each of BioSante s three standing board committees.

Director	Audit and Finance	Compensation	Nominating and Corporate Governance
Louis W. Sullivan, M.D.	√	Chair	√
Stephen M. Simes			
Fred Holubow	Chair		√
Ross Mangano	√	√	√
John T. Potts, Jr., M.D.			
Edward C. Rosenow III, M.D.		√	
Stephen A. Sherwin, M.D.		√	Chair

Audit and Finance Committee

***Responsibilities*.** The primary responsibilities of the Audit and Finance Committee include:

- overseeing BioSante s accounting and financial reporting processes, systems of internal control over financial reporting and disclosure controls and procedures on behalf of the Board of Directors and reporting the results or findings of its oversight activities to the Board;

- having sole authority to appoint, retain and oversee the work of BioSante s independent registered public accounting firm and establishing the compensation to be paid to the independent registered public accounting firm;

- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls and/or or auditing matters and for the confidential, anonymous submission by BioSante s employees of concerns regarding questionable accounting or auditing matters;

- reviewing and pre-approving all audit services and permissible non-audit services to be performed for BioSante by its independent registered public accounting firm as provided under the federal securities laws and rules and regulations of the SEC; and

- overseeing BioSante s system to monitor and manage risk, and legal and ethical compliance programs, including the establishment and administration (including the grant of any waiver from) a written code of ethics applicable to each of BioSante s principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

Table of Contents

The Audit and Finance Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition and Audit Committee Financial Expert. The current members of the Audit and Finance Committee are Messrs. Holubow and Mangano and Dr. Sullivan. Mr. Holubow is the chair of the Audit and Finance Committee.

Each current member of the Audit and Finance Committee qualifies as independent for purposes of membership on audit committees pursuant to the Listing Rules of The NASDAQ Stock Market and the rules and regulations of the SEC and is financially literate as required by the Listing Rules of The NASDAQ Stock Market. In addition, the Board of Directors has determined that Mr. Holubow qualifies as an audit committee financial expert as defined by the rules and regulations of the SEC and meets the qualifications of financial sophistication under the Listing Rules of The NASDAQ Stock Market as a result of his Masters in Business Administration in Finance, and his previous experience as an investment analyst and portfolio manager for over 40 years and as a former member of an audit committee of another public company. Stockholders should understand that these designations related to the Audit and Finance Committee members experience and understanding with respect to certain accounting and auditing matters are disclosure requirements of the SEC and The NASDAQ Stock Market and do not impose upon any of them any duties, obligations or liabilities that are greater than those generally imposed on a member of the Audit and Finance Committee or of the Board of Directors.

Compensation Committee

Responsibilities. The primary responsibilities of the Compensation Committee include:

- recommending to the Board of Directors, for its determination, the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to BioSante s chief executive officer and other executive officers;

- reviewing and making recommendations to the Board of Directors regarding any revisions to corporate goals and objectives with respect to compensation for BioSante s chief executive officer and other executive officers and establishing and leading a process for the full Board of Directors to evaluate the performance of BioSante s chief executive officer and other executive officers in light of those goals and objectives;

- administering BioSante s equity-based compensation plans applicable to any employee of BioSante and recommending to the Board of Directors specific grants of options and other awards for all executive officers and determining specific grants of options and other awards for all other employees, under BioSante s equity-based compensation plans; and

- reviewing and discussing with BioSante s President and Chief Executive Officer and reporting periodically to the Board of Directors plans for executive officer development and corporate succession plans for the President and Chief Executive Officer and other key executive

officers and employees.

The Compensation Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Composition. The current members of the Compensation Committee are Dr. Sullivan, Mr. Mangano, Dr. Rosenow and Dr. Sherwin. Dr. Sullivan is the chair of the Compensation Committee. Each of the four current members of the Compensation Committee is an independent director under the Listing Rules of The

Table of Contents

NASDAQ Stock Market and a non-employee director within the meaning of Rule 16b-3 under the Securities Exchange Act of 1934, as amended.

Nominating and Corporate Governance Committee

Responsibilities. The primary responsibilities of the Nominating and Corporate Governance Committee are:

- identifying individuals qualified to become Board members;

- recommending director nominees for each annual meeting of BioSante s stockholders and director nominees to fill any vacancies that may occur between meetings of stockholders;

- being aware of the best practices in corporate governance and developing and recommending to the Board of Directors a set of corporate governance standards to govern the Board of Directors, its committees, the company and its employees in the conduct of the business and affairs of the company;

- developing and overseeing the annual Board and Board committee evaluation process; and

- establishing and leading a process for determination of the compensation applicable to the non-employee directors on the Board.

The Nominating and Corporate Governance Committee has the authority to engage the services of outside experts and advisors as it deems necessary or appropriate to carry out its duties and responsibilities.

Processes and Procedures for Consideration and Determination of Director Compensation. As described in more detail above under the heading Responsibilities, the Board of Directors has delegated to the Nominating and Corporate Governance Committee the responsibility, among other things, to establish and lead a process for determination of compensation payable to BioSante s non-employee directors. The Nominating and Corporate Governance Committee makes recommendations regarding compensation payable to BioSante s non-employee directors to the entire Board of Directors, which then makes the final decisions. Under the terms of its formal written charter, the Nominating and Corporate Governance Committee has the power and authority to delegate any of its duties and responsibilities to subcommittees as the Nominating and Corporate Governance Committee may deem appropriate in its sole discretion. Historically, the Nominating and Corporate Governance Committee has not generally delegated any of its duties and responsibilities to subcommittees, but rather has taken such actions as a committee, as a whole.

In making final recommendations and decisions regarding compensation to be paid to BioSante s directors, the Nominating and Corporate Governance Committee and the Board of Directors consider the recommendations of Radford, an independent compensation consultant, but also other factors, such as its own views as to the form and amount of compensation to be paid, the peer group data provided by Radford, the current and anticipated time demands placed on directors and other factors that may be relevant.

Composition. The current members of the Nominating and Corporate Governance Committee are Dr. Sullivan, Mr. Holubow, Mr. Mangano and Dr. Sherwin. Dr. Sherwin is the chair of the Nominating and Corporate Governance Committee. Each of the four current members of the Nominating and Corporate Governance Committee is an independent director within the meaning of the Listing Rules of The NASDAQ Stock Market.

Table of Contents

Director Nominations Process

Pursuant to a Director Nominations Process adopted by the Board of Directors, in selecting nominees for the Board of Directors, the Nominating and Corporate Governance Committee first determines whether the incumbent directors are qualified to serve, and wish to continue to serve, on the Board. The Nominating and Corporate Governance Committee believes that BioSante and its stockholders benefit from the continued service of qualified incumbent directors because those directors have familiarity with and insight into BioSante s affairs that they have accumulated during their tenure with the company. Appropriate continuity of Board membership also contributes to the Board s ability to work as a collective body. Accordingly, it is the practice of the Nominating and Corporate Governance Committee, in general, to re-nominate an incumbent director at the upcoming annual meeting of stockholders if the director wishes to continue his or her service with the Board, the director continues to satisfy the Nominating and Corporate Governance Committee s criteria for membership on the Board, the Nominating and Corporate Governance Committee believes the director continues to make important contributions to the Board, and there are no special, countervailing considerations against re-nomination of the director.

Pursuant to the Director Nominations Process adopted by the Board of Directors, in identifying and evaluating new candidates for election to the Board, the Nominating and Corporate Governance Committee intends to first solicit recommendations for nominees from persons whom the Nominating and Corporate Governance Committee believes are likely to be familiar qualified candidates having the qualifications, skills and characteristics required for Board nominees from time to time. Such persons may include members of the Board of Directors and senior management of BioSante. In addition, the Nominating and Corporate Governance Committee may engage a search firm to assist it in identifying qualified candidates. The Nominating and Corporate Governance Committee then intends to review and evaluate each candidate whom it believes merits serious consideration, taking into account available information concerning the candidate, any qualifications or criteria for Board membership established by the Nominating and Corporate Governance Committee, the existing composition of the Board, and other factors that it deems relevant. In conducting its review and evaluation, the Nominating and Corporate Governance Committee may solicit the views of BioSante s management, other Board members, and any other individuals it believes may have insight into a candidate. The Nominating and Corporate Governance Committee may designate one or more of its members and/or other Board members to interview any proposed candidate.

The Nominating and Corporate Governance Committee will consider recommendations for the nomination of directors submitted by BioSante s stockholders. The Nominating and Corporate Governance Committee will evaluate candidates recommended by stockholders in the same manner as those recommended as stated above.

There are no formal requirements or minimum qualifications that a candidate must meet in order for the Nominating and Corporate Governance Committee to recommend the candidate to the Board of Directors. The Nominating and Corporate Governance Committee believes that each nominee should be evaluated based on his or her merits as an individual, taking into account the needs of BioSante and the Board of Directors. However, in evaluating candidates, there are a number of criteria that the Nominating and Corporate Governance Committee generally views as relevant and is likely to consider. Some of these factors include:

- whether the candidate is an independent director under the Listing Rules of The NASDAQ Stock Market and meets any other applicable independence tests under the federal securities laws and rules and regulations of the SEC;

- whether the candidate is financially sophisticated and otherwise meets the requirements for serving as a member of an audit committee under the Listing Rules of The NASDAQ Stock Market;

Table of Contents

- whether the candidate is an audit committee financial expert under the rules and regulations of the SEC;

- the needs of BioSante with respect to the particular talents and experience of BioSante s directors;

- the personal and professional integrity and reputation of the candidate;

- the candidate s level of education and business experience;

- the candidate s broad-based business acumen;

- the candidate s level of understanding of BioSante s business and its industry and other industries relevant to BioSante s business;

- the candidate s ability and willingness to devote adequate time to work of the Board of Directors and its committees;

- the fit of the candidate s skills and personality with those of other directors and potential directors in building a board of directors that is effective, collegial and responsive to the needs of BioSante;

- whether the candidate possesses strategic thinking and a willingness to share ideas;

- the candidate s diversity of experiences, expertise and background; and

- the candidate s ability to represent the interests of all stockholders and not a particular interest group.

While BioSante does not have a stand-alone diversity policy, in considering whether to recommend any director nominee, including candidates recommended by stockholders, the Nominating and Corporate Governance Committee will consider the factors above, including the candidate s diversity of experiences, expertise and background. The Nominating and Corporate Governance Committee seeks nominees with a broad diversity of experience, expertise and backgrounds. The Nominating and Corporate Governance Committee does not assign specific weights to

particular criteria and no particular criterion is necessarily applicable to all prospective nominees. BioSante believes that the backgrounds and qualifications of the directors, considered as a group, should provide a significant mix of experience, knowledge and abilities that will allow the Board of Directors to fulfill its responsibilities.

During the fourth quarter of 2012, BioSante made no material changes to the procedures by which stockholders may recommend nominees to the Board of Directors, as described in BioSante s most recent proxy statement.

Code of Conduct and Ethics

BioSante s Code of Conduct and Ethics applies to all of BioSante s employees, officers and directors, including BioSante s principal executive officer and principal financial officer, and meets the requirements of the Securities and Exchange Commission. A copy of BioSante s Code of Conduct and Ethics is filed as an exhibit to this report. BioSante intends to satisfy the disclosure requirements of Item 5.05 of Form 8-K and The NASDAQ Global Market regarding amendments to or waivers from any provision of BioSante s Code of Conduct and Ethics by posting such information on BioSante s corporate website located at www.biosantepharma.com.

Table of Contents

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires BioSante s directors and executive officers and all persons who beneficially own more than 10 percent of the outstanding shares of BioSante common stock to file with the SEC initial reports of ownership and reports of changes in ownership of BioSante common stock. Directors, executive officers and greater than 10 percent beneficial owners also are required to furnish BioSante with copies of all Section 16(a) forms they file. To BioSante s knowledge, based on review of the copies of such reports and amendments to such reports furnished to BioSante with respect to the year ended December 31, 2012, and based on written representations by BioSante s directors and executive officers, all required Section 16 reports under the Securities Exchange Act of 1934, as amended, for BioSante s directors, executive officers and beneficial owners of greater than 10 percent of BioSante common stock were filed on a timely basis during the year ended December 31, 2012.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

In this Compensation Discussion and Analysis, or CD&A, BioSante describes the key principles and approaches it uses to determine elements of compensation paid to, awarded to and earned by the following named executive officers, whose compensation is set forth in the Summary Compensation Table found later in this report:

- Stephen M. Simes, who serves as BioSante s Vice Chairman, President and Chief Executive Officer, or CEO ;
- Phillip B. Donenberg, who serves as BioSante s Senior Vice President of Finance, Chief Financial Officer and Secretary, or CFO ; and
- Michael C. Snabes, M.D., Ph.D., who serves as BioSante s Senior Vice President of Medical Affairs.

This CD&A should be read in conjunction with the accompanying compensation tables, corresponding notes and narrative discussion, as they provide additional information and context to BioSante s compensation disclosures.

Key 2012 and Recent Compensation-Related Actions

During 2012, BioSante took a number of actions that supported BioSante s executive compensation philosophy and objective of ensuring that BioSante s executive compensation program reinforces pay for performance, is market competitive in order to attract and retain key employees and is aligned with the interests of BioSante stockholders.

- BioSante s Compensation Committee consulted with an independent compensation consultant, Radford, an Aon Hewitt Company, to provide advice to BioSante s Compensation Committee with respect to executive compensation, and during 2011, at the request of the Compensation Committee, Radford recommended a peer group of companies, collected relevant market data from these companies to allow the Compensation Committee to compare elements of BioSante s compensation program to those of BioSante s peers, provided information on executive compensation trends and implications for BioSante and made other recommendations to BioSante s Compensation Committee regarding certain aspects of BioSante s executive compensation program.

Table of Contents

- In light of the results of BioSante s two LibiGel Phase III efficacy trials and in the interests of conserving cash, BioSante froze the base salaries of all executives and other employees for 2012.

- In light of changes in BioSante s corporate strategy during 2012, BioSante did not establish formal bonus goals under its annual performance incentive plan in the beginning of 2012 or otherwise, as is permitted under the annual performance incentive plan. However, in accordance with the terms of the performance incentive plan which allows for flexibility and discretion by the Compensation Committee and the Board, in February 2013, after reviewing recent accomplishments of BioSante s management team, not relating to the pending merger with ANI, including in particular the sale of the GVAX cancer vaccines to Aduro BioTech, the amendment to the license and development agreement with Teva and other developments with respect to LibiGel, the Board of Directors, upon recommendation of the Compensation Committee, awarded annual cash bonuses to BioSante s executive and other officers, although such bonuses amounted to less than, and in some cases substantially less than, target bonuses under BioSante s annual performance incentive plan.

