

BIOSANTE PHARMACEUTICALS INC  
Form 10-K  
March 16, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-K**

(Mark one)

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

For the fiscal year ended December 31, 2010

**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)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

**Delaware**

(State or other jurisdiction of incorporation or organization)

**58-2301143**

(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
<b>Common Stock, par value \$0.0001 per share</b>	<b>The NASDAQ Stock Market</b>

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  NO

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  NO

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

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

Indicate by check mark 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.

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):

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

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, 2010 (the last business day of the registrant's second fiscal quarter) as reported by The NASDAQ Global Market on that date was approximately \$119.8 million.

As of March 10, 2011, 93,590,612 shares of common stock of the registrant were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Part III of this annual report on Form 10-K incorporates by reference information (to the extent specific sections are referred to herein) from the registrant's Proxy Statement for its 2011 Annual Meeting of Stockholders to be held on May 26, 2011.

---

Table of Contents

**TABLE OF CONTENTS**

---

	<b>Page</b>
<u>PART I</u>	1
<u>Item 1.</u>	<u>BUSINESS</u>
	1
<u>Item 1A.</u>	<u>RISK FACTORS</u>
	17
<u>Item 1B.</u>	<u>UNRESOLVED STAFF COMMENTS</u>
	38
<u>Item 2.</u>	<u>PROPERTIES</u>
	38
<u>Item 3.</u>	<u>LEGAL PROCEEDINGS</u>
	38
<u>Item 4.</u>	<u>[REMOVED AND RESERVED]</u>
	38
<u>Item 4A.</u>	<u>EXECUTIVE OFFICERS OF THE REGISTRANT</u>
	39
<u>PART II</u>	40
<u>Item 5.</u>	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>
	40
<u>Item 6.</u>	<u>SELECTED FINANCIAL DATA</u>
	42
<u>Item 7.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>
	43
<u>Item 7A.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>
	53
<u>Item 8.</u>	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>
	54
<u>Item 9.</u>	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>
	85
<u>Item 9A.</u>	<u>CONTROLS AND PROCEDURES</u>
	85
<u>Item 9B.</u>	<u>OTHER INFORMATION</u>
	85
<u>PART III</u>	86
<u>Item 10.</u>	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>
	86
<u>Item 11.</u>	<u>EXECUTIVE COMPENSATION</u>
	87
<u>Item 12.</u>	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>
	87
<u>Item 13.</u>	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>
	88

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

<u>Item 14.</u>	<u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	88
<u>PART IV</u>		89
<u>Item 15.</u>	<u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	89
<u>EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K</u>		92

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 Form 10-K 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 or continue, the negative of these words, other words and terms of similar meaning or the use of future dates. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the headings Part I. Item I. Business Forward-Looking Statement and Part I. Item 1A. Risk Factors. These factors may cause our actual results to differ materially from any forward-looking statement.*

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

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

Table of Contents

**PART I**

---

**Item 1. BUSINESS**

**Company Overview**

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

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

- LibiGel – once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD).
- Elestrin – once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.
- The Pill-Plus (triple component contraceptive) – once daily use of various combinations of estrogens, progestogens and androgens in Phase II development for the treatment of FSD in women using oral or transdermal contraceptives.
- Bio-T-Gel – once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.
- Cancer vaccines – a portfolio of cancer vaccines in Phase II clinical development for the treatment of various cancers.

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up

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

post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future. The Phase III safety study is currently enrolling women, and as of the end of February 2011 had enrolled approximately 2,900 women. In February 2011, we announced that based upon the fifth review of study conduct and unblinded safety data from the safety study by the study's independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If enrollment is not completed sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 women. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit an NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women. It is our objective to submit the LibiGel NDA to the FDA so that LibiGel may be approved in 2012.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), BioSante's licensee, is marketing Elestrin in the U.S. using Azur's women's health sales force which targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur's sales of Elestrin. We maintain the right to receive up to \$140



Table of Contents

million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, we believe our receipt of such payments unlikely in the near term, if at all.

Our portfolio of cancer vaccines is designed to stimulate the patient's immune system to fight effectively the patient's own cancer. Multiple Phase II trials of these vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia and breast cancer. We anticipate Phase II trials for prostate cancer to begin in the first half of 2011. Four of these vaccines have been granted FDA orphan drug designation.

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. CaP currently is in development as a facial line filler (BioLook) in the area of aesthetic medicine.

**BioSante's Primary Product Portfolio**

<b>Product</b>	<b>Indication</b>	<b>Early Human Clinical</b>	<b>Late Human Clinical</b>	<b>FDA Approval</b>	<b>Collaborations</b>
Elestrin (estradiol gel)	Menopausal symptoms				Azur Pharma
LibiGel® (testosterone gel)	Female sexual dysfunction (FSD)				Non-partnered
Bio-T-Gel (testosterone gel)	Male Hypogonadism				Teva
The Pill Plus (birth control with androgen)	Contraception				Pantarhei for oral use Non-partnered for TD use
Cancer Vaccines	Various Cancers				Johns Hopkins

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

**Description of Our Female Sexual Health, Menopause, Contraception and Male Hypogonadism Products**

**Overview.** Our products for female sexual health, menopause, contraception and male hypogonadism include our gel formulations of estradiol or testosterone and combinations of estrogen, progestogen and androgen: LibiGel, Elestrin, Bio-T-Gel and Pill-Plus, our triple component

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

contraceptive that uses various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

Our gel products are designed to be quickly absorbed 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. We believe our gel products have a number of benefits over competitive products, including the following:

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

Table of Contents

- our transdermal gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;
- our 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.