- At BioSante s 2011 Annual Meeting of Stockholders, BioSante s stockholders had the opportunity to provide an advisory vote on the compensation paid to BioSante s named executive officers, or a say-on-pay vote. Approximately 67 percent of the votes cast by BioSante s stockholders were in favor of the say-on-pay vote. While the Compensation Committee believes that such results generally affirmed stockholder support of BioSante s approach to executive compensation and did not make any significant changes to BioSante s executive compensation program solely in response to the vote, the Compensation Committee, nonetheless, has kept and intends to continue to keep a watchful eye on BioSante s executive compensation program in order to ensure that it reinforces pay for performance, is market competitive in order to attract and retain key employees and is aligned with the interests of BioSante s stockholders.

- At BioSante s 2011 Annual Meeting of Stockholders, BioSante s stockholders had the opportunity to provide an advisory vote on the frequency with which they believed BioSante should hold a say-on-pay vote. In response to the voting results for the frequency of the say-on-pay vote, in which the frequency of a say-on-pay vote every three years received the highest number of votes, BioSante intends to provide BioSante s stockholders with the opportunity to provide a say-on-pay advisory vote every three years until the next required vote on the frequency of a say-on-pay vote.

Compensation Best Practices

BioSante maintains certain compensation best practices, which support BioSante s executive compensation objectives and philosophy, as well as benefit the BioSante stockholders. Some of these practices include the following:

- BioSante ties compensation directly to performance. Payouts under BioSante s performance incentive plan typically are based on pre-determined corporate and individual performance goals. For BioSante s performance incentive plan payouts, BioSante requires that certain minimum threshold levels of performance be met in order for there to be a payout, and even if maximum levels of performance are exceeded, BioSante s performance incentive plan payouts are capped at 150 percent of target. As mentioned above, and as is permitted under BioSante s annual performance incentive plan in light of changes in BioSante s corporate strategy during 2012, BioSante did not establish formal bonus goals under its performance incentive plan in the beginning of 2012 or otherwise. However, in accordance with the terms of the performance incentive plan which allows for flexibility and discretion by the Compensation Committee and the Board, in February 2013, after reviewing recent accomplishments of BioSante s management team, not relating to the pending merger with ANI, including in particular the sale of the GVAX

120

Table of Contents

cancer vaccines to Aduro BioTech, the amendment to the license and development agreement with Teva and other developments with respect to LibiGel, the Board of Directors, upon recommendation of the Compensation Committee, awarded annual cash bonuses to BioSante s executive and other officers, although such bonuses amounted to less than and, in some cases substantially less than, target bonuses under BioSante s annual performance incentive plan.

- A significant portion of BioSante s executives compensation is typically performance-based or at risk.

- Value received under BioSante s long-term equity-based incentive awards is tied to four-year vesting and any value received by BioSante s executives from stock option grants is contingent upon long-term stock price performance in that the stock options only have value if the price of BioSante common stock exceeds the exercise price of the options.

- Although BioSante does not have any detailed stock retention or ownership guidelines, the Board of Directors has adopted Corporate Governance Standards that address ownership of BioSante common stock by BioSante s executives and which encourage BioSante s executives to have a financial stake in BioSante in order to align the interests of BioSante stockholders and management.

- BioSante s stock incentive plan and related award agreements include a clawback mechanism, which gives BioSante the right to cancel an executive s stock awards and require the executive to surrender and return to BioSante any profit from such awards if the executive engages in certain acts of wrongdoing.

- BioSante does not provide tax gross up payments under BioSante s employment agreements or in connection with any other compensation, benefits or perquisites provided to BioSante s executives, with the exception of payment of taxes associated with reimbursements for supplemental life insurance and excess long-term disability insurance premiums to BioSante s CEO and CFO which amounted to approximately $7,000 for BioSante s CEO and CFO in 2012.

- BioSante provides only limited and immaterial perquisites to BioSante s executives as described under Executive Compensation Components All Other Compensation.

Compensation Objectives and Philosophy

BioSante s executive compensation program is designed to:

- Attract and retain executives important to the success of BioSante and the creation of value for BioSante s stockholders;

- Motivate BioSante s executives to achieve company and individual performance objectives and create stockholder value; and

- Reward BioSante s executives for the achievement of company and individual performance objectives, the creation of stockholder value in the short and long term and their contributions, in general, to the success of BioSante.

In order to achieve these objectives, the Compensation Committee and the Board of Directors make compensation decisions based on the following philosophy and principles:

- BioSante favors having a significant component of compensation tied to the achievement of corporate and individual goals over solely fixed compensation.

Table of Contents

- BioSante seeks to reward achievement of key corporate goals that create value for BioSante s stockholders, such as successful clinical testing, obtaining regulatory approvals for BioSante s products, executing in-licensing and out-licensing agreements, entering into strategic relationships to develop, market and sell BioSante s products and raising additional financing on terms favorable to BioSante.

- A greater percentage of total compensation should be tied to performance, and therefore at risk, as position and responsibility increases. Individuals, such as BioSante s executives, with greater roles and responsibilities associated with achieving BioSante s objectives should bear a greater proportion of the risk if those objectives are not achieved than other employees and should receive a greater proportion of the reward if objectives are met or surpassed.

- BioSante seeks to align the interests of BioSante s executives with the interests of BioSante stockholders through the use of long-term, equity-based incentive compensation in the form of stock options and further emphasized through change in control arrangements which are designed to provide financial motivation to BioSante s executives to complete a transaction that the Board of Directors believes is in the best interests of BioSante stockholders.

How BioSante Determines Compensation

In order to implement effectively BioSante s compensation objectives and philosophy, there are several individuals and groups of individuals involved in making executive compensation decisions. These individuals and groups and their roles are described briefly below.

Role of Compensation Committee and Board. The responsibilities of BioSante s Compensation Committee include recommending to the Board of Directors, for its determination, the annual salaries, incentive compensation, long-term incentive compensation, special or supplemental benefits or perquisites and any and all other compensation applicable to BioSante s CEO and other executive officers; reviewing and making recommendations to the Board of Directors regarding any revisions to corporate goals and objectives with respect to compensation for BioSante s CEO and other executive officers and establishing and leading a process for the full Board of Directors to evaluate the performance of BioSante s CEO and other executive officers in light of those goals and objectives. Typically, the Compensation Committee makes recommendations and the Board of Directors approves such recommendations.

In setting or recommending executive compensation for BioSante s named executive officers and other officers, the Compensation Committee considers the following primary factors:

- each executive s position within the company and the level of responsibility;

- the ability of the executive to affect key business initiatives;

- the executive s individual experience and qualifications;
- compensation paid to executives of comparable positions by companies similar to BioSante;
- company performance, generally and as compared to specific goals;
- individual performance, generally and as compared to specific goals;
- the executive s current and historical compensation levels;
- recommendations of BioSante s CEO;

Table of Contents

- advancement potential and succession planning considerations;

- an assessment of the risk that the executive would leave BioSante and the harm to BioSante s business initiatives if the executive left;

- the retention value of executive equity holdings, including outstanding stock options; and

- the dilutive effect on BioSante s stockholders of long-term equity-based incentive awards; and

- BioSante s cash position and anticipated ability to raise any necessary additional financing.

The significance of any individual factor described above in setting executive compensation will vary from year to year and may vary among BioSante s executives. In making recommendations and decisions regarding the form and amount of compensation to be paid to BioSante s named executive officers (other than BioSante s CEO) and other officers, BioSante s Compensation Committee considers and gives weight to the recommendations of BioSante s CEO recognizing that due to his reporting and otherwise close relationship with each executive, the CEO often is in a better position than the Compensation Committee to evaluate the performance of each executive (other than himself). In making recommendations and decisions regarding the form and amount of compensation to be paid to BioSante s CEO, the Compensation Committee considers the recommendation of the CEO with respect to his own compensation and the Compensation Committee s own assessment of the CEO s annual performance and input from BioSante s other Board members. The Compensation Committee meets in executive session with its independent compensation consultant and counsel without the presence of the CEO or any executive or employee of BioSante regularly and makes all compensation decisions without the presence of the CEO or any executive or employee of BioSante. In making final executive compensation decisions, the Board of Directors typically accepts and approves the recommendations of the Compensation Committee and makes any such decision without the presence of the CEO or any executive or employee of BioSante.

Role of Management. BioSante s CEO assists BioSante s Compensation Committee primarily by making formal recommendations regarding the amount and type of compensation to be paid to BioSante s executives (including himself). In making such recommendations, BioSante s CEO considers many of the same factors listed above that the Compensation Committee considers in setting or recommending executive compensation, including in particular an assessment of each executive s annual performance and the executive s achievement of his or her pre-established individual performance goals established in connection with BioSante s performance incentive plan described below. Final deliberations and decisions regarding the compensation to be paid to each of BioSante s executives, however, are made by BioSante s Board of Directors and Compensation Committee without the presence of the CEO or any of the executives.

Role of Consultant. BioSante s Compensation Committee has retained the services of Radford to provide advice with respect to executive compensation. Radford was engaged directly by BioSante s Compensation Committee and did not advise BioSante s management and only worked with management with the express permission of the Compensation Committee. Radford did not provide any services to BioSante other than those for which it was retained by the Compensation Committee.

Although Radford s role during 2012 was much more limited than in prior years, Radford s engagement by the Compensation Committee typically includes reviewing and advising on all significant aspects of executive compensation. This includes base salaries, short-term cash incentives and long-term equity incentives for BioSante s executive and other officers, and cash compensation and long-term equity incentives for BioSante s non-employee directors. In so doing, at the request of the Compensation Committee, Radford typically recommends a peer group of companies, collects relevant market data from these companies to allow the Compensation Committee to compare elements of BioSante s compensation program to those of BioSante s peers, provides information on executive compensation trends and implications for BioSante and makes other recommendations to the Compensation Committee regarding certain aspects of BioSante s

Table of Contents

executive compensation program. BioSante s CEO, the chair of BioSante s Compensation Committee and BioSante s outside legal counsel typically regularly consult with representatives of Radford prior to Compensation Committee meetings. A representative of Radford periodically attends meetings of BioSante s Compensation Committee. In making recommendations and decisions regarding the form and amount of compensation to be paid to BioSante s executives, BioSante s Compensation Committee considers the information gathered by and recommendations of Radford. The Compensation Committee values especially Radford s benchmarking information and input regarding best practices and trends in executive compensation matters, especially with respect to small public companies in the biopharmaceutical and life sciences industry.

Use of Peer Group Data. To assist BioSante s Compensation Committee and Board of Directors in determining appropriate levels of compensation for certain elements of BioSante s executive compensation program, BioSante s Compensation Committee reviews typically annually the compensation levels of BioSante s named executive officers and other officers against the compensation levels of comparable positions with companies similar to BioSante in terms of products, revenue, market capitalization and number of employees. The elements of BioSante s executive compensation program to which the Compensation Committee benchmarks or uses to base or justify a compensation decision or to structure a framework for compensating executives include base salary, short-term cash incentive opportunity and long-term equity incentives. With respect to other elements of BioSante s executive compensation program, such as perquisites, severance and change in control arrangements, BioSante s Compensation Committee benchmarks these elements on a periodic or as needed basis and in some cases uses peer group or market data more as a market check after determining the compensation on some other basis.

The Compensation Committee believes that compensation paid by peer group companies is representative of the compensation required to attract, retain and motivate BioSante s executive talent. BioSante s Compensation Committee believes that use of a peer group provides more relevant comparisons for purposes of benchmarking than broader survey data since the Compensation Committee believes that the compensation paid by the peer companies which are in the same business, with similar products and operations, and with revenue and market capitalization in a range similar to ours is typically more representative than broader survey data.

In November 2010, Radford worked with BioSante s Compensation Committee to identify a peer group of 20 other publicly-held life science companies in late stage clinical development, with market capitalizations, revenues and organization sizes similar to BioSante. Almost all of the members of BioSante s peer group at the time the peer group was created had a market capitalization between $50 million and $450 million, revenue of less than $125 million and an organization size of under 300 employees. The Compensation Committee used this information to assist it in determining the amount of base salary, target annual incentive compensation, target total compensation and the form and amount of long-term equity-based incentive compensation to pay BioSante s executives during 2011 and 2012. BioSante used the same peer group for purposes of analyzing BioSante s director compensation program in 2011 and 2012.

The companies in the peer group included:

Alexza Pharmaceuticals, Inc.	Antares Pharma, Inc.	Cornerstone Therapeutics Inc.
Curis, Inc.	Cytokinetics, Incorporated	CytRx Corporation
Dyax Corp.	GTx, Inc.	Idenix Pharmaceuticals, Inc.
Inspire Pharmaceuticals, Inc.	Ista Pharmaceuticals, Inc.	Jazz Pharmaceuticals, Inc.
Ligand Pharmaceuticals Incorporated	NPS Pharmaceuticals, Inc.	Omeros Corporation
OncoGenex Pharmaceuticals, Inc.	Oncothyreon Inc.	Pozen Inc.
Progenics Pharmaceuticals, Inc.	Sucampo Pharmaceuticals, Inc.	

In light of the fact that base salaries for BioSante s executive officers and employees were frozen in January 2012 and in order to conserve cash resources, the Compensation Committee did not request Radford to update the benchmarking data in 2012.

Table of Contents

In reviewing benchmarking data, the Compensation Committee recognizes that benchmarking may not always be appropriate as a stand-alone tool for setting compensation due to the aspects of BioSante s business and objectives that may be unique to BioSante. Nevertheless, the Compensation Committee believes that gathering this information is an important part of its compensation-related decision-making process. The Compensation Committee believes that compensation paid by peer group companies is representative of the compensation required to attract, retain and motivate BioSante s executive talent. However, where a sufficient basis for comparison does not exist between the peer group data and an executive, the Compensation Committee gives less weight to the peer group data. For example, relative compensation benchmarking analysis does not consider individual specific performance or experience or other case-by-case factors that may be relevant in hiring or retaining a particular executive.

Market Positioning. The Compensation Committee targets base salary, target total cash compensation and target total direct compensation at the 50th percentile of companies in BioSante s peer group. The Compensation Committee believes that median positioning attracts and retains executive talent, but at the same time recognizes BioSante s cost structure, especially with respect to fixed base compensation. The actual target compensation for each individual executive may be higher or lower than the targeted market position based on the individual s skills, experience, contribution, performance, tenure or other factors that the Compensation Committee may take into account that are relevant to the individual executive.

Executive Compensation Components

The principal elements of BioSante s executive compensation program for 2012 were:

- base salary;
- short-term cash incentive compensation;
- long-term equity-based incentive compensation, in the form of stock options; and
- other compensation arrangements, such as benefits made generally available to BioSante s other employees, limited executive benefits and perquisites, and severance and change in control arrangements.

In determining the form of compensation to pay BioSante s named executive officers and other officers, the Compensation Committee views these elements of BioSante s executive compensation program as related but distinct. The Compensation Committee does not believe that significant compensation derived by an executive from one element of BioSante s compensation program should necessarily result in a reduction in the amount of compensation the executive receives from other elements. At the same time, the Compensation Committee does not believe that minimal compensation derived from one element of compensation should result necessarily in an increase in the amount the executive should receive from one or more other elements of compensation.

Except as described below, the Compensation Committee has not adopted any formal or informal policies or guidelines for allocating compensation between long-term and currently paid out compensation, between cash and non-cash compensation, or among different forms of non-cash compensation. However, the Compensation Committee s philosophy is to make a greater percentage of an executive s compensation performance-based, and therefore at risk, as the executive s position and responsibility increases given the influence more senior level executives generally have on company performance. Thus, individuals with greater roles and responsibilities associated with achieving BioSante s objectives should bear a greater proportion of the risk if those goals are not achieved and should receive a greater proportion of the reward if objectives are met or surpassed. For example, this philosophy is illustrated by the higher cash incentive targets and equity-based awards of BioSante s CEO as compared to BioSante s other two named executive officers.

Table of Contents

Base Salary

BioSante provides a base salary for BioSante s named executive officers and other officers, which, unlike some of the other elements of BioSante s executive compensation program, is not subject to company or individual performance risk. BioSante recognizes the need for most executives to receive at least a portion of their total compensation in the form of a guaranteed base salary that is paid in cash semi-monthly throughout the year.

BioSante initially fixes base salaries for BioSante s executives at a level BioSante believes enables BioSante to hire and retain them in a competitive environment and to reward satisfactory individual performance and a satisfactory level of contribution to BioSante s overall business objectives. BioSante typically increases the base salaries of its executives in the beginning of each year in an amount equal to an approximate cost of living adjustment. BioSante does so to recognize annual increases in the cost of living and to ensure that its base salaries remain market competitive. In addition, BioSante may make additional upward adjustments to a particular executive s base salary to compensate an executive for assuming increased roles and responsibilities, to reward an executive for superior individual performance, to retain an executive at risk of recruitment by other companies, and/or to bring an executive s base salary closer to the 50th percentile of companies in BioSante s peer group.

The table below shows the base salaries for BioSante s named executive officers for 2011, 2012 and 2013 and the percentage increases between periods:

Named Executive Officer	2011	2012	Percent Change	2012	2013	Percent Change
Mr. Simes	$ 496,700	$ 496,700	0.0%	$ 496,700	$ 496,700	0.0%
Mr. Donenberg	308,000	308,000	0.0%	308,000	308,000	0.0%
Dr. Snabes	376,000	376,000	0.0%	376,000	376,000	0.0%

In January 2012, the Board of Directors, upon recommendation of the Compensation Committee, determined base salaries for 2012. Although BioSante believes its two LibiGel Phase III efficacy trials were well executed and completed in a timely fashion, in light of the results of those trials and in the interests of conserving cash, no merit or other increases were made to the base salaries of any of BioSante s executives or other employees.

In 2011, when the base salaries of BioSante s named executive officers were last increased, Mr. Simes s and Mr. Donenberg s base salaries were between the peer 25th and 50th percentile and Dr. Snabes s base salary was above the peer 75th percentile. Since his initial hiring as an executive of BioSante, Dr. Snabes s base salary has been above market primarily because of his historical compensation prior to BioSante hiring him as an executive and his background and experience as a medical doctor.

Short-Term Cash Incentive Compensation

BioSante s short-term cash incentive compensation is intended to be paid as an annual bonus or payout under BioSante s performance incentive plan. Under the terms of BioSante s performance incentive plan, each participant, including BioSante s executive officers, is eligible to earn a

bonus based primarily on the achievement of corporate and individual performance goals that may be achieved over a period of time (e.g., during a calendar year). The performance incentive plan is designed to reward eligible employees for achieving certain corporate and individual performance goals and to align closely their accomplishments with the interests of BioSante s stockholders.

Each participant has an annual incentive target bonus under the plan, expressed as a percentage of his or her annual base salary. Each participant s target bonus percentage is based on the individual s position and level of responsibility within the company. Each participant s payout under the performance incentive plan is

Table of Contents

determined by multiplying the participant s annual incentive target bonus amount (the participant s target bonus percentage times his or her annual base salary) by a payout percentage equal to between 0 percent and 150 percent and determined based primarily on the achievement of corporate and, in most cases, individual performance goals. The maximum payout percentage is 150 percent and the minimum threshold payout percentage is 50 percent, with no payout for performance below the minimum threshold payout percentage of 50 percent.

To determine payouts, all corporate and individual performance goals typically are rated (on a scale from one to five with a rating of three representing target or on plan performance) and then weighted based on relative importance in order to obtain a weighted performance rating for each goal. All weighted performance ratings typically are added together to obtain an overall rating for each executive. An aggregate average for all of the goals must meet at least a 1.5 to meet the minimum 50 percent payout threshold. Increments between rating levels are interpolated on a linear basis to determine an actual incentive percentage. For example, an overall rating of 3.5 equaled a 112.5 percent incentive percentage. For each executive, the actual incentive percentage was multiplied by the target bonus percentage to calculate the award. For example, a 112.5 percent actual incentive percentage times 50 percent target bonus equaled an award of 56.3 percent of base salary.

Annual Incentive Targets. The annual incentive target for each named executive officer under the plan is set forth in the table below, as well as the threshold, target and maximum annual bonus opportunity.

	Annual Incentive Target	**Annual Bonus Opportunity for Each Executive**		
Named Executive Officer	**(% of Base Salary)**	**Threshold (50%)**	**Target (100%)**	**Maximum (150%)**
Mr. Simes	60%	$ 149,010	$ 298,020	$ 447,030
Mr. Donenberg	40%	61,600	123,200	184,800
Dr. Snabes	40%	75,200	150,400	225,600

Consistent with BioSante s philosophy that executives with greater roles and responsibilities associated with achieving BioSante s performance objectives should bear a greater proportion of the risk that those objectives are not achieved and should receive a greater proportion of the reward if the objectives are met or surpassed, BioSante s CEO has the highest annual incentive target and BioSante s two Senior Vice Presidents have the next highest annual incentive targets. Based on an executive compensation analysis by Radford in November 2010, the annual incentive targets of all of BioSante s executive officers are at the 50th percentile of comparable positions of companies in BioSante s peer group, which is consistent with BioSante s philosophy that BioSante target total cash compensation and target total direct compensation at the 50th percentile of companies in BioSante s peer group, except in the case of Dr. Snabes, whose incentive target is at the 75th percentile compared to the incentive targets of executives with comparable positions at companies in BioSante s peer group. At the recommendation of Radford, the Compensation Committee set Dr. Snabes s target bonus percentage at the same level as Mr. Donenberg s since both executives are Senior Vice Presidents and the Compensation Committee believes that positions of similar scope and impact should have the same pay-at-risk as a percent of salary.

In setting the annual incentive targets for BioSante s named executive officers, the Compensation Committee considered the resulting target total cash compensation (sum of annual base salary and target annual cash incentive award) and the comparison to the peer 50th percentile. Mr. Simes s target total cash compensation was slightly above the peer 50th percentile and Mr. Donenberg s target total cash compensation was slightly below the peer 50th percentile. Dr. Snabes s target total cash compensation was significantly above the peer 50th percentile because as previously discussed, both Dr. Snabes s base salary and incentive target is more aligned with the 75th percentile than the 50th percentile based on his prior experience and compensation when joining BioSante.

Performance Goals. In light of changes in BioSante s corporate strategy during 2012, BioSante did not establish formal performance goals under its performance incentive plan for 2012.

Table of Contents

2012 Payouts. In light of changes in BioSante s corporate strategy during 2012, BioSante did not establish formal bonus goals under its annual performance incentive plan in the beginning of 2012 or otherwise, as is permitted under the annual performance incentive plan.. However, in accordance with the terms of the performance incentive plan which allows for some flexibility and discretion, in February 2013, after reviewing recent accomplishments of BioSante s management team, not relating to the pending merger with ANI, including in particular the sale of the GVAX cancer vaccines to Aduro BioTech, the amendment to the license and development agreement with Teva and other developments with respect to LibiGel, the Board of Directors, upon recommendation of the Compensation Committee, awarded annual cash bonuses to BioSante s executive and other officers. The amount of the bonuses ranged from $25,000 to $200,000 and, in the case of each executive, amounted to less than, and in some cases substantially less than, target bonuses under the performance incentive plan. The bonuses to be paid to BioSante s named executive officers are as follows: Stephen M. Simes, Vice Chairman, President and Chief Executive Officer ($200,000); Phillip B. Donenberg, Senior Vice President, Chief Financial Officer and Secretary ($100,000) and Michael C. Snabes, M.D., Ph.D., Senior Vice President, Medical Affairs ($25,000). The amount of the bonuses was determined by the Compensation Committee based on its determination as to each executive s individual efforts with respect to the specific accomplishments upon which the bonuses were paid. Although the bonuses are not being paid in connection with BioSante s merger transaction with ANI or as a result of the merger, because of the importance of net cash in the merger agreement between BioSante and ANI and the acknowledgement by BioSante that the bonuses will reduce BioSante s net cash, the bonuses will not be paid until shortly before completion of the merger so as to give the BioSante Board of Directors continuing comfort that there will be no issue with the minimum net cash condition to completion of the merger or any other condition to completion of the merger as a result of the payment of the bonuses.

Long-Term Equity-Based Incentive Compensation

Although BioSante does not have any detailed stock retention or ownership guidelines, the Board of Directors has adopted Corporate Governance Standards that address ownership of BioSante common stock by BioSante s executives and which encourage BioSante s executives to have a financial stake in BioSante in order to align the interests of BioSante stockholders and management. BioSante s Compensation Committee s primary objectives with respect to long-term equity-based incentives are to align the long-term interests of BioSante s executives with the long-term interests of BioSante stockholders by creating a strong and direct linkage between compensation and long-term stockholder return, promote stock ownership and create significant incentives for retention. Long-term equity-based incentives typically comprise a significant portion of each named executive officer s compensation package, consistent with BioSante s executive compensation philosophy discussed above. For 2012, equity-based compensation comprised 36.6 percent of the total compensation for BioSante s CEO, 25.5 percent and 17.1 percent of the total compensation for BioSante s other two named executive officers, assuming grant date fair value for equity awards. For 2011, equity-based compensation comprised 45.4 percent of the total compensation for BioSante s CEO, 38.7 percent and 20.7 percent of the total compensation for BioSante s other two named executive officers, assuming grant date fair value for equity awards.

BioSante grants all of BioSante s equity-based incentive awards, which are in the form of stock options, to BioSante s executives, as well as BioSante s other employees and directors, under BioSante s stockholder-approved stock incentive plan. For more information concerning the terms of BioSante s stock incentive plan, see Executive Compensation Grants of Plan-Based Awards BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. All equity-based incentive awards granted to BioSante s named executive officers during 2012 were made under BioSante s stock incentive plan.

An important objective of BioSante s long-term incentive compensation is to strengthen the relationship between the long-term value of the price of BioSante common stock and the potential financial gain for employees. BioSante believes that stock options are an important part of BioSante s overall compensation program. BioSante believes that options effectively incentivize BioSante s employees to maximize BioSante performance, as the value of awards is directly tied to an appreciation in the value of

Table of Contents

BioSante common stock, and provide an effective retention mechanism as a result of the applicable vesting mechanics of the options.

Stock options provide recipients with the opportunity to purchase BioSante common stock at a price fixed on the grant date regardless of future market price. The vesting of BioSante s stock options is generally time-based and vest in four as nearly equal as possible annual installments. BioSante s policy is to grant options with an exercise price equal to 100 percent of the fair market value of BioSante common stock on the grant date. A stock option becomes valuable for an employee only if the per share price of BioSante common stock increases above the per share exercise price of the option and the holder of the option remains employed during the period required for the option to vest. This provides an incentive for an option holder to remain employed by BioSante. In addition, stock options link a portion of an employee s compensation to the interests of BioSante stockholders by providing an incentive to achieve corporate goals and increase the market price of BioSante common stock over the four-year vesting period. However, unless the price of BioSante common stock increases after the stock option grants are made, they deliver no value to the option holders. As of December 31, 2012, all of BioSante s outstanding options held by its named executive officers were out-of-the-money meaning that the per share exercise prices of the options exceed the per share market value of BioSante common stock.

BioSante generally grants incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, in order to provide BioSante s executives and other employees the additional tax benefit associated with incentive stock options, which BioSante believes as a result of BioSante s net loss position outweighs BioSante s interest in obtaining the federal corporate income tax deduction which would be available if BioSante granted non-statutory stock options.

In determining the number of stock options to grant BioSante s executives, the Compensation Committee typically targets long-term incentive values and grants as a percent of company at the peer 50th percentile and a reasonable annual gross burn rate.

The table below describes the stock option grants made to BioSante s named executive officers in 2012 and the grant date fair value of such grants. All BioSante share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Named Executive Officer	Number of Options	Grant Date Fair Value(1)
Mr. Simes	133,333	$ 419,999
Mr. Donenberg	47,500	149,625
Dr. Snabes	27,500	86,625

(1) All of the stock options granted to the named executive officers in 2012 were out-of-the-money as of December 31, 2012 since the exercise price of such options exceeded the fair market value of BioSante common stock as of such date.

Despite the fact that both Mr. Donenberg and Dr. Snabes are Senior Vice Presidents, the Compensation Committee believed that Mr. Donenberg deserved a larger stock option grant than Dr. Snabes in light of Mr. Donenberg s long history with and dedication and loyalty to the company.