We license the technology underlying certain of our gel products, including LibiGel and Elestrin, from Antares Pharma, Inc. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the licensed technology. Bio-T-Gel was developed and is fully-owned by us and licensed to Teva for further development and commercialization. We license the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

**LibiGel.** We believe LibiGel, if approved by the FDA, could be a very successful product. LibiGel is a once daily transdermal testosterone gel designed to treat FSD, specifically HSDD in menopausal women. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes associated with aging or following surgical menopause. LibiGel successfully has completed a Phase II clinical trial, and three Phase III safety and efficacy clinical studies currently are underway. We have completed enrollment in the first efficacy trial, plan to complete enrollment in the second efficacy trial in the near future and the safety study currently is enrolling women.

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of HSDD in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. We have three SPAs in place concerning LibiGel. The first SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. The second SPA covers our LibiGel program in the treatment of FSD in naturally menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

Both Phase III safety and efficacy trials are randomized, double-blind, placebo-controlled, multi-center trials of approximately 500 surgically menopausal women each, exposed to LibiGel or placebo for six months. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future. The Phase III safety study currently is enrolling women and is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular and breast cancer safety study of between approximately 3,000 and 4,000 women

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

exposed to LibiGel or placebo for a minimum average of 12 months. After data analysis and following NDA submission and potential FDA approval and product launch, we will continue to follow each woman in the safety study for 60 total months of exposure.

In February 2011, based upon the fifth review of study conduct and unblinded safety data from the safety study by the study's independent data monitoring committee, the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. The DMC's review was based on unblinded adverse events of the subjects who have been enrolled in the safety study. Additional unblinded reviews will be conducted by the DMC every approximately 90 days from the previous review. However, according to the

Table of Contents

protocol, the DMC may meet earlier after each two additional adjudicated cardiovascular events. As of the date of the DMC's most recent review, there had been only 17 adjudicated cardiovascular (CV) events, a rate of approximately 0.58 percent, and only eight diagnoses of breast cancer, a rate of approximately 0.27 percent, after approximately 2,900 women-years of exposure in the study, or an average of more than 12 months per subject. As of the end of February 2011, approximately 2,900 women were enrolled in the study. At each review of safety data, the study potentially could be fully enrolled based on predefined statistical analyses. If enrollment is not completed sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 women.

There is no pharmaceutical product currently approved in the United States for FSD, specifically HSDD, and we are not aware of any other product for the treatment of HSDD in active Phase III clinical development in the U.S. other than LibiGel.

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, two million testosterone prescriptions were written off-label for women by U.S. physicians in 2009 and according to independent primary market research, at least 2 million additional prescriptions of compounded testosterone were written off-label for women. Female sexual dysfunction is defined as a 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.

Treatment with LibiGel in our Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD. 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 study, 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, conducted in the United States, in surgically menopausal women distressed by their low sexual desire and activity.

In July 2010, we announced the initiation of a LibiGel clinical trial to evaluate its effect on cognitive function in menopausal women. The trial is a randomized, double-blind, placebo-controlled six-month comparison in 120 women of the effect of LibiGel compared to placebo treatment on a variety of learning and memory tasks. The study is being conducted by Dr. Susan Davis, Professor of Women's Health, Department of Medicine, Monash University Women's Health Program in Australia.

**Elestrin.** Elestrin is our 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. The lower dose of Elestrin is one of the lowest daily doses of estradiol approved by the FDA for the treatment of hot flashes and is 67 percent lower than the lowest dose, FDA-approved estrogen patch for hot flashes on the market. The Elestrin FDA approval was a non-conditional and full approval.

Elestrin is subject to a license agreement and an asset purchase agreement with Azur for the marketing of Elestrin and the sale of certain assets related to Elestrin pursuant to which we received approximately \$3.3 million. In April

Table of Contents

2009, we announced the initiation of sales and marketing activity of Elestrin by Azur. Subsequently, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur's sales of Elestrin. We maintain the right to receive up to \$140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, we believe our receipt of such payments unlikely in the near term, if at all. Azur is marketing Elestrin in the U.S. using Azur's women's health sales force which targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists.

Elestrin is also subject to an exclusive agreement with PharmaSwiss SA (to be acquired by Valeant Pharmaceuticals) for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. Israeli authorities have approved Elestrin and plans for marketing Elestrin.

**Bio-T-Gel.** Bio-T-Gel is our once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men. Unlike LibiGel and Elestrin, Bio-T-Gel is owned by us with no royalty or milestone obligations to any other party.

Bio-T-Gel is subject to a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA has agreed to develop and market Bio-T-Gel for the U.S. market. The financial terms of the development and license agreement included a \$1.5 million upfront payment by Teva USA, certain milestones and royalties on sales of the product, if and when approved and marketed, in exchange for rights to develop and market the product. Teva USA also is responsible under the terms of the agreement for continued development, regulatory filings and all manufacturing and marketing associated with the product. It is anticipated that Teva USA will submit an application for approval to market Bio-T-Gel to the FDA during the first half of 2011.

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. Approximately five million men in the United States, primarily over age 40, have lower than normal levels of testosterone. 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 formulated gel 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. We are aware of two gel testosterone products for men currently on the market in the United States and two others have been FDA approved but have not been commercially launched yet. According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 17 percent in 2010 to \$1.1 billion from \$968 million in 2009.

**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

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

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



Table of Contents

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 progesterone in normal oral contraceptives. The Pill-Plus is designed to improve the symptoms of female sexual dysfunction in oral contraceptive users.

We have an 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 financial terms of the license include an upfront payment, regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

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. We may receive certain development and regulatory milestones for the first product developed under the license. In addition, we 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, we will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. We have retained all rights under our licensed patents to the transdermal delivery of triple component contraceptives.

In June 2010, we announced positive results in a Phase II study of the Pill-Plus triple component oral contraceptive. The study was a Phase II double-blind, randomized clinical trial in 82 women comprising a cross-over design of two treatment periods of five months each. The study compared use of an oral contraceptive alone to the same oral contraceptive with the addition of an oral androgen (DHEA). The study was performed by the Department of Sexology of the Academic Medical Center in Amsterdam, The Netherlands in close collaboration with Pantarhei Bioscience B.V. in The Netherlands, our licensee.