Additional information concerning the long-term incentive compensation information for BioSante s named executive officers for 2012 is included in the Summary Compensation Table and Grants of Plan-Based Awards Table later in this report.

Target Total Direct Compensation. As described previously, when analyzing compensation, BioSante typically looks at base salary, target total cash compensation and target total direct compensation in comparison to the peer 50th percentile when establishing new base salary levels, target annual cash incentive awards and long-term incentive awards in the form of stock option grants. As discussed above, actual value

Table of Contents

realized from long-term incentive awards in the form of stock option grants is dependent on BioSante s stock price at the time of exercise. Therefore, it is difficult to assess actual total direct compensation on an annual basis in comparison to the market since the market data may have changed significantly when actual long-term incentive results are fully realized if such long-term incentive results are ever fully realized. For example, all of the stock options granted to the named executive officers in 2012 were out-of-the-money as of December 31, 2012 since the exercise price of such options exceeded the fair market value of BioSante common stock as of such date. Nonetheless, BioSante believes it is important to continue to review target total direct compensation when granting long-term incentive awards. The target total direct compensation (including the supporting data) for BioSante s named executive officers for 2012 and its position relative to the peer 50th percentile is reflected in the table below for each named executive officer.

Named Executive Officer	2012 Annual Base Salary	2012 Target Annual Bonus Award	2012 Target Long-Term Incentives(1)	2012 Target Total Direct Compensation	2012 Target Total Direct Compensation Compared to 50th Percentile
Mr. Simes	$ 496,700	$ 298,020	$ 419,999	$ 1,214,719	Between 25th and 50th percentile
Mr. Donenberg	308,000	123,200	149,625	580,825	Between 25th and 50th percentile
Dr. Snabes	376,000	150,400	86,625	613,025	Between 50th and 75th percentile

(1) All of the 2012 target long-term incentives, in the form of stock options, granted to the named executive officers in 2012 were out-of-the-money as of December 31, 2012 since the exercise price of such options exceeded the fair market value of BioSante common stock as of such date.

All Other Compensation

Perquisites and Other Benefits. It is generally BioSante s policy not to extend perquisites and other benefits to BioSante s executive officers that generally are not available to all of BioSante s employees. The only perquisites that BioSante provides to its executives are those that are required under the terms of their employment letter and offer letter agreements. Each of BioSante s executives receives a monthly auto allowance. In addition, Mr. Simes and Mr. Donenberg receive reimbursement for supplemental life insurance and excess long-term disability insurance premiums and taxes associated with the premiums. BioSante is required to provide these benefits to these executives under their employment letter and offer letter agreements. BioSante believes the cost of providing these benefits is not material. BioSante s executives also receive benefits, which are received by BioSante s other employees, including 401(k) matching contributions, health, dental and life insurance benefits, and reimbursement for certain minimal health club costs ($50/month) to encourage physical activity and good health. BioSante does not provide supplemental retirement benefits, pension arrangements or post-retirement health coverage for its employees, including its executives. BioSante also does not provide any nonqualified defined contribution or other deferred compensation plans.

Change in Control Arrangements. To encourage continuity, stability and retention when considering the potential disruptive impact of an actual or potential corporate transaction, BioSante has established change in control arrangements, including provisions in BioSante s stock incentive plan, written employment and other agreements with its executives and other key employees and officer and broad-based plans and policies, to incentivize its executives and other employees to remain with BioSante in the event of a change in control or potential change in control. Pursuant to the terms of BioSante s stock incentive plan and the individual agreements provided to recipients of awards under that plan, all stock options under the plan become immediately vested and exercisable upon the completion of a change in control of BioSante. Thus, the immediate vesting of stock options is triggered by the change in control, itself, and thus is known as a single trigger change in control

arrangement. BioSante believes its single trigger equity acceleration change in

Table of Contents

control arrangements provide important retention incentives during what can often be an uncertain time for employees and provide executives with additional monetary motivation to focus on and complete a transaction that the Board of Directors believes is in the best interests of BioSante stockholders rather than seeking new employment opportunities. If an executive were to leave prior to the completion of the change in control, non-vested options held by the executive would terminate. These arrangements have not changed since 2008. In light of the fact, however, that all of the options currently held by BioSante s executives are out-of-the-money, BioSante s single trigger equity acceleration arrangements have little retentive effect in connection with BioSante s proposed merger with ANI.

In addition, BioSante has entered into employment and other agreements with its named executive officers and other officers and has adopted an officer severance policy that requires BioSante to provide its executives certain payments and benefits in the event of a change in control, most of which are payable only in the event their employment is terminated in connection with the change in control. These change in control protections were initially offered to induce the executives to accept or continue employment with BioSante and are primarily intended to retain BioSante s executives and to provide continuity of management in connection with a threatened or actual change in control transaction.

These arrangements, and a quantification of the payment and benefits provided under these arrangements, are described in more detail under the heading Executive Compensation Potential Payments Upon Termination or Change in Control Change in Control Arrangements. Other than the immediate acceleration of equity-based awards which is intended to align BioSante s executives interests with those of BioSante stockholders by allowing executives to participate fully in the benefits of a change in control as to all of their equity, in order for BioSante s named executive officers to receive any other payments or benefits as a result of a change in control of BioSante, there must be a termination of the executive s employment, in most cases, either by BioSante without cause or by the executive for good reason. The termination of the executive s employment by the executive without good reason will not give rise to additional payments or benefits either in a change in control situation or otherwise. Thus, these additional payments and benefits will not just be triggered by a change in control, but also will require a termination event not within the control of the executive, and thus are known as double trigger change in control arrangements. As opposed to the immediate acceleration of equity-based awards, BioSante believes that other change in control payments and benefits should properly be tied to termination following a change in control, given the intent that these amounts provide economic security to ease in the executive s transition to new employment. Unlike the change in control arrangements for BioSante s other executive and other officers and employees, the employment agreements for Mr. Simes and Mr. Donenberg contain a limited modified single trigger provision, which gives these two executives the right to terminate their employment for any reason during the 13th month after the completion of a change in control and receive their severance benefits. These employment agreements were put in place in connection the hiring of these executives in 1998 and have not been amended since July 2008. The Compensation Committee believes that such provisions are appropriate for Mr. Simes and Mr. Donenberg in light of their history with the company and long-standing dedication and service to the company.

BioSante believes that BioSante s change in control arrangements are an important part of BioSante s executive compensation program. BioSante believes that these arrangements mitigate some of the risk that exists for executives working in a smaller company, where there is a meaningful likelihood that the company may be acquired. These arrangements are intended to attract and retain qualified executives who may have employment alternatives that may appear to them, in light of a possible change in control of BioSante, to be less risky absent these arrangements. BioSante believes that relative to BioSante s overall value, BioSante s potential change in control benefits are relatively minor. BioSante confirms this belief by reviewing annually the change in control and severance benefits potentially payable to each executive. BioSante also believes that the form and amount of such benefits are reasonable in light of those provided to executives by companies in BioSante s peer group and other companies with which BioSante competes for executive talent and the amount of time typically required to find executive employment opportunities. Therefore, BioSante believes BioSante

Table of Contents

must continue to offer such protections in order to remain competitive in attracting and retaining executive talent.

Other Severance Arrangements. Each of BioSante s named executive officers and other officers is entitled to receive severance benefits upon certain other qualifying terminations of employment, other than a change in control, pursuant to the provisions of such executive s employment agreement, or in the case of Dr. Snabes, BioSante s officer severance policy since the severance policy provides for greater severance benefits than Dr. Snabes was entitled to receive under his written agreement. Similar to BioSante s change in control arrangements, BioSante s other severance arrangements were initially offered to induce the executives to accept or continue employment with BioSante and are primarily intended to retain BioSante s executives. For more information on BioSante s employment agreements and severance arrangements with BioSante s named executive officers, see the discussions below under the headings Executive Compensation Summary of Cash and Other Compensation and Executive Compensation Potential Payments Upon a Termination or Change in Control.

Compensation Committee Report

The Compensation Committee has reviewed and discussed the foregoing Compensation Discussion and Analysis section of this report with BioSante s management. Based on this review and discussion, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis section be included in this report for filing with the Securities and Exchange Commission.

Compensation Committee

Louis W. Sullivan, M.D., Chair

Ross Mangano

Edward C. Rosenow, III, M.D.

Stephen A. Sherwin, M.D.

Executive Compensation

Summary of Cash and Other Compensation

The table below provides summary information concerning all compensation awarded to, earned by or paid to BioSante s principal executive officer and BioSante s principal financial officer and BioSante s only other executive officer during the years ended December 31, 2012, 2011 and 2010. BioSante did not have any other executive officers as of December 31, 2012. The three individuals named in the table below are referred to as BioSante s named executive officers or BioSante s executives in this report.

SUMMARY COMPENSATION TABLE - 2012

Stephen M. Simes	2012	$ 496,700	$ 0	$ 419,999	$ 200,000	$ 31,749	$ 1,148,448
Vice Chairman, President and	2011	496,700	0	695,500	302,490	38,739	1,533,429
Chief Executive Officer	2010	486,231	270,900	156,000	0	36,248	949,379
Phillip B. Donenberg	2012	308,000	0	149,625	100,000	28,113	585,738
Senior Vice President of Finance,	2011	308,000	0	288,900	122,357	27,368	746,625
Chief Financial Officer and Secretary	2010	285,552	112,000	104,000	0	28,663	530,215
Michael C. Snabes, M.D., Ph.D.	2012	376,000	0	86,625	25,000	18,450	506,075
Senior Vice President of Medical Affairs	2011	376,000	0	128,400	98,700	18,200	621,300
	2010	374,487	109,500	26,000	0	18,200	528,187

Table of Contents

(1) 2010 amounts include $34,731, $19,885 and $26,154 paid to Mr. Simes, Mr. Donenberg and Dr. Snabes, respectively, for unused accrued vacation time. See the information under the heading Payout of Certain Accrued Vacation Balances for more information regarding these payments.

(2) Represents discretionary performance cash bonuses earned in year as indicated, but in the case of some years, paid during the following year prior to the establishment of the BioSante Pharmaceuticals, Inc. Performance Incentive Plan. For fiscal 2011, annual bonuses are reflected in the Non-Equity Incentive Plan Compensation column.

(3) Amounts reported in the Option Awards column represent the aggregate grant date fair value for option awards granted to each named executive officer during each of the years presented, as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. The grant date fair value is determined based on BioSante s Black-Scholes option pricing model. The following table sets forth the specific assumptions used in the valuation of each such option award:

Grant Date	Grant Date Fair Value Per Share	Risk Free Interest Rate	Expected Life	Expected Volatility	Expected Dividend Yield
01/25/12	$ 3.15	1.105%	6.25 years	93.91%	0%
01/03/11	6.42	2.38%	6.25 years	69.55%	0%
02/02/10	6.24	2.37%	6 years	76.87%	0%

All of the stock options granted to the named executive officers in 2012, 2011 and 2010 were out-of-the-money as of December 31, 2012 since the exercise price of such options exceeded the fair market value of BioSante common stock as of such date.

(4) Represents amounts paid under the BioSante Pharmaceuticals, Inc. Performance Incentive Plan. The amount reflected for reflects the annual cash incentive bonus earned for that year but paid during the following year. See the information under the heading Grants of Plan-Based Awards BioSante Pharmaceuticals, Inc. Performance Incentive Plan and Compensation Discussion and Analysis Executive Compensation Components Short-Term Cash Incentive Compensation for more information.

(5) The amounts shown in the All Other Compensation column for 2012 include the following with respect to each named executive officer:

Name	401(k) Match(a)	Insurance Premiums(b)	Tax Gross-Up(c)	Auto Allowance
Stephen M. Simes	$ 11,250	$ 6,433	$ 2,066	$ 12,000
Phillip B. Donenberg	11,250	7,867	1,796	7,200
Michael C. Snabes, M.D., Ph.D.	11,250	0	0	7,200

(a) Based on 50 percent of the amount the named executive officer voluntarily contributed to the plan.

(b) Includes reimbursement for premiums paid by the named executive officer for long-term disability insurance and for supplemental term life insurance.

(c) Based on the named executive officer s tax rate at the time the premium was paid.

Simes Employment Letter Agreement. In January 1998, BioSante entered into an employment letter agreement with Stephen M. Simes. BioSante amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Section 409A of the Internal Revenue Code of 1986 and to make certain changes to the change in control provisions. BioSante has not amended the agreement since July 2008. The current term of the agreement continues until December 31, 2013. On January 1 of each year, the term is automatically extended for an additional one year unless on or before October 1 immediately preceding the extension, either party gives written notice to the other of the termination of the agreement or cessation of further extensions. Under the agreement, Mr. Simes is entitled to a base salary in an amount determined by the Board of Directors, which base salary, however, must be adjusted

Table of Contents

upward each year at a minimum equal to changes in the Consumer Price Index. Mr. Simes is entitled to receive an annual discretionary performance bonus, the amount and terms of which will be determined in the discretion of the Board of Directors. Mr. Simes also is entitled to a monthly stipend of $1,000 for automobile use, reimbursement of premiums for supplemental term life and long-term disability insurance and taxes associated with such premiums and four weeks paid vacation each year. If Mr. Simes is terminated without cause or upon a change in control or if he terminates his employment for good reason, he will be entitled to certain payments and benefits as described in more detail under the heading Potential Payments Upon Termination or Change in Control. Under the agreement, Mr. Simes is subject to customary assignment of inventions, confidentiality and non-competition provisions.

Donenberg Employment Letter Agreement. In June 1998, BioSante entered into an employment letter agreement with Phillip B. Donenberg. BioSante amended the agreement in July 2008 to ensure compliance with regulations on non-qualified deferred compensation severance benefits as mandated by Section 409A of the Internal Revenue Code of 1986 and to make certain changes to the change in control provisions. BioSante has not amended the agreement since July 2008. The term of the agreement continues until either party gives 30 days written notice to the other of the termination of the agreement. Under the agreement, Mr. Donenberg is entitled to a base salary in an amount determined by the Board of Directors, which base salary, however, must be adjusted upward each year at a minimum equal to changes in the Consumer Price Index. Mr. Donenberg is entitled to receive an annual discretionary performance bonus, the amount and terms of which will be determined in the discretion of the Board of Directors. Mr. Donenberg also is entitled to a monthly stipend of $600 for automobile use, reimbursement of premiums for supplemental term life and long-term disability insurance and taxes associated with such premiums and four weeks paid vacation each year. If Mr. Donenberg is terminated without cause or upon a change in control or if he terminates his employment for good reason, he will be entitled to certain payments and benefits as described in more detail under the heading Potential Payments Upon Termination or Change in Control. Under the agreement, Mr. Donenberg is subject to customary assignment of inventions, confidentiality and non-competition provisions.