**Other Products.** Marketing rights to our 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 our company, 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 our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made.

**Description of Our Cancer Vaccines and Other Technologies**

**Cancer Vaccine Technology.** Our cancer vaccines are designed to stimulate the patient's immune system to effectively fight cancer. Our cancer vaccines are comprised of tumor cells that are genetically modified to secrete an immune-stimulating cytokine known as granulocyte-macrophage colony-stimulating factor, or GM-CSF, and are then irradiated for safety. Since our cancer vaccines consist of whole tumor cells, the cancer patient's immune system can be activated against multiple tumor cell components, or antigens, potentially resulting in greater clinical benefit than if the vaccine consisted of only a single tumor cell component. Additionally, the secretion of GM-CSF by the modified tumor cells can enhance greatly the immune response by recruiting and activating dendritic cells at the injection site, a critical step in the optimal response by the immune system to any immunotherapy product. The antitumor immune response which occurs throughout the body following administration of our cancer vaccine potentially can result in the destruction of tumor cells that persist or recur following surgery, radiation therapy or chemotherapy treatment.

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

Our cancer vaccines can be administered conveniently in an outpatient setting as an injection into the skin, a site where immune cells, including in particular dendritic cells, can be optimally accessed and activated. These cancer vaccines are being tested as patient-specific, or autologous, products and as non patient-specific, or allogeneic, products. Multiple Phase II trials of these vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia and breast cancer. We anticipate Phase II trials for prostate cancer to begin in 2011. Four of these vaccines have been granted FDA orphan drug designation.

**2A/Furin Protein Expression Technology.** The 2A/furin technology is a novel expression system for producing high levels of multimeric proteins. The 2A/furin technology allows for continuous, equimolar expression of at least

Table of Contents

two proteins at high concentrations from a single expression vector making it particularly useful for recombinant antibody expression. The technology expression technology has been used successfully to express antibodies from several species, including murine, rat and human, as well as a variety of antibody isotypes. The 2A/furin expression technology has several potential applications including preclinical lead and target validation, gene therapy, production of stable, high producer antibody cell lines, and commercial production of antibodies and other proteins. The 2A/furin technology can increase the efficiency of antibody production by cutting the cost and reducing the time to manufacture antibodies. According to the Global Monoclonal Antibodies Review, the antibody market in the U.S. is estimated to be more than \$30 billion per year.

In April 2010, we entered into an option agreement with an undisclosed pharmaceutical company to obtain a non-exclusive license for the use of our 2A/furin technology. The undisclosed company has chosen not to exercise this option. We are evaluating further development of our 2A/furin technology.

***Oncolytic Virus Technology.*** On November 15, 2010, we entered into an assignment and technology transfer agreement with Cold Genesys, Inc. pursuant to which we sold to Cold Genesys exclusive, worldwide rights to develop and commercialize our 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, we received a 19.9 percent ownership position in Cold Genesys and a \$95,000 upfront cash payment and are eligible to receive future milestone and royalty payments.

***CaP Technology.*** Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. Our CaP technology is subject to a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial line filler in aesthetic medicine (BioLook). Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received a minor ownership position in MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

Pre-clinical work to date by MATC indicates that our BioLook nanotechnology performs well as a facial line filler and may be at least as long lasting and safe as other injectable fillers. Preliminary results indicate long lasting effects with no adverse events. BioLook should be extremely user friendly with minimal risk of side effects and may improve both facial wrinkles and fulfill larger facial volume needs. Human clinical testing of BioLook for this use is being planned and is expected to be initiated by MATC in 2011.

Although we believe our CaP technology has other potential commercial uses, we are not devoting any of our cash resources to pursuing any of these other potential uses.

**Sales and Marketing**

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

We currently have no sales and marketing personnel to sell any of our products on a commercial basis. Under our license agreements, our licensees have agreed to market the products covered by the agreements in certain countries. For example, under our license agreement with Azur, Azur has agreed to use commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States.

If and when we are ready to launch commercially a product not covered by our license agreements, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist us with this function.

Table of Contents

**Research and Product Development**

We spend a significant amount of our financial resources on product development activities, with the largest portion being spent on clinical studies of our products, including in particular LibiGel. We spent approximately \$39.7 million in 2010, \$13.7 million in 2009 and \$15.8 million in 2008 on research and development activities. We spent an average of approximately \$3.3 million per month on our research and development activities during 2010, the substantial majority of which was spent on our LibiGel Phase III clinical studies. The increase in research and development expenses in 2010 compared to 2009 was primarily the result of the conduct of the LibiGel Phase III clinical studies. In April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study in order to conserve cash; however, in January 2010, we reinitiated screening and enrollment in our safety study. The amount of our actual research and development expenditures in 2011 and beyond may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash available; (2) our development schedule, including the timing and scope of our clinical studies; (3) results of studies, clinical studies and regulatory decisions, including in particular the number of subjects required in our LibiGel Phase III safety study; (4) the amount of our clinical recruitment expenditures intended to complete enrollment in our LibiGel safety study; (5) whether we or our licensees are funding the development of our products; and (6) competitive developments

**Manufacturing**

We currently do not have any facilities suitable for manufacturing on a commercial scale basis any of our products nor do we have any experience in volume manufacturing. We currently use third-party current Good Manufacturing Practices, or cGMP, manufacturers to manufacture our products in accordance with FDA and other appropriate regulations. LibiGel for our clinical studies is currently manufactured by an approved U.S.-based manufacturer under FDA-approved, cGMP conditions.

**Patents, Licenses and Proprietary Rights**

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

**Gel Products.** We licensed the technology underlying LibiGel, Elestrin and certain of our other gel products, other than Bio-T-Gel, from Antares Pharma, Inc. Under the agreement, Antares granted us 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. We are 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, we are required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the in-licensed technology. The patents covering the formulations used in these gel products are expected to expire in 2022 unless patent-term extensions are granted. In addition, we have other patents pending, which, if issued, may expire later than 2022. Bio-T-Gel was developed and is fully-owned by us and not covered under the Antares license.

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

***The Pill Plus.*** We licensed the technology underlying our triple component contraceptives, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed. The patents covering the technology underlying The Pill Plus expire in 2016.

***Cancer Vaccine Technology.*** We own development and commercialization rights to our cancer vaccine technology as a result of our merger with Cell Genesys in October 2009. The original core patent applications

Table of Contents

covering our cancer vaccine technology were licensed exclusively to Cell Genesys from Johns Hopkins University and The Whitehead Institute for Biomedical Research in 1992. Rights to additional patents and patent applications were licensed from Johns Hopkins University in 2001. In addition, we own several patents and patent applications that build upon our in-licensed technology, and provide for significant additional patent term.

Our cancer vaccine patent estate broadly covers our cancer vaccine products and pipeline. The cancer vaccine patent estate includes 17 patent families, comprising over 60 issued US and foreign patents, directed to various aspects of our cancer vaccine technology. The patents expire between 2012 and 2026.

Under the various agreements, we are required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the in-licensed technology.

**2A/Furin Protein Expression Technology.** We own development and commercialization rights to our 2A/furin protein expression technology as a result of our merger with Cell Genesys in October 2009. Our 2A/furin patent estate includes five patent families, including four issued US patents and additional patent applications, directed to various aspects of the 2A/furin technology, including compositions and methods for producing recombinant antibodies. The patents expire between 2023 and 2026.

**CaP Technology.** In June 1997, we entered into a licensing agreement with the Regents of the University of California, which subsequently has been amended, pursuant to which the University granted us an exclusive license to certain United States patents owned by the University, including rights to sublicense such patents, in fields of use pertaining to vaccine adjuvants and drug delivery systems. The last of the expiration dates for these patents is 2014. We also own several of our own additional patents and patent applications covering the CaP technology expiring beginning in 2021. The University of California also has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan. The license agreement requires us to pay royalties to the University based on a percentage of the net sales of any products we sell or a licensee sells incorporating the licensed technology until expiration of the licensed patents. As described earlier in this report, we have entered into agreements with respect to our CaP technology, including a license agreement covering the use of our CaP as a facial line filler (BioLook) in aesthetic medicine. Although we are maintaining the patents for our CaP to be used as a facial line filler, we have discontinued maintaining any of the other CaP patents.

**Other License Agreements.** As described earlier in this report, we have entered into several other license agreements pursuant to which we have sublicensed to third parties certain rights with respect to our products, none of which we view as material to our business. The financial terms of these agreements generally include an upfront license fee and subsequent milestone and royalty payments to us if a product incorporating the licensed technology gets approved and subsequently is marketed and a portion of any payments received from subsequent successful out-licensing efforts.

**Trademarks and Trademark Applications/Registrations.** We own trademark registrations in the U.S. and/or in certain foreign jurisdictions for several marks, including BIOSANTE®, LIBIGEL® and BIO-E-GEL®. In addition, we have filed trademark applications for several other marks including ELESTRIN (pursuant to our license of Elestrin to Azur in the U.S., we transferred the Elestrin trademark in the U.S. to Azur) and BIO-T-GEL. In addition, we own common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, ELESTRIN, BIO-E-GEL®, BIO-T-GEL, THE PILL-PLUS, LIBIGEL-E/T, and BIOLOOK. 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.*** We require our employees, consultants and advisors having access to our confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with us. These agreements generally provide that all confidential information we develop or make known to the individual during the course of the individual's employment or consulting relationship with us must be kept confidential by the individual and not disclosed to any third parties. We also require all of our employees and consultants who perform research and development for us to execute



## Table of Contents

agreements that generally provide that all inventions and works-for-hire conceived by these individuals during their employment by us will be our property.

## **Competition**

There is intense competition in the biopharmaceutical industry, the market for prevention and/or treatment of the same infectious diseases we target and in the acquisition or licensing of new products. 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 our competitors have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than we do, as well as substantially greater experience than us 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 becoming more 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 ours; they include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc. (a subsidiary of Hisamitsu Pharmaceutical Co., Inc.), Pfizer Inc., Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc., KV Pharmaceutical Co., and Abbott Laboratories. Competitor products include oral tablets, transdermal patches, a spray and gels. We expect our FDA-approved product, Elestrin, and our other products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. 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.

With regard to our cancer vaccine technology and other recently acquired technologies, we face substantial competition in the development of products for cancer and other diseases. This competition from other manufacturers is expected to continue in both U.S. and international markets. Cancer vaccines are evolving areas in the biotechnology industry and are expected to undergo many changes in the coming years as a result of technological advances. We currently are aware of a number of groups that are developing cancer vaccines including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. Examples in the cancer vaccine area include Dendreon Corporation, which has an FDA approved product for prostate cancer, Onyvax Ltd., Antigenics, Inc., Oncothyreon Inc., GlaxoSmithKline, Warner Chilcott plc and Boehringer Ingelheim USA Corporation also are developing vaccine products for other types of cancers.

## **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 countries. Any products developed by us 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.

Table of Contents

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 our product development that may affect approval, delay the submission or review of an application or require additional expenditures by us. We may not be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our 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 our 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 three 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 product that preclude submission of an abbreviated new drug application. A 505(b)(2) NDA is in order 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;

Table of Contents

- 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 the referenced application, it may not be required to conduct some of these steps.

***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.

Our submission of an IND, or those of our 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, or 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.

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

Table of Contents

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 or independent websites (e.g., [www.clinicaltrials.gov](http://www.clinicaltrials.gov)), 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 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.