Snabes Offer Letter and Change of Control and Severance Agreement. In April 2008, BioSante entered into an offer letter agreement with Michael C. Snabes, M.D., Ph.D. Dr. Snabes is employed at-will and is not guaranteed employment for any specified duration. The offer letter does not contain any commitments regarding future salary increases or benefits, except for the timing of payments and a general description of benefits. Dr. Snabes is entitled to receive an annual discretionary performance bonus of up to 30 percent of his then base salary, the amount and terms of which will be determined in the discretion of the Board of Directors. Dr. Snabes also is entitled to a monthly stipend of $600 for automobile use, reimbursement for reasonable monthly cell phone charges and 20 days paid vacation each year. Although BioSante entered into a separate change of control and severance agreement with Dr. Snabes, if Dr. Snabes is terminated without cause or upon a change in control, he will be entitled to certain payments and benefits under the BioSante Pharmaceuticals, Inc. Officer Severance Policy since the severance policy provides for greater severance benefits than Dr. Snabes is currently entitled to receive under his current agreement with BioSante. The officer severance policy is described in more detail under the heading Potential Payments Upon Termination or Change in Control. Dr. Snabes is subject to customary assignment of inventions, confidentiality and non-competition obligations.

Payout of Certain Accrued Vacation Balances. The Salary column for 2010 includes $34,731, $19,885 and $26,154 paid to Mr. Simes, Mr. Donenberg and Dr. Snabes, respectively, for unused accrued vacation time. In February 2010, the Board of Directors, upon recommendation of the Compensation Committee, approved a one-time cash payment of certain accrued vacation balances and a corresponding change to BioSante s vacation policy that limited the number of vacation days any employee could accrue and carry over from one year to the next year. Under the terms of the payout, each of BioSante s employees, including BioSante s executives, was paid cash for the number of the employee s accrued vacation balance days as of December 31, 2009 that exceed the equivalent of one year s vacation for such employee (if any) multiplied by the employee s daily base rate of pay at the time of such payment. No employee, however,

Table of Contents

received payment for more than one year s vacation and each employee s accrued vacation balance was then reduced by the number of days paid out. The purpose of the accrued vacation payout was to reduce the amount of accrued vacation balances on BioSante s balance sheet and soften the impact of the change to BioSante s vacation policy limiting the number of vacation days any employee could accrue and carry over from one year to the next year.

401(k) Savings Plan. BioSante maintains a 401(k) Savings Plan under which all participant employees, including executive officers, may voluntarily contribute up to 100% of their plan compensation (subject to certain IRS limits) as pre-tax 401(k) deferrals. BioSante may make discretionary matching contributions to this plan and in 2010 BioSante made matching contributions equal to 50% of each participants 401(k) deferrals.

Perquisites and Personal Benefits. It is generally BioSante s policy not to extend perquisites and other benefits to BioSante s executive officers that generally are not available to BioSante s employees. The only perquisites that BioSante provides to its executives are those that are required under the terms of their employment letter and offer letter agreements. Each of BioSante s executives receives a monthly auto allowance. In addition, Mr. Simes and Mr. Donenberg receive reimbursement for supplemental life insurance and excess long-term disability insurance premiums and taxes associated with the premiums. BioSante is required to provide these benefits to BioSante s executives under their employment letter and offer letter agreements. BioSante believes the cost of providing such benefits is not material. BioSante s executives also receive benefits, which are received by BioSante s other employees, including 401(k) matching contributions, health, dental and life insurance benefits, and reimbursement for certain minimal health club costs ($50/month) to encourage physical activity and good health. BioSante does not provide supplemental retirement benefits, pension arrangements or post-retirement health coverage for its employees, including its executives. BioSante also does not provide any nonqualified defined contribution or other deferred compensation plans.

Indemnification Agreements. BioSante has entered into agreements with all of its named executive officers under which BioSante is required to indemnify its officers against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of BioSante s executive officers. BioSante will be obligated to pay these amounts only if the executive officer acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to BioSante s best interests. With respect to any criminal proceeding, BioSante will be obligated to pay these amounts only if the executive officer had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

Grants of Plan-Based Awards

The table below provides information concerning grants of plan-based awards to each of BioSante s named executive officers during the year ended December 31, 2012. The option awards were granted to BioSante s named executive officers under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (As Amended and Restated). The material terms of these awards and the material plan provisions relevant to these awards are described in the notes to the table below or in the narrative following the table below. During the year ended December 31, 2012, BioSante did not grant any non-equity or equity incentive plan awards or stock awards, in each case, within the meaning of the SEC rules. All BioSante share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Table of Contents

GRANTS OF PLAN-BASED AWARDS - 2012

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options(6) (#)	Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value Stock and Option Awards(6) ($)
Stephen M. Simes				
Stock option	01/25/12	133,333	$ 4.11	$ 419,999
Phillip B. Donenberg				
Stock option	01/25/12	47,500	4.11	149,625
Michael C. Snabes, M.D., Ph.D.				
Stock option	01/25/12	27,500	4.11	86,625

(1) Represents an option granted under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (As Amended and Restated), the material terms of which are described in more detail below under the heading BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. The option has a ten-year term and vests over a four-year period, with one-fourth of the underlying shares vesting on each of January 25, 2013, January 25, 2014, January 25, 2015 and January 25, 2016, so long as the individual remains an employee of BioSante as of such date.

(2) See note (3) to the Summary Compensation Table for a discussion of the assumptions made in calculating the grant date fair value of the option awards.

BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. Under the terms of the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan, as amended and restated, BioSante s named executive officers, in addition to other employees and individuals, are eligible to receive equity-based incentive awards, such as stock options. Although the 2008 plan is an omnibus plan that permits the grant of equity-based incentive awards besides stock options, such as restricted stock, restricted stock units, stock appreciation rights, performance units and stock bonuses, to date, only incentive and non-statutory stock options have been granted.

The 2008 plan contains both an overall limit on the number of shares of BioSante common stock that may be issued, as well as individual and other grant limits. Under the terms of the 2008 plan, no more than 1,833,333 shares of BioSante common stock may be issued pursuant to the plan or the exercise of incentive options and no more than 250,000 shares of BioSante common stock may be issued or issuable in connection with restricted stock grants, stock unit awards, performance awards and stock bonuses, in each case subject to adjustment and certain exceptions. In addition, shares subject to outstanding awards granted under BioSante s 1998 plan also become available under the 2008 plan, but only to the extent that such outstanding awards are forfeited, expire or otherwise terminate without the issuance of such shares.

Incentive stock options must be granted with a per share exercise price equal to at least the fair market value of a share of BioSante common stock on the date of grant. For purposes of the 2008 plan, the fair market value of BioSante common stock is the closing sale price of BioSante common stock, as reported by The NASDAQ Stock Market. BioSante set the per share exercise price of all stock options granted under the plan at an amount equal to the closing sale price of BioSante common stock on the date of grant.

As described in more detail under the heading Potential Payments Upon Termination or Change in Control, if there is a change in control of BioSante, then, under the terms of the 2008 plan, unless otherwise provided by the Compensation Committee or the Board of Directors in its sole discretion either in the agreement evidencing an incentive award at the time of grant or at any time after the grant of an incentive award, all options will become immediately exercisable in full and will remain exercisable for the remainder of their terms, regardless of whether the holder to whom such option have been granted remains in the employ or service of BioSante or any subsidiary.

Other Information Regarding Plan-Based Awards. Under a provision contained in Mr. Simes s and Mr. Donenberg s employment letter agreements, upon the termination of their employment by BioSante without cause, all stock options then held by them would be accelerated and all such options would become fully vested and immediately exercisable for a period of one year after the termination date, as described in

Table of Contents

more detail under the heading Potential Payments Upon Termination or Change in Control. Dr. Snabes does not have a similar provision in his offer letter agreement or change in control and severance agreement.

Table of Contents

Outstanding Equity Awards at Fiscal Year End

The table below provides information regarding unexercised stock option awards for each of BioSante s named executive officers that remained outstanding at December 31, 2012. BioSante did not have any equity incentive plan awards or stock awards, each within the meaning of the SEC rules, outstanding at December 31, 2012. All BioSante share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END 2012

	Option Awards			
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable(1)**	**Option Exercise Price ($)**	**Option Expiration Date**
Stephen M. Simes	21,111	0	$ 12.60	05/29/2013
	41,666	0	16.65	01/11/2017
	16,666	0	23.97	01/14/2018
	50,000	0	9.06	02/01/2019
	16,666	8,334(2)	9.24	02/01/2020
	27,083	81,250(3)	9.96	01/02/2021
	0	133,333(4)	4.11	01/24/2022
Phillip B. Donenberg	13,194	0	12.60	05/29/2013
	4,166	0	22.29	07/18/2015
	4,166	0	22.29	07/18/2015
	10,416	0	23.22	03/15/2016
	8,333	0	16.65	01/11/2017
	10,000	0	23.97	01/14/2018
	20,833	0	9.06	02/01/2019
	11,111	5,555(2)	9.24	02/01/2020
	11,250	33,750(3)	9.96	01/02/2021
	0	47,500(4)	4.11	01/24/2022
Michael C. Snabes, M.D., Ph.D.	8,333	0	26.58	03/19/2017
	16,666	0	24.54	04/13/2018
	8,333	0	9.06	02/01/2019
	2,777	1,389(2)	9.24	02/01/2020
	5,000	15,000(3)	9.96	01/02/2021
	0	27,500(4)	4.11	01/24/2022

(1) Upon the occurrence of a change in control, the unvested and unexercisable options described in this table will be accelerated and become fully vested and immediately exercisable as of the date of the change in control. For more information, see the discussion under the heading Potential Payments Upon Termination or Change in Control. Under a provision contained in Mr. Simes s and Mr. Donenberg s employment letter agreements, upon the termination of their employment by BioSante without cause, all stock options then held by them would be accelerated and all such options would become fully vested and immediately exercisable for a period of one year after the termination date, as described in more detail under the heading Potential Payments Upon Termination or Change in Control.

(2) This option vests over a three-year period, one-third of the underlying shares vesting on each of February 2, 2011, February 2, 2012 and February 2, 2013, so long as the executive remains an employee or consultant of BioSante as of such date.

Table of Contents

(3) This option vests over a four-year period, one-fourth of the underlying shares vesting on each of January 3, 2012, January 3, 2013, January 3, 2014 and January 3, 2015, so long as the executive remains an employee or consultant of BioSante as of such date.

(4) This option vests over a four-year period, one-fourth of the underlying shares vesting on each of January 25, 2013, January 25, 2014, January 25, 2015 and January 25, 2016, so long as the executive remains an employee or consultant of BioSante as of such date

Options Exercised and Stock Vested During Fiscal Year

None of BioSante s named executive officers exercised any stock options during the year ended December 31, 2012. BioSante does not have any outstanding stock awards and thus did not have any stock awards vest during the year ended December 31, 2012.

Potential Payments Upon Termination or Change in Control

General. BioSante has entered into agreements with Mr. Simes, Mr. Donenberg and Dr. Snabes and BioSante maintains the BioSante Pharmaceuticals, Inc. Officer Severance Policy, which may require BioSante to provide certain payments to these executives upon a termination of their employment or change in control of BioSante. Whether an executive receives a payment and the amount of such payment, if applicable, depends upon the triggering event. For more information regarding the individual agreements, see the discussion under the headings Summary of Cash and Other Compensation Simes Employment Letter Agreement, Summary of Cash and Other Compensation Donenberg Employment Letter Agreement and Summary of Cash and Other Compensation Snabes Offer Letter and Change of Control and Severance Agreement. In addition, BioSante s equity-based compensation plans also provide benefits as a result of a change in control of BioSante.

Termination by BioSante for Cause. If the employment of any of BioSante s executives is terminated by BioSante for cause, the executive would be entitled to be paid his annual base salary, car allowance and any out-of-pocket expenses incurred through the date of his termination and any amounts the executive would be entitled to under any company benefit plan. For purposes of Mr. Simes s and Mr. Donenberg s agreements, cause means any of the following: (1) dishonesty or fraud; (2) theft or embezzlement of BioSante s assets; (3) a violation of law involving moral turpitude; (4) repeated and willful failure to follow instructions of the Board of Directors provided that the conduct has not ceased or the offense cured within 30 days following written warning from BioSante; and (5) conviction of willfully engaging in illegal conduct constituting a felony or gross misdemeanor under federal or state law which is materially and demonstrably injurious to the company or which impairs the executive s ability to substantially perform his duties for the company. For purposes of Dr. Snabes s agreement and the officer severance policy, cause means any of the following: (1) dishonesty or fraud; (2) theft or embezzlement of BioSante s assets; (3) any unlawful or criminal activity of a serious nature; (4) breach of any terms of his employee confidentiality and assignment of inventions agreement; (5) failure to carry out the duties of his position in a competent manner; and (6) failure to comply with BioSante s policies and procedures. The agreements also provide that the executive must abide by certain non-competition provisions for one year after termination for cause. Under the terms of BioSante s equity-based compensation plans, if an executive s employment is terminated by BioSante for cause, the executive s outstanding stock options will immediately terminate and may not then be exercisable.

Termination by BioSante Without Cause. Under the terms of each of Mr. Simes s and Mr. Donenberg s employment letter agreements, if Mr. Simes s or Mr. Donenberg s employment is terminated by BioSante without cause or if in the case of Mr. Simes, BioSante gives notice of BioSante s intent not to renew his employment agreement, the executive would be entitled to be paid his annual base salary, car allowance and

any out-of-pocket expenses incurred through the date of termination. Additionally, the executives would be entitled to receive:

Table of Contents

- a severance payment, which would be paid in one lump sum in the case of Mr. Simes, and in 12 equal monthly installments in the case of Mr. Donenberg, equal to, in the case of Mr. Simes, the sum of his annual base salary, most recent annual bonus and annual car allowance, and in the case of Mr. Donenberg, his annual base salary at the time of termination;

- continued term life and disability insurance at BioSante s expense, which, in the case of Mr. Simes, would be for a period of one year from the date of his termination or the remaining term of his agreement, whichever is longer, and in the case of Mr. Donenberg, would be for a period of one year from the date of his termination, unless in either case the executive obtains full-time employment;

- continued participation by the executive and his family at BioSante s expense in BioSante s group health and dental insurance programs, which in the case of Mr. Simes, would be for a period of one year from the date of his termination or the remaining term of his agreement, whichever is longer, and in the case of Mr. Donenberg, would be for a period of one year from the date of his termination, unless in either case the executive becomes eligible to participate in another employer s corresponding group insurance plans;

- in the case of Mr. Simes, provision of outplacement services up to a maximum amount of $30,000 and use of an office and reasonable secretarial support for one year, unless Mr. Simes becomes otherwise employed within such period; and

- payment for all unused vacation days accrued to the date of termination.

In addition, in the event BioSante terminates Mr. Simes s or Mr. Donenberg s employment without cause, all outstanding stock options then held by the executive at such time will become immediately exercisable and the executive will have one year from the date following his termination of employment to exercise such options.

If Dr. Snabes s employment is terminated by BioSante without cause, Dr. Snabes would be entitled to be paid his annual base salary, car allowance, any out-of-pocket expenses incurred through the date of termination and payment for all unused vacation days accrued to the date of termination. In addition, Dr. Snabes would receive nine months of his annual base salary at the time of termination paid in accordance with BioSante s normal payroll practices and eligibility for continuation coverage under BioSante s medical, dental and other group health plans for nine months following the termination date and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Dr. Snabes immediately prior to his termination date to obtain such coverage. Under the terms of BioSante s equity-based compensation plans, Dr. Snabes would have three months to exercise any options outstanding and vested at the time of termination.

Termination by Executive for Good Reason. Under the terms of each of Mr. Simes s and Mr. Donenberg s employment letter agreements, Mr. Simes or Mr. Donenberg may terminate his agreement upon 30 days written notice to BioSante for good reason. For purposes of the agreements, good reason means (1) assignment of duties inconsistent with his position or a change in responsibilities, title or office; (2) the failure of BioSante to continue, or the taking of action by BioSante that could adversely affect, benefits plans in which the executive is participating (with some exceptions); (3) reduction of salary or car allowance or failure to increase salary as provided in the agreement; and (4) any other breach by BioSante of the agreement. If Mr. Simes or Mr. Donenberg terminates his agreement for good reason other than in connection with a change in control, then BioSante must provide him the payments and benefits described above under Termination by BioSante

Without Cause. Under the terms of BioSante s equity-based compensation plans, all outstanding stock options then held by the executive at such time will remain exercisable to the extent then exercisable for a period of three months. Dr. Snabes does not have the ability under his agreement to terminate

Table of Contents

his employment for good reason and receive severance benefits except as described below under Change in Control.

Termination in the Event of Death or Permanent Disability. Each of Mr. Simes s and Mr. Donenberg s employment letter agreements terminates in the event of the executive s death or permanent disability. In the event of death, the executive s base salary and car allowance will be terminated as of the end of the month in which the executive s death occurs. Upon an executive s disability, BioSante can terminate the executive s employment upon 30 days written notice. For purposes of the agreements, disability means an inability, due to illness, accident or any other physical or mental incapacity, to substantially perform the executive s duties for a period of four consecutive months or for a total of six months in any 12 month period. Upon termination of an executive s employment due to disability, the executive will be entitled to receive compensation until the later of (1) the date of termination of employment for disability or (2) the date upon which the executive begins to receive long-term disability insurance benefits. In addition, in the event the executive s employment is terminated as a result of the executive s death or permanent disability, all outstanding stock options then held by the executive at such time will become immediately exercisable and the executive or his estate will have one year from the date of termination of employment to exercise such options.

In the event of the termination of Dr. Snabes s employment as a result of his death or disability, Dr. Snabes (or his estate or heirs) would be entitled to be paid his annual base salary, car allowance, any out-of-pocket expenses incurred through the date of termination and payment for all unused vacation days accrued to the date of termination. Under the terms of BioSante s equity-based compensation plans, Dr. Snabes (or his estate or heirs) would have one year to exercise any options outstanding and vested at the time of termination.

Change in Control. Each of Mr. Simes, Mr. Donenberg and Dr. Snabes has received stock options under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan, which remain unvested. Under the terms of such plan, such stock options become fully exercisable following a change in control of BioSante, which is defined under the plan as:

- the sale, lease, exchange or other transfer of all or substantially all of the assets of BioSante to a corporation that is not controlled by BioSante;

- the approval by BioSante s stockholders of any plan or proposal for the liquidation or dissolution of BioSante;

- certain merger or business combination transactions;

- more than 50 percent of BioSante s outstanding voting shares are acquired by any person or group of persons who did not own any shares of common stock on the effective date of the plan; or

- certain changes in the composition of the Board of Directors.

In order for BioSante s executives to receive any other payments or benefits as a result of a change in control of BioSante, there must be a termination event, such as a termination by BioSante for any reason other than for cause or a termination by the executive for good reason. For Mr. Simes and Mr. Donenberg, such termination event must occur either within the period beginning on the date of the change in control and ending on the last day of the first full calendar month following the second year anniversary date of the change in control or prior to the change in control if the termination of employment was either a condition of the change in control or was at the request or insistence of a person related to the change in control. Dr. Snabes has the ability to terminate his employment for good reason if such termination occurs on the date of a change in control and ending on the 12 month anniversary of the date of the change in control. For purposes of the change in control provisions for Mr. Simes and Mr. Donenberg, the definition of good reason is broader than outside the context of change in control and includes: (1) BioSante s failure to obtain from any successor the assent to assume the employment letter agreements; (2) any purported termination by BioSante of the

Table of Contents

executive s employment that is not properly effected; (3) a requirement that the executive be based at any office or location that is more than 30 miles further from the office or location thereof immediately preceding the change in control; and (4) any termination by the executive of his employment for any reason during the 13th month after the completion of the change in control. For Dr. Snabes, the definition of good reason includes: (1) a material diminution in the his authority, duties or responsibilities; (2) a material diminution in his base compensation; (3) a material diminution in the authority, duties or responsibilities of the supervisor to whom he reports; (4) a material change in the geographic location at which BioSante require him to be based as compared to the location where he was previously based; and (5) any other action or inaction that constitutes a material breach by BioSante under his agreement.

If such a termination event occurs, the executive would be entitled to be paid his annual base salary, car allowance and any out-of-pocket expenses incurred through the date of termination. Additionally, the executive would be entitled to receive:

- a severance payment, which would be paid in one lump sum equal to, in the case of Mr. Simes, the sum of: (1) two times his annual base salary, plus (2) his most recent annual bonus, plus (3) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs, in the case of Mr. Donenberg, the sum of: (1) 1½ times his annual base salary, plus (2) his maximum annual bonus (100 percent of base salary) for the year in which the change in control occurs, and in the case of Dr. Snabes, the sum of: (1) one times his annual base salary, plus (2) 100 percent of his target annual incentive bonus for the year in which the change in control occurs.

- in the case of Mr. Simes and Mr. Donenberg, substantially the same health, dental, life and disability insurance benefits the executive received prior to his termination for a period of up to 24 months for Mr. Simes, 18 months for Mr. Donenberg and in the case of Dr. Snabes, 12 months following the termination date and reimbursement for any costs incurred in securing such continuation coverage that are in excess of costs that would have been incurred by Dr. Snabes immediately prior to his termination date to obtain such coverage;

- provision of outplacement services up to a maximum amount of $30,000 in the case of Mr. Simes and Mr. Donenberg and $15,000 in the case of Dr. Snabes;

- reimbursement for out-of-pocket expenses incurred by the executive on behalf of BioSante; and

- payment for all unused vacation days accrued to the date of termination.

If any payments to an executive under the agreements or otherwise are considered contingent upon a change in control for purposes of Section 280G of the Internal Revenue Code of 1986, and therefore would constitute a parachute payment under the Internal Revenue Code, then such payments either would be reduced to the largest amount as will result in no portion of such payments being subject to the tax imposed by Section 4999 of the Internal Revenue Code or would require the executive to pay any additional 20 percent excise tax on the amount of any parachute payment received, whichever is more beneficial to the executive.

Table of Contents

Potential Payments to Named Executive Officers. The table below describes the potential payments to each of BioSante s executives in the event of a termination of his employment on December 31, 2012 or a change in control of BioSante on December 31, 2012. The table below does not include any accrued and unpaid base salary to which the executives also would be entitled.

Name	Executive Benefits and Payments	Termination For Cause	Termination Upon Death or Disability	Termination Without Cause or for Good Reason	Change in Control - No Termination Event	Change in Control - With Termination Event
Stephen M. Simes	Severance Payment	$ 0	$ 0	$ 811,190	$ 0	$ 1,490,100
	Unvested and Accelerated Stock Options(1)	0	0	0	0	0
	Term Life and Disability Insurance(2)	0	0		0	
	Group Health and Dental Plan Benefits(3)	0	0	26,221	0	52,441
	Accrued but Unpaid Vacation	159,517	159,517	159,517		159,517
	Outplacement Services	0	0	30,000	0	30,000
	Office Space and Administrative Services(4)	0	0	36,000	0	0
	Total:	$ 159,517	$ 159,517	$ 1,062,928	$ 0	$ 1,732,058
Phillip B. Donenberg	Severance Payment	$ 0	$ 0	$ 308,000	$ 0	$ 770,000
	Unvested and Accelerated Stock Options(1)	0	0	0	0	0
	Term Life and Disability Insurance(2)	0	0		0	
	Group Health and Dental Plan Benefits(3)	0	0	26,201	0	39,331
	Accrued but Unpaid Vacation	37,908	37,908	37,908	0	37,908
	Outplacement Services	0	0	0	0	30,000
	Total:	$ 37,908	$ 37,908	$ 372,109	$ 0	$ 877,239
Michael C. Snabes, M.D., Ph.D.	Severance Payment	$ 0	$ 0	$ 282,000	$ 0	$ 526,400
	Unvested and Accelerated Stock Options(1)	0	0	0	0	0
	Group Health and Dental Plan Benefits(3)	0	0	26,221	0	
	Accrued but Unpaid Vacation	36,154	36,154	36,154	0	36,154
	Outplacement Services	0	0	0	0	15,000
	Total:	$ 36,154	$ 36,154	$ 344,375	$ 0	$ 577,554

(1) The value of the automatic acceleration of the vesting of unvested stock options held by an executive is based on the difference between: (a) the market price of the shares of BioSante common stock underlying the unvested stock options held by such officer as of December 31, 2012, which is based on the closing sale price of BioSante common stock on December 31, 2012 ($1.23), and (b) the exercise price of the options, which range from $4.11 to $9.96 per share.

(2) The value of the term life and disability insurance is based on BioSante s current group plans and any applicable supplemental insurance provided to such executives at the 2012 rates actually paid.

(3) The value of the group health plan benefits is based on premium rates in effect in December 2012.

(4) The value of office space and administration services is based on current market information for the Chicago, Illinois area received from a third party.

Required Resignations and Releases; Confidentiality and Other Provisions. Mr. Simes and Mr. Donenberg have agreed upon any termination of their employment to resign from any and all director, officer, trustee, agent and any other positions with BioSante or BioSante s affiliates, such as BioSante s

Table of Contents

employee benefit plans. Dr. Snabes must sign a separation agreement and release prior to receiving any change in control or severance benefits. In addition, certain terms of their agreements will survive any termination of their employment, including the assignment of inventions and confidentiality provisions and in the event of certain terminations, portions of the non-competition provisions. Finally, any payments made to the executives as a result of a separation of service under the non-qualified deferred compensation rules of Section 409A under the Internal Revenue Code will be suspended for six months, if necessary.

Risk Assessment of Compensation Policies, Practices and Programs

At the beginning of 2013, the Compensation Committee performed an assessment of BioSante s compensation policies, practices and programs for all of BioSante s employees, focusing in particular on incentive compensation, to determine whether the risks arising from these policies, practices and programs are reasonably likely to have a material adverse effect on BioSante. In connection with such assessment, the Compensation Committee reviewed and analyzed each of BioSante s material compensation policies, practices and programs, and considered various risk control features, including without limitation key design features of BioSante s performance incentive plan, including use of appropriate incentive maximums or caps (which are 150 percent of the target award); the mix of corporate and individual performance measures and goals; the mix between fixed and variable compensation and annual versus long-term performance; stock ownership by executives and non-employee directors; clawback provisions; and the BioSante s compensation governance structure. Based on such assessment, the Compensation Committee concluded that BioSante s policies, practices and programs do not create risks that are reasonably likely to have a material adverse effect on BioSante.

As part of BioSante s assessment, BioSante noted in particular the following:

- annual base salaries for all employees are not subject to performance risk and, for most non-executive employees, constitute the largest part of their total compensation;

- while performance-based, or at risk, compensation constitutes a significant percentage of the overall total compensation of many of BioSante s employees, including in particular BioSante s named executive officers, and thereby BioSante believes motivates its employees to help achieve corporate and individual performance goals and increase the price of BioSante common stock, the non-performance based compensation for most employees for most years is also a sufficiently high percentage of their overall total compensation that BioSante does not believe that unnecessary or excessive risk taking is encouraged by the performance-based compensation;

- BioSante s performance-based compensation has appropriate maximums;

- a significant portion of performance-based compensation of BioSante s employees is in the form of stock options which do not encourage unnecessary or excessive risk because they generally vest over a four-year period of time thereby focusing BioSante s employees on BioSante s long-term interests; and

- performance-based or variable compensation awarded to BioSante s employees, which for BioSante s higher-level employees, including BioSante s named executive officers, constitutes the largest part of their total compensation, is appropriately balanced between annual and long-term performance and cash and equity compensation, and utilizes performance goals that BioSante believes are drivers of long-term success for BioSante and its stockholders.

As a matter of best practice, BioSante will continue to monitor BioSante s compensation policies, practices and programs to ensure that they continue to align the interest of BioSante s employees, including in particular BioSante s executives, with those of BioSante s long-term stockholders while avoiding unnecessary or excessive risk.