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 advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or 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. The FDA typically takes from 10 to 18 months to review an NDA after it has been accepted for filing. 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 or 505(b)(2) NDA does not satisfy the criteria for approval.





Table of Contents

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.

**Special Protocol Assessments.** The special protocol assessment, or SPA, 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 may benefit from a statutory period of non-patent marketing exclusivity. 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 an existing drug, 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 application 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 we received three years marketing exclusivity for Elestrin and expect to receive three years of marketing exclusivity for LibiGel.

**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. New Drug Applications designated as orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits up to 50% 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



Table of Contents

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. We currently do not have any manufacturing capability. In the event we undertake any manufacturing activities or contract with a third-party manufacturer to perform our manufacturing activities, we intend to establish a quality control and quality assurance program to ensure that our products are manufactured in accordance with the cGMP regulations and any other applicable regulations.

**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.

**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 countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. We intend to seek and utilize foreign partners to apply for foreign approvals of our products.

**Employees**

We had 45 employees as of December 31, 2010, including 38 in product development and seven in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We also engage independent contractors from time to time on an as needed 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, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including,

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

in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, would, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate these words, other words and terms of similar meaning or the use of future dates. These forward-looking statements may be contained in the notes to our 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. Our forward-looking statements generally relate to:

Table of Contents

- the timing of the commencement, enrollment and successful completion of our clinical studies, the submission of new drug applications and other regulatory status of our products in development;
- approval by the FDA of our products that are currently in clinical development and other regulatory decisions and actions;
- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes and licensure or acquisition of new products;
- our spending on general and administrative expenses;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market size and market acceptance of our products;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading "Part I. Item 1A. Risk Factors" below. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading "Part I. Item 1A. Risk Factors" below, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our

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

forward-looking statements can be affected by inaccurate assumptions we 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 us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

### **Available Information**

We are a Delaware corporation that was initially formed as a corporation organized under the laws of the Province of Ontario in August 1996. We 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 us, and we are the surviving corporation.

Our principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Our telephone number is (847) 478-0500, and our Internet web site address is [www.biosantepharma.com](http://www.biosantepharma.com). The information contained on our web site or connected to our web site is not incorporated by reference into and should not be considered part of this annual report on Form 10-K.

Table of Contents

We make available, free of charge and through our Internet web site, our 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 we electronically file such material with, or furnish it to, the SEC. We also make available, free of charge and through our Internet web site, to any stockholder who requests, our corporate governance guidelines, the charters of our board committees and our 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 risk factors known to us that could have a material adverse effect on our business, financial condition or operating results.

**Risks Related to Our Financial Condition and Future Capital Requirements**

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

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

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

Developing products requires substantial amounts of capital. In particular, we expect the Phase III clinical study program of LibiGel to continue to require significant resources. We currently do not have sufficient cash resources to obtain regulatory approval of LibiGel or any of our other products in development. Our future capital requirements will depend upon numerous factors, including:

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

- the progress, timing, cost and results of our clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;
- subject recruitment and enrollment in our current and future clinical studies, including in particular our LibiGel Phase III safety study;
- our ability to license LibiGel or our other products in development;
- the success, progress, timing and costs of our business development efforts to seek strategic partners and implement business collaborations, licenses and other business combinations or transactions, including our efforts to continue to seek a strategic partner for LibiGel and evaluate various strategic alternatives available with respect to our cancer vaccines and other technologies that we acquired as a result of our merger with Cell Genesys, our products and our company;
- the cost, timing and outcome of regulatory reviews of our products in development;



Table of Contents

- the rate of technological advances;
- the commercial success of our products;
- our general and administrative expenses;
- the timing and cost of obtaining third party reimbursement for our products; and
- the activities of our competitors.

Therefore, we may need to continue to raise substantial additional capital to fund our operations. Although we believe that our cash and cash equivalents of \$38.2 million at December 31, 2010 and the additional \$23.8 million in net proceeds we received from our March 2011 registered direct offering will be sufficient to meet our liquidity requirements through at least the next 15 to 18 months, this estimate may prove incorrect since it is based on our currently projected expenditures for the remainder of 2011 and 2012. Our projected expenditures are based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may differ significantly from our projections. Alternatively, we may decide to raise additional financing earlier in order to create a cash cushion and take advantage of favorable financing conditions.

To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, or at all. This is particularly true if economic and market conditions deteriorate, our Phase III clinical study program for LibiGel is unsuccessful or takes longer than we anticipate to complete or the FDA decides not to approve LibiGel during the time frame within which we anticipate or at all. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to delay our Phase III clinical study program for LibiGel or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, e.g., our cancer vaccines, to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

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

If we raise additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of our stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. If we incur additional debt financing, the payment of principal and interest on such indebtedness may limit funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our

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

stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on the ability of us to create liens, pay dividends, redeem our stock or make investments. As an alternative to raising additional financing by issuing additional equity or debt securities, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product to a third party, e.g., our cancer vaccines, who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company. If we raise additional funds through licensing arrangements, we may be required to relinquish greater or all rights to our products at an earlier stage of development or on less favorable terms than we otherwise would choose.

Table of Contents

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

We have a committed equity financing facility with Kingsbridge that expires in December 2011. The committed equity financing facility entitles us to sell and obligates Kingsbridge to purchase, from time to time through the expiration date, up to the lesser of (i) an aggregate of \$25 million in or (ii) 5,405,840 shares of our common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include a minimum price for our common stock of \$1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of our common stock issued or issuable to Kingsbridge; and the continued listing of our stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the facility if Kingsbridge determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. If we are unable to access funds through the committed equity financing facility, or if the facility is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all. As of the date of this report, we had not sold any shares to Kingsbridge under the committed equity financing facility.

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

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

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

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

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

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

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

Table of Contents

contingent or other liabilities or problems may arise, which could have an adverse effect on our business, operating results and financial condition.

**Risks Related to Our Business**

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

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

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

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

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

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

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

Table of Contents

Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

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

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

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

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

LibiGel has not been approved for marketing by the FDA and is still subject to risks associated with its clinical development and obtaining regulatory approval. We believe based on agreements with the FDA, including a Special Protocol Assessment received in January 2008, that

two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, HSDD in menopausal women. The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel. These SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD in naturally menopausal women. We have an additional SPA agreement which covers the LibiGel stability, or shelf life studies for the intended commercialization of LibiGel product. The SPA agreements, however, are not guarantees of LibiGel approval by the FDA or approval of any permissible claims about LibiGel. In particular, SPA agreements are not binding on the FDA if previously unrecognized public health concerns later comes to light, other new scientific concerns regarding product safety or effectiveness arise, we fail to comply with the protocol agreed upon, or the FDA's reliance on data, assumptions or information are determined to be wrong. Even after an SPA agreement is finalized, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results



Table of Contents

from any study that is the subject of the SPA agreement. In addition, the data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval.

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

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

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

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

- the information submitted may be insufficient to demonstrate that a product is safe and effective;
- the FDA might not approve the processes or facilities of a company, or those of its vendors, that will be used for the commercial manufacture of a product; or
- the FDA's interpretation of the nonclinical, clinical or manufacturing data provided in an NDA may differ from a company's interpretation of such data.

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

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

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

Table of Contents

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

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

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

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

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

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



Table of Contents

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

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

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical studies;
  
- delay in developing, or our inability to obtain, a clinical dosage form, insufficient supply or deficient quality of our products or other materials necessary to conduct our clinical studies;
  
- negative or inconclusive results from clinical studies, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;
  
- serious and/or unexpected product-related side effects experienced by subjects in our clinical studies; or
  
- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

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

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

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

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

Table of Contents

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

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

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

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

- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications

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

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

We intend to enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, our products in development, including in particular LibiGel. We face significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic relationships on



Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

- business combinations or significant changes in a strategic partner's business strategy may adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our partnered products;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;
- strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of our partnered products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our partnered products or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not maintain properly or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including our competitors; and

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

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

Elestrin is our first FDA approved product. Azur Pharma International II Limited is marketing Elestrin in the U.S. using its women's health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur's sales of Elestrin. We maintain the right to receive up to \$140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year. We cannot assure you that Azur will be successful in marketing Elestrin, Elestrin will be widely accepted in the marketplace or that Azur will remain focused on the commercialization of Elestrin, especially if Azur does not experience significant Elestrin sales. Market penetration of Elestrin during 2010 was low. Based on such low sales of Elestrin, we believe it is unlikely that we will receive any sales-based milestone payments from Azur in the foreseeable future or at all.

Table of Contents

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

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

- demonstration of efficacy and safety in clinical trials;
- the existence, prevalence and severity of any side effects;
- the availability of alternative treatments and potential or perceived advantages or disadvantages compared to alternative treatments;
- perceptions about the relationship or similarity between our products and the parent drug compound upon which the product is based;
- the timing of market entry relative to competitive treatments;
- the ability to offer our products for sale at competitive prices;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our products by third-party payors and governmental and other payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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

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

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

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

- private health insurers;
- health maintenance organizations;

Table of Contents

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

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

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

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

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

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



Table of Contents

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

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

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

- we and our strategic partners may be unable to initiate or continue clinical studies of our products that are under development;
- we and our strategic partners may be delayed in submitting applications for regulatory approvals for our products that are under development; and
- we and our strategic partners may be unable to meet commercial demands for any approved products.

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

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

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

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

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

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

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

Table of Contents

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

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

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

We are subject to changing rules and regulations of federal and state governments as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the SEC and the NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from our other business activities.

**Risks Related to Our Industry**

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

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



Table of Contents

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

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

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

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

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

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

#### **Risks Related to Our Intellectual Property**

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

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

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

Table of Contents

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

We have licensed our CaP technology for use as a facial line filler to MATC and some of our gel products to third parties, including Azur, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA (to be acquired by Valeant Pharmaceuticals). All of these parties, except for Azur, have agreed to be responsible for continued development, regulatory filings and all have agreed to manufacturing and marketing associated with the products. In addition, in the future we may enter into additional similar license agreements. Our products that we have licensed to others thus are subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. Our current and future licensees may have different and, sometimes, competing priorities. We cannot assure you that our strategic partners or any future third party to whom we may license our products will remain focused on the development and commercialization of our partnered products or will not otherwise breach the terms of our agreements with them, especially since these third parties also may compete with us with respect to some of our products. For example, in 2005, we were notified that Teva USA had discontinued development of our male testosterone gel, Bio-T-Gel, product. Although in June 2007, we signed an amendment to the agreement under which we and Teva reinitiated our collaboration on the development of Bio-T-Gel for the U.S. market, no assurance can be provided that Teva will continue such development. Any future breach of this agreement by Teva or any other breach by our strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered products in these agreements if we are unable to license the products to another party on substantially the same or better terms or continue the development and future commercialization of the products ourselves.

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

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

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

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

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



Table of Contents

expiration of the applicable patent could have a material adverse effect on the sales and profitability of our products.

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

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

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

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

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

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

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

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

Table of Contents

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

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our potential gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

**Risks Related to Our Common Stock**

*The price of our common stock has been volatile. As a result, we could become subject to class action litigation, which even if without merit, could be costly to defend and could divert the time and attention of our management, which could harm our business and financial condition.*

Since January 1, 2010, the sale price of our common stock has ranged from a low of \$1.29 to a high of \$2.54. It is likely that the price of our common stock will continue to fluctuate in the future. The securities of small capitalization, biopharmaceutical companies, including our company, from time to time experience significant price fluctuations, often unrelated to the operating performance of these companies. In particular, the market price of our common stock 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 our company or our business.