Table of Contents

Director Compensation

Overview of Director Compensation Program

As described in more detail under the heading Corporate Governance Nominating and Corporate Governance Committee Responsibilities, the Board of Directors has delegated to the Nominating and Corporate Governance Committee the responsibility, among other things, to establish and lead a process for the determination of compensation payable to BioSante s non-employee directors. The Nominating and Corporate Governance Committee makes recommendations regarding compensation payable to BioSante s non-employee directors to the entire Board of Directors, which then makes final decisions regarding such compensation. The processes and procedures the Nominating and Corporate Governance Committee and the Board of Directors use to consider and determine director compensation are described under the heading Corporate Governance Nominating and Corporate Governance Committee Processes and Procedures for Determination of Director Compensation.

The principal elements of BioSante s director compensation program for 2012 included:

- annual cash retainers;
- meeting fees; and
- long-term equity-based incentive compensation, in the form of stock options.

BioSante does not compensate Mr. Simes separately for serving on the Board of Directors. BioSante does, however, reimburse each member of the Board of Directors, including Mr. Simes, for out-of-pocket expenses incurred in connection with attending Board and Board committee meetings.

Cash Compensation

The cash compensation paid to BioSante s non-employee directors consists of the following described annual Board and Board committee cash retainers and meeting fees.

Description

	Annual Cash Retainer
Board Member	$ 25,000
Chairman of the Board (in addition to Board member retainer)	22,500
Audit and Finance Committee Chair	15,000
Compensation Committee Chair	10,000
Nominating and Corporate Governance Committee Chair	7,000
Audit and Finance Committee Member (other than Chair)	7,500
Compensation Committee Member (other than Chair)	5,000
Nominating and Corporate Governance Committee Member (other than Chair)	3,500

Description	Meeting Fees
Board Meeting (in person)	$ 2,000
Board Meeting (telephonic)	1,000
Board Committee (in person or telephonic)	1,000

The annual cash retainers are paid on a quarterly basis in the beginning of each calendar quarter. For example, the retainers paid in the beginning of the first calendar quarter are for the period from January 1 through March 31. The meeting fees are paid in arrears after the end of each calendar quarter.

Table of Contents

Stock Options

Each of BioSante s non-employee directors receives an automatic grant of options to purchase shares of BioSante common stock upon the director s initial election to the Board of Directors and on an annual basis on the last business day of March each year. In addition, BioSante s Chairman of the Board receives an additional automatic option grant. The options have a ten-year term and an exercise price equal to the fair market value of BioSante common stock on the grant date. The initial options vest and become exercisable in four equal annual installments and the annual options vest and become exercisable in full on the one-year anniversary of the grant date.

The table below sets forth the number of options granted to each of BioSante s non-employee directors as initial and annual grants and the additional option grant to BioSante s Chairman of the Board. All BioSante share and per share numbers have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

Description	Number of Shares Underlying Option Grants
New Board Member (initial grant)	8,333
Board Member (annual basis)	4,166
Chairman of the Board (annual basis)	1,666

See note 1 to the Director Compensation Table above for a summary of all options granted to BioSante s directors, excluding Mr. Simes, during the year ended December 31, 2012. See note 2 to the Director Compensation Table above for a summary of all options to purchase shares of BioSante common stock held by BioSante s directors, excluding Mr. Simes, as of December 31, 2012. Information regarding stock option grants to Mr. Simes during the year ended December 31, 2012 is set forth under the heading Executive Compensation Grants of Plan-Based Awards and information regarding all stock options held by Mr. Simes as of December 31, 2012 is set forth under the heading Executive Compensation Outstanding Equity Awards at Fiscal Year End.

Under the terms of BioSante s stock option agreements, upon a director s termination of service with BioSante, other than for cause, such director s vested and outstanding options as of such date remain vested and outstanding for a period of three months and all non-vested options terminate. Depending upon the circumstances of a director s separation of service with BioSante, however, BioSante may change these terms, although any adverse change would require the consent of the director.

Indemnification Agreements

BioSante has entered into agreements with all of its directors under which BioSante is required to indemnify directors against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of BioSante s directors. BioSante will be obligated to pay these amounts only if the director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to BioSante s best interests. With respect to any criminal proceeding, BioSante will be obligated to pay these amounts only if the director had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

146

Table of Contents

Summary of Cash and Other Compensation

The table below provides summary information concerning the compensation of each individual who served as a director of BioSante during the year ended December 31, 2012, other than Stephen M. Simes, BioSante s Vice Chairman, President and Chief Executive Officer, whose compensation is set forth under the heading Executive Compensation. All BioSante share and per share numbers in the notes to the table below have been adjusted retroactively to reflect the one-for-six reverse stock split effected on June 1, 2012.

DIRECTOR COMPENSATION - 2012

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	All Other Compensation ($)(3)	Total ($)
Louis W. Sullivan, M.D.	$ 91,500	$ 17,904	$ 0	$ 109,404
Fred Holubow	68,500	12,790	0	81,290
Ross Mangano	68,000	12,790	0	80,790
John T. Potts, Jr., M.D.	38,000	12,790	0	50,790
Edward C. Rosenow III, M.D.	49,000	12,790	0	61,790
Stephen A. Sherwin, M.D.	57,000	12,790	0	69,790

(1) On March 30, 2012, each of BioSante s non-employee directors received an option to purchase 4,166 shares of BioSante common stock at an exercise price of $4.08 per share granted under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan, the material terms of which are described in more detail under the heading Executive Compensation Grants of Plan-Based Awards BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. In addition, Dr. Sullivan, as Chairman of the Board, received an option to purchase an additional 1,666 shares of BioSante common stock. Such options expire on March 29, 2022 and will vest in full on March 30, 2013. Amounts reported in the Option Awards column represent the aggregate grant date fair value for option awards granted to each director in 2012 computed in accordance with FASB ASC Topic 718. The grant date fair value is determined based on BioSante s Black-Scholes option pricing model. The grant date fair value per share for the options granted on March 30, 2012 was $3.07 and was determined using the following specific assumptions: risk free interest rate: 1.04%; expected life: 5.5 years; expected volatility: 97.20%; and expected dividend yield: 0%.

(2) The table below provides information regarding the aggregate number of options to purchase shares of BioSante common stock outstanding at December 31, 2012 and held by each of the directors listed in the table:

Name	Aggregate Number of Securities Underlying Options	Exercisable/ Unexercisable	Range of Exercise Price(s)		Range of Expiration Date(s)	
Louis W. Sullivan, M.D.	33,331	27,499/5,832	$4.08	26.43	03/15/2016	03/29/2022
Fred Holubow	28,329	24,163/4,166	4.08	26.43	03/15/2016	03/29/2022
Ross Mangano	28,329	24,163/4,166	4.08	26.43	03/15/2016	03/29/2022
John T. Potts, Jr., M.D.	12,498	8,332/4,166	4.08	11.88	10/13/2019	03/29/2022
Edward C. Rosenow III, M.D.	28,329	24,163/4,166	4.08	26.43	03/15/2016	03/29/2022
Stephen A. Sherwin, M.D.**(a)**	32,221	28,055/4,166	4.08	220.92	02/03/2015	03/29/2022

(a) Of the total number of options held by Dr. Sherwin, options to purchase an aggregate of 19,726 shares of BioSante common stock at a weighted average exercise price of $107.40 were granted under equity-based compensation plans of Cell Genesys, Inc. and assumed by BioSante in its October 2009 merger with Cell Genesys.

(3) BioSante does not provide perquisites or other personal benefits to BioSante s directors.

Table of Contents

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Stock Ownership

The following table sets forth information known to BioSante with respect to the beneficial ownership of each class of BioSante capital stock as of February 15, 2013 for:

- each person known by BioSante to beneficially own more than five percent of any class of BioSante s voting securities;
- each of BioSante s directors;
- each of BioSante s executive officers; and
- all of BioSante s current directors and executive officers as a group.

The number of shares beneficially owned by a person includes shares subject to options held by that person that are currently exercisable or that become exercisable within 60 days of February 15, 2013 . Percentage calculations assume, for each person and group, that all shares that may be acquired by such person or group pursuant to options currently exercisable or that become exercisable within 60 days of February 15, 2013 are outstanding for the purpose of computing the percentage of BioSante capital stock owned by such person or group. However, such unissued shares of BioSante capital stock are not deemed to be outstanding for calculating the percentage of BioSante capital stock owned by any other person. Except as otherwise indicated and subject to the voting agreements executed in connection with the proposed merger between BioSante and ANI, BioSante believes that the beneficial owners of BioSante capital stock listed in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to community property laws where applicable. Unless otherwise indicated in the notes below, the address for each of the stockholders in the table below is c/o BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069.

	Shares Beneficially Owned(1)(2)					
	BioSante Common Stock		BioSante Class C Special Stock		BioSante Common Stock and Common Stock Equivalents	Percent of Total Voting Power(3)
Name and Address of Beneficial Owner	Number	Percent	Number	Percent		
Louis W. Sullivan, M.D.	41,314	*	16,666	25.6%	57,980	*
Stephen M. Simes	275,652(4)	1.1%			275,652	1.1%

Fred Holubow	38,538	*			38,538	*
Ross Mangano	422,563(5)	1.7%			422,563	1.7%
Edward C. Rosenow, III, M.D.	31,752	*			31,752	*
John T. Potts, Jr., M.D.	12,802(6)	*			12,802	*
Stephen A. Sherwin, M.D.	46,056	*			46,056	*
Phillip B. Donenberg	129,536	*			129,536	*
Michael C. Snabes, M.D., Ph.D.	54,373	*			54,373	*
Hans Michael Jebsen(7)	12,500	*	16,666	25.6%	29,166	*
Marcus Jebsen(8)	4,166	*	8,333	12.8%	12,499	*
Angela Ho(9)	1,219	*	16,666	25.6%	17,885	*
All directors and executive officers as a group (9 persons)	1,052,586(10)	4.2%	16,666	25.6%	1,069,252	4.3%

* Represents beneficial ownership of less than one percent.

Table of Contents

(1) Includes for the persons listed below the following shares of BioSante common stock subject to options held by such persons that are currently exercisable or become exercisable within 60 days of February 15, 2013:

Name	Shares of BioSante Common Stock Underlying Stock Options
Directors	
Louis W. Sullivan, M.D.	33,331
Stephen M. Simes	241,942
Fred Holubow	28,329
Ross Mangano	28,329
Edward C. Rosenow, III, M.D.	28,329
John T. Potts, Jr., M.D.	11,873
Stephen A. Sherwin, M.D.	31,596
Named Executive Officers	
Stephen M. Simes	241,942
Phillip B. Donenberg	122,149
Michael C. Snabes, M.D., Ph.D.	54,373
All directors and executive officers as a group (9 persons)	580,251

(2) Includes shares of BioSante common stock held by the following persons in securities brokerage accounts, which in certain circumstances under the terms of the standard brokerage account form may involve a pledge of such shares as collateral: Dr. Sullivan (1,666 shares), Mr. Simes (15,788 shares), Mr. Holubow (10,209 shares), Mr. Mangano (11,133 shares), Dr. Rosenow (3,333 shares), Dr. Sherwin (14,460 shares) and Mr. Donenberg (7,387 shares).

(3) In calculating the percent of total voting power, the voting power of shares of BioSante common stock and shares of BioSante class C special stock is combined.

(4) Mr. Simes s beneficial ownership includes 33,694 shares of BioSante common stock held by a trust and 16 shares of BioSante common stock held by Mr. Simes s child.

(5) Mr. Mangano s beneficial ownership includes: (a) 321,610 shares of common stock held by JO & Co., of which Mr. Mangano is President; (b) 5,000 shares of common stock held by Oliver & Co., of which Mr. Mangano is the trustee; and (c) an aggregate of 39,998 shares of common stock held in various accounts, of which Mr. Mangano is an advisor and/or a trustee. Mr. Mangano has sole voting and investment power over these shares.

(6) Includes 487 shares of BioSante common stock held in irrevocable trusts for Dr. Potts s children, as to which Dr. Potts disclaims any beneficial ownership.

(7) The address of Hans Michael Jebsen is c/o Jebsen & Co. Ltd., 28/F Caroline Center, 28 Yun Ping Road, Causeway Bay, Hong Kong, China.

(8) The address of Marcus Jebsen is c/o MF Jebsen International Ltd., 24/F Caroline Centre, 28 Yun Ping Road, Causeway Bay, Hong Kong.

(9) The address of Angela Ho address is c/o Jet Asia Ltd., 39/F Shun Tak Center, 200 Connaught Road Central, Hong Kong, China.

(10) The amount beneficially owned by all current directors and executive officers as a group includes 486,227 shares of BioSante common stock issuable upon the exercise of stock options held by these individuals, 62,513 shares of BioSante common stock held in trusts and 16 shares of BioSante common stock held by immediate family members of the directors and executive officers. See notes (1), (4), (5) and (6) above.

Table of Contents

Securities Authorized for Issuance Under Equity Compensation Plans

The following table and notes provide information about shares of BioSante common stock that may be issued under all of BioSante s equity compensation plans as of December 31, 2012. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan are within the discretion of the Compensation Committee of BioSante s Board of Directors and BioSante s Board of Directors; and therefore, cannot be ascertained at this time.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,065,800(1)(2)	$	10.71	1,040,883(3)
Equity compensation plans not approved by security holders	39,059	$	118.38	0
Total	1,104,859	$	14.51	1,040,883

(1) Amount includes shares of BioSante common stock issuable upon the exercise of stock options outstanding as of December 31, 2012 under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan, as amended and restated (the 2008 Plan) and the BioSante Pharmaceuticals, Inc. 1998 Stock Plan, as amended and restated (the 1998 Plan).

(2) Excludes options assumed by BioSante in connection with BioSante s merger with Cell Genesys, Inc. As of December 31, 2012, a total of 39,059 shares of BioSante common stock were issuable upon exercise of the assumed options. The weighted average exercise price of the outstanding assumed options as of such date was $118.38 per share and they have an average weighted life remaining of 3.4 years. All of the options assumed and outstanding in connection with BioSante s merger with Cell Genesys were exercisable as of December 31, 2012. No additional options, restricted stock units or other equity incentive awards may be granted under the assumed Cell Genesys, Inc. plans.

(3) As of December 31, 2012, these shares remain available for future issuance under the 2008 Plan. Under the terms of the 2008 Plan, any shares of BioSante common stock subject to outstanding awards under the 1998 Plan as of the approval of the 2008 Plan by the BioSante stockholders on May 30, 2012 that are forfeited, expired or otherwise terminated become available for issuance under the 2008 Plan. No awards will be granted or shares issued under the 1998 Plan except upon the exercise of options outstanding as of the effective date of the 2008 Plan.