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

- our ability to obtain needed financing;
- equity sales by us to fund our operations;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products in development or our competitors' products;
- actual or anticipated results of our clinical studies or those of our competitors;
- changes in laws or regulations applicable to our products;
- changes in the anticipated or actual timing of our development programs, including delays or cancellations of clinical studies for our products;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors or licensees of our technology;
- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;

Table of Contents

- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- developments or disputes concerning patents or other proprietary rights;
- period-to-period fluctuations in our financial results, including our 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 our larger stockholders, officers or directors;
- reports issued by securities analysts regarding our common stock and articles published regarding our business and/or products;
- changes in the market valuations of other life science or biotechnology companies; and
- other financial announcements, including delisting of our common stock from the NASDAQ Global Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in our filings with the SEC or our failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this report or otherwise in reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our 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. We may become the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

***We may issue additional equity securities which would dilute your share ownership and could cause our stock price to decrease.***

We currently have the ability to offer and sell common stock, preferred stock and warrants under currently effective universal shelf registration statements. We typically sell shares of our common stock and warrants to purchase shares of our common stock to raise additional financing and fund our operations. We may issue additional equity securities to raise capital and through the exercise of options and warrants that are

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

outstanding or may be outstanding. These additional issuances would dilute your share ownership. In addition, these sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

***Future exercises by holders of warrants and options and conversions by holders of our convertible senior notes could substantially dilute our common stock.***

As of March 10, 2011, we had warrants to purchase an aggregate of 23.7 million shares of our common stock outstanding that are exercisable at prices ranging from \$2.00 per share to \$39.27 per share and options to purchase an aggregate of 5.3 million shares of our common stock outstanding that are exercisable at prices ranging from \$1.41 per share to \$36.82 per share. In addition, as of March 10, 2011, we had \$1.2 million in principal amount of convertible senior notes that are convertible into an aggregate of 24,789 shares of our common stock at a conversion price of \$49.78 per share and an additional \$20.8 million in principal amount of convertible senior notes that are convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of \$3.72 per share. Our stockholders, therefore, could experience substantial dilution of their investment upon exercise of these warrants and options and conversion of these notes. A substantial majority of these shares of common stock issuable upon exercise of the warrants and options and conversion of the notes currently are registered and thus will be available for immediate resale in the public market.

Table of Contents

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

In order for our common stock to be eligible for continued listing on the NASDAQ Global Market, we must remain in compliance with certain listing standards, including a \$1.00 minimum closing bid price per share requirement, a \$50 million market capitalization and a \$15 million public float requirement or a \$12 million minimum stockholders' equity requirement, and certain corporate governance standards. If our common stock were to be delisted from the NASDAQ Global Market, we could apply to list our common stock on the NASDAQ Capital Market or our common stock could be traded in the over-the-counter market on an electronic bulletin board established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. Any delisting could adversely affect the market price of, and liquidity of the trading market for, our common stock, our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors.

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

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

***Evolving regulation of corporate governance and public disclosure may result in additional expenses, use of resources and continuing uncertainty.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Stock Market rules are creating uncertainty for public companies. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of these costs. For example, the SEC has adopted regulations that will require us to file corporate financial statement information in a new interactive data format known as XBRL beginning with our quarterly report on Form 10-Q for our second quarter of 2011. We will incur significant costs and need to invest considerable resources to implement and to remain in compliance with these new requirements.

These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to maintain high standards of corporate governance and public disclosure. As a result, we intend to invest the resources necessary to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply

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

with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, due to ambiguities related to practice or otherwise, regulatory authorities may initiate legal proceedings against us, which could be costly and time-consuming, and our reputation and business may be harmed.



Table of Contents

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

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

- authorizing the issuance of blank check preferred shares that could be issued by our 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 our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

*Sales of our common stock by our officers and directors may lower the market price of our common stock.*

As of March 10, 2011, our officers and directors beneficially owned an aggregate of approximately 5,085,504 shares (or approximately 6.1 percent) of our outstanding common stock, including stock options exercisable within 60 days. If our officers and directors, or other stockholders, sell a substantial amount of our common stock, even if such sales occur in connection with broker-assisted cashless exercises of stock options, it could cause the market price of our common stock to decrease and could hamper our ability to raise capital through the sale of our equity securities.

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

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

**Item 1B.**

**UNRESOLVED STAFF COMMENTS**

This Item 1B is not applicable to BioSante as a smaller reporting company.

**Item 2. PROPERTIES**

Our principal executive office is located in a leased facility in Lincolnshire, Illinois, where we lease approximately 20,000 square feet of office space for approximately \$31,000 per month. Our lease for this space expires in February 2014. Management of our company considers our leased properties suitable and adequate for our current and foreseeable needs.

**Item 3. LEGAL PROCEEDINGS**

We presently are not involved in any legal action, 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 our 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. [REMOVED AND RESERVED]**

Table of Contents**Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT**

Our executive officers, their ages and the offices held, as of March 10, 2011, are as follows:

Name	Age	Title
Stephen M. Simes	59	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	50	Senior Vice President of Finance, Chief Financial Officer and Secretary
Michael C. Snabes, M.D., Ph.D.	62	Senior Vice President, Medical Affairs

Each of our executive officers serves at the discretion of our 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 our directors or executive officers. Information regarding the business experience of our executive officers is set forth below.

**Stephen M. Simes** has served as our Vice Chairman, President and Chief Executive Officer and a director of our company 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 Abbott Laboratories) 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' career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.). Mr. Simes currently serves as our 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 our Senior Vice President of Finance since August 2010 and Chief Financial Officer and Secretary since July 1998. Before joining our company, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of Abbott Laboratories) from January 1995 to July 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 our Senior Vice President, Medical Affairs since August 2010. Dr. Snabes also served as our Vice President of Clinical Development from April 2008 to August 2010. Prior to this, Dr. Snabes served as a medical consultant to us on clinical and regulatory matters since 2005. Before joining our company, 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.



Table of Contents**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Price**

Our 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 our common stock, as reported by the NASDAQ Global Market, for each calendar quarter during 2010 and 2009.

<b>2010</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 2.081	\$ 1.43
Second Quarter	\$ 2.50	\$ 1.75
Third Quarter	\$ 1.76	\$ 1.29
Fourth Quarter	\$ 2.1685	\$ 1.40

<b>2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 2.33	\$ 1.03
Second Quarter	\$ 2.67	\$ 1.30
Third Quarter	\$ 2.70	\$ 1.45
Fourth Quarter	\$ 2.15	\$ 1.33

**Number of Record Holders; Dividends**

As of March 10, 2011, there were 783 record holders of our common stock and six record holders of our class C stock. To date, we have not declared or paid any cash dividends on our common stock and our class C stock is not eligible to receive dividends.

**Recent Sales of Unregistered Equity Securities**

Except as otherwise described below, during the fourth quarter ended December 31, 2010, we did not issue or sell any equity securities of ours without registration under the Securities Act of 1933, as amended.

On November 22, 2010, we issued a warrant to purchase 180,000 shares of our common stock to one of our investor relations firms. Such warrant has an exercise price of \$2.00 per share and will become exercisable with respect to 50 percent of the underlying shares on each of May 22, 2011 and November 22, 2011 and expires on November 21, 2013.

On December 30, 2010, we issued a warrant to purchase 317,647 shares of our common stock to our placement agent in connection with our December 2010 registered direct offering. Such warrant has an exercise price of \$2.125 per share, is fully exercisable and expires on June 9, 2015.

Such warrants were issued in reliance upon Section 4(2) under the Securities Act of 1933, as amended, as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. In all such transactions, we made certain inquiries to establish that such sales qualified for such exemption from the registration requirements. In particular, we confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) all offers of sales and sales were made by personal contact from our officers and directors or other persons closely associated with us, (ii) each recipient made representations that such recipient was sophisticated in relation to his, her or its investment (and we had no reason to believe that such representations were

Table of Contents

incorrect), (iii) each recipient gave assurance of investment intent and the certificates for the shares bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

**Issuer Purchases of Equity Securities**

We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2010. Our Board of Directors has not authorized any repurchase plan or program for the purchase of our shares of 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**Item 6. SELECTED FINANCIAL DATA**

The following selected financial information has been derived from our 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,				
	2010	2009	2008	2007	2006
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Revenue					
Licensing revenue	\$ 116	\$	\$ 3,384	\$ 199	\$ 14,136
Grant revenue	52	116	65	59	247
Royalty revenue	2,306	1,142	34	69	
Other revenue			298	166	55
Total revenue	2,474	1,258	3,781	493	14,438
Expenses					
Research and development	39,706	13,681	15,790	4,751	3,908
General and administration	5,940	5,374	5,125	4,331	4,550
Acquired in-process research and development		9,000			
Excess consideration paid over fair value		20,192			
Licensing expense	269	300	836		3,500
Depreciation and amortization	168	137	43	90	118
Total expenses	46,083	48,684	21,794	9,172	12,076
Other (expense) income					
Convertible note fair value adjustment	(1,871)	33			
Other expense - Investment impairment charge	(286)				
Other expense - Interest expense	(688)	(147)			
Other income	245				
Other income - Interest income	13	12	588	1,095	429
Net (loss) income	\$ (46,196)	\$ (47,528)	\$ (17,425)	\$ (7,584)	\$ 2,791
Basic and diluted net (loss) income per common share	\$ (0.70)	\$ (1.40)	\$ (0.64)	\$ (0.30)	\$ 0.13
Weighted average number of common shares and common equivalent shares outstanding	65,912	33,952	27,307	25,486	21,484

	As of December 31,				
	2010	2009	2008	2007	2006
	(in thousands)				
<b>Balance Sheet Data:</b>					
	\$ 38,155	\$ 29,858	\$ 14,787	\$ 30,655	\$ 11,450



Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Cash, cash equivalents and  
short-term investments

Total assets	44,767	36,437	17,679	31,241	22,371
Total current liabilities (includes short-term convertible senior notes)	8,183	3,930	3,853	1,516	4,300
Convertible senior notes, total long- and short-term	18,547	16,676			
Stockholders' equity	19,147	15,830	13,826	29,725	18,071

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 our 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 our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report. This Management's Discussion and Analysis is organized in the following major sections:

- **Business Overview.** This section provides a brief overview description of our business, focusing in particular on developments during the most recent fiscal year.
- **Summary of 2010 Financial Results and Outlook for 2011.** This section provides a brief summary of our financial results and financial condition for 2010 and our outlook for 2011.
- **Critical Accounting Policies and Estimates.** This section discusses the accounting estimates that are considered important to our financial condition and results of operations and require us to exercise subjective or complex judgments in their application. All of our significant accounting policies, including our critical accounting estimates, are summarized in Note 2 to our financial statements.
- **Results of Operations.** This section provides our analysis of the significant line items in our statements of operations.
- **Liquidity and Capital Resources.** This section provides an analysis of our liquidity and cash flows and a discussion of our outstanding indebtedness and commitments.
- **Recent Accounting Pronouncements.** This section discusses recently issued accounting pronouncements that have had or may affect our results of operations and financial condition.

**Business Overview**

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

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

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

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD).
- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.
- The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II development for the treatment of FSD in women using oral or transdermal contraceptives.
- Bio-T-Gel once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.
- Cancer vaccines a portfolio of cancer vaccines in Phase II clinical development for the treatment of various cancers.

Table of Contents

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future. The Phase III safety study is currently enrolling women, and as of the end of February 2011 had enrolled approximately 2,900 women. In February 2011, we announced that based upon the fifth review of study conduct and unblinded safety data from the safety