Table of Contents

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Director and Executive Officer Compensation

Please see Item 11. Executive Compensation for information regarding the compensation of BioSante s directors and executive officers and for information regarding employment, indemnification and other agreements BioSante has entered into with BioSante s current and former directors and executive officers.

Policies and Procedures Regarding Related Party Transactions

The Board of Directors has delegated to the Audit and Finance Committee, pursuant to the terms of a written policy, the authority to review, approve and ratify related party transactions. If it is not feasible for the Audit and Finance Committee to take an action with respect to a proposed related party transaction, the Board of Directors or another committee of the Board of Directors, may approve or ratify it. No member of the Board of Directors or any committee may participate in any review, consideration or approval of any related party transaction with respect to which such member or any of his or her immediate family members is the related party.

BioSante s policy defines a related party transaction as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which BioSante (including any of BioSante s subsidiaries) was, is or will be a participant and in which any related party had, has or will have a direct or indirect interest.

Prior to entering into or amending any related party transaction, the party involved must provide notice to BioSante s finance department of the facts and circumstances of the proposed transaction, including:

- the related party s relationship to BioSante and his or her interest in the transaction;

- the material facts of the proposed related party transaction, including the proposed aggregate value of such transaction or, in the case of indebtedness, the amount of principal that would be involved;

- the purpose and benefits of the proposed related party transaction with respect to BioSante;

- if applicable, the availability of other sources of comparable products or services; and

- an assessment of whether the proposed related party transaction is on terms that are comparable to the terms available to an unrelated third party or to employees generally.

If BioSante s finance department determines the proposed transaction is a related party transaction and the amount involved will or may be expected to exceed $10,000 in any calendar year, the proposed transaction will be submitted to the Audit and Finance Committee for its prior review and approval or ratification. In determining whether to approve or ratify a proposed related party transaction, the Audit and Finance Committee will consider, among other things, the following:

- the purpose of the transaction;

- the benefits of the transaction to BioSante;

Table of Contents

- the impact on a director s independence in the event the related party is a non-employee director, an immediate family member of a non-employee director or an entity in which a non-employee director is a partner, shareholder or executive officer;

- the availability of other sources for comparable products or services;

- the terms of the transaction; and

- the terms available to unrelated third parties or to employees generally.

Related party transactions that involve $10,000 or less must be disclosed to the Audit and Finance Committee but are not required to be approved or ratified by the Audit and Finance Committee.

BioSante also produces quarterly reports to the Audit and Finance Committee of any amounts paid or payable to, or received or receivable from, any related party. These reports allow BioSante to identify any related party transactions that were not previously approved or ratified. In that event, the transaction will be promptly submitted to the Audit and Finance Committee for consideration of all the relevant facts and circumstances, including those considered when a transaction is submitted for pre-approval. Under BioSante s policy, certain related party transactions as defined under BioSante s policy, such as certain transactions not requiring disclosure under the rules of the SEC, will be deemed to be pre-approved by the Audit and Finance Committee and will not be subject to these procedures.

Director Independence

The Board of Directors has determined that six of BioSante s seven current directors Louis W. Sullivan, M.D., Fred Holubow, Ross Mangano, Edward C. Rosenow III, M.D., John T. Potts, Jr., M.D. and Stephen A. Sherwin, M.D. are independent directors under the Listing Rules of The NASDAQ Stock Market. The Listing Rules of The NASDAQ Stock Market provide a non-exclusive list of persons who are not considered independent. For example, under these rules, a director who is, or during the past three years was, employed by the company or by any parent or subsidiary of the company, other than prior employment as an interim chairman or chief executive officer, would not be considered independent. No director qualifies as independent unless the Board of Directors affirmatively determines that the director does not have a material relationship with the listed company that would interfere with the exercise of independent judgment. In making an affirmative determination that a director is an independent director, the Board of Directors reviewed and discussed information provided by these individuals and by BioSante with regard to each of their business and personal activities as they may relate to BioSante and BioSante s management.

Table of Contents

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit, Audit-Related, Tax and Other Fees

The table below presents fees billed to BioSante for professional services rendered by Deloitte & Touche LLP and its affiliates (collectively Deloitte) for the years ended December 31, 2012 and December 31, 2011.

	Aggregate Amount Billed by Deloitte	
	2012	2011
Audit Fees(1)	$ 389,000	$ 275,000
Audit-Related Fees	0	0
Tax Fees(2)	15,000	0
All Other Fees	0	0

(1) Audit fees consisted of the audit of BioSante s annual financial statements, including the attestation of BioSante s internal control over financial reporting, reviews of financial statements included in BioSante s quarterly reports on Form 10-Q and services provided in connection with BioSante s statutory and regulatory filings, including the review of registration statements and the issuance of consents, with the increase over the prior year due to the services provided in connection with Form S-4 registration statement filings associated with the proposed merger with ANI.

(2) Tax fees consisted of advice related to tax matters associated with the proposed ANI merger.

Pre-Approval Policies and Procedures

The Audit and Finance Committee has adopted procedures pursuant to which all audit, audit-related and tax services, and all permissible non-audit services provided by Deloitte & Touche LLP to BioSante, are pre-approved by the Audit and Finance Committee. All services rendered by Deloitte & Touche LLP to BioSante during 2012 were permissible under applicable laws and regulations, and all such services provided by Deloitte & Touche LLP to BioSante, other than de minimis non-audit services allowed under applicable law, were approved in advance by the Audit and Finance Committee in accordance with the rules adopted by the SEC in order to implement requirements of the Sarbanes-Oxley Act of 2002.

Table of Contents

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

BioSante s financial statements are included in Item 8 of Part II of this report.

The exhibits to this report are listed on the Exhibit Index to this report. A copy of any of the exhibits listed will be furnished at a reasonable cost, upon receipt from any person of a written request for any such exhibit. Such request should be sent to BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, Attn: Stockholder Information.

The following is a list of each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K pursuant to Item 15(a):

A. Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes (incorporated by reference to Exhibit 10.1 to BioSante s current report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)).

B. Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg (incorporated by reference to Exhibit 10.2 to BioSante s current report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)).

C. Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 contained in BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)).

D. Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes (incorporated by reference to Exhibit 10.4 contained in BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)).

E. BioSante Pharmaceuticals, Inc. Officer Severance Policy (incorporated by reference to Exhibit 10.5 contained in BioSante s quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2011 (File No. 001-31812)).

F. BioSante Pharmaceuticals, Inc. Performance Incentive Plan (incorporated by reference to Exhibit 10.4 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)).

G. BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)).

H. Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)).

Table of Contents

I. Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)).

J. Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)).

K. BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.1 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)).

L. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.5 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 000-28637)).

M. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.30 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)).

N. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.31 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)).

O. Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors and Executive Officers (incorporated by reference to Exhibit 10.30 to BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)).

P. Description of Non-Employee Director Compensation Arrangements (filed herewith).

Q. Cell Genesys, Inc. 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 contained in Cell Genesys s quarterly report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-19986)).

R. Cell Genesys, Inc. Amended and Restated 1998 Incentive Stock Plan (incorporated by reference to Exhibit 10.2 contained in Cell Genesys s quarterly report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-19986)).

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 28, 2013

BIOSANTE PHARMACEUTICALS, INC.

By /s/ STEPHEN M. SIMES
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer (Principal Executive Officer)

By /s/ PHILLIP B. DONENBERG
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
/S/ STEPHEN M. SIMES Stephen M. Simes	Vice Chairman, President and Chief Executive Officer	February 28, 2013
/S/ LOUIS W. SULLIVAN, M.D. Louis W. Sullivan, M.D.	Chairman of the Board	February 28, 2013
/S/ FRED HOLUBOW Fred Holubow	Director	February 28, 2013
/S/ ROSS MANGANO Ross Mangano	Director	February 28, 2013
/S/ JOHN T. POTTS, JR., M.D. John T. Potts, Jr., M.D.	Director	February 28, 2013
/S/ EDWARD C. ROSENOW, III, M.D. Edward C. Rosenow, III, M.D.	Director	February 28, 2013
/S/ STEPHEN A. SHERWIN, M.D. Stephen A. Sherwin, M.D.	Director	February 28, 2013

156

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2012

Exhibit No.	Exhibit	Method of Filing
1.1	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 as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
1.2	Placement Agent Agreement dated as of March 4, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
1.3	Placement Agent Agreement dated as of June 20, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
1.4	Placement Agent Agreement dated as of December 27, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
1.5	Placement Agent Agreement dated March 3, 2011 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
1.6	Underwriting Agreement, dated July 28, 2011 by and between BioSante Pharmaceuticals, Inc. and Jefferies & Company, Inc., as Representative of the Several Underwriters Named in Schedule A Thereto	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 28, 2011 (File No. 001-31812)
1.7	Placement Agent Agreement dated August 16, 2012 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
2.1	Agreement and Plan of Merger dated as of October 3, 2012 by and between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 2.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
2.2	Amendment No. 1 to Agreement and Plan of Merger dated as of November 13, 2012 by and between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 2.2 to BioSante s Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (Reg. No. 333-185391)
2.3	Agreement and Plan of Merger dated as of June 29, 2009 by and between BioSante Pharmaceuticals, Inc. and Cell Genesys, Inc. (1)	Incorporated by reference to Exhibit 2.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 30, 2009 (File No. 001-31812)
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 as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
3.2	Amendment to Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
3.3	Amended and Restated Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
4.1	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 as filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-19986)
4.2	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 as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
4.3	Warrant dated December 15, 2008 issued by BioSante Pharmaceuticals, Inc. to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
4.4	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the August 2009 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
4.5	Form of Replacement Warrant issued to Investors in Cell Genesys, Inc. s April 2007 Registered Direct Offering	Incorporated by reference to Exhibit 4.9 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
4.6	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the March 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
4.7	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the June 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
4.8	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the December 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
4.9	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placement Agent in the March 2011 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
4.10	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors in the August 2012 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.3	Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 contained in BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.4	Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes	Incorporated by reference to Exhibit 10.4 contained in BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.5	BioSante Pharmaceuticals, Inc. Officer Severance Policy	Incorporated by reference to Exhibit 10.5 contained in BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011 (File No. 001-31812)
10.6	BioSante Pharmaceuticals, Inc. Performance Incentive Plan	Incorporated (by reference to Exhibit 10.4 contained in BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)
10.7	BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.8	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.9	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 1, 2012 (File No. 001-31812)
10.10	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.4 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)
10.11	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.12	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.5 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.13	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.14	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.31 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.15	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its Directors and Executive Officers	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
10.16	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.17	Cell Genesys, Inc. 2005 Equity Incentive Plan, as amended	Incorporated by reference to Exhibit 10.3 to Cell Genesys s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-19986)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.18	Cell Genesys, Inc. Amended and Restated 1998 Incentive Stock Plan	Incorporated by reference to Exhibit 10.2 to Cell Genesys s Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-19986)
10.19	Office Lease, dated December 19, 2003, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.29 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.20	First Amendment to Lease, dated February 26, 2004, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2004 (File No. 001-31812)
10.21	Second Amendment to Lease dated as of January 4, 2005, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 6, 2005 (File No. 001-31812)
10.22	Third Amendment to Lease dated as of January 27, 2006 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 1, 2006 (File No. 001-31812)
10.23	Fourth Amendment to Lease dated as of March 7, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2007 (File No. 001-31812)
10.24	Fifth Amendment to Lease dated as of November 2, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago.	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 6, 2007 (File No. 001-31812)
10.25	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 21, 2008 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.26	Seventh Amendment to Lease dated as of November 17, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.22 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.27	Eighth Amendment to Lease dated as of September 8, 2009 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.23 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.28	Ninth Amendment to Lease dated as of January 19, 2011 by and between 111 Barclay Associates, the sole beneficiary under Chicago Title Land Trust Company, as successor trustee to LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 27, 2011 (File No. 001-31812)
10.29	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.27 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.30	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.28 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.31	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.32	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.33	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.31 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.34	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.32 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.35	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.33 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.36	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (2)	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.37	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (2)	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.38	Development and License Agreement dated December 27, 2002 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.39	First Amendment to Development and License Agreement dated March 13, 2003 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.2 to BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.40	Letter Agreement dated June 4, 2007 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. Regarding Development and License Agreement dated December 27, 2002 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.3 to BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.41	Third Amendment to Development and License Agreement dated as of October 17, 2012 between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.4 to BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.42	Registration Rights Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.43	Amendment to Registration Rights Agreement dated as of dated as of June 26, 2009 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.3 to BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2009 (File No. 001-31812)
10.44	Form of Securities Purchase Agreement, dated August 13, 2009, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
10.45	Form of Securities Purchase Agreement, dated March 4, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
10.46	Form of Securities Purchase Agreement, dated June 20, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the June 2010 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
10.47	Form of Securities Purchase Agreement, dated December 27, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the December 2010 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
10.48	Form of Securities Purchase Agreement, dated March 3, 2011, between BioSante Pharmaceuticals, Inc. and each of the investors in the March 2011 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2012 (File No. 001-31812)
10.49	Form of Securities Purchase Agreement, dated August 16, 2012, between BioSante Pharmaceuticals, Inc. and each of the investors in the August 2012 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.50	Form of Voting Agreement dated as of October 3, 2012 between certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.51	Form of Voting Agreement dated as of October 3, 2012 between Meridian Venture Partners II, L.P. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.52	Form of Voting Agreement dated as of October 3, 2012 between certain stockholders, directors and officers of BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
10.53	Form of Lock-Up Agreement dated as of October 3, 2012 between the chief executive officer and chief financial officer and certain stockholders of ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.4 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 4, 2012 (File No. 001-31812)
14.1	Code of Conduct and Ethics	Incorporated by reference to Exhibit 14.1 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
23.1	Consent of Deloitte & Touche LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to Rule 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 Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

Table of Contents

Exhibit No.	Exhibit	Method of Filing
101	The following materials from BioSante Pharmaceuticals, Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the audited Balance Sheets, (ii) the audited Statements of Operations, (iii) the audited Statements of Stockholders Equity; (iv) the audited Statements of Cash Flows, and (v) Notes to Financial Statements.*	Furnished herewith

(1) All exhibits and schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Securities and Exchange Commission.

(2) Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.

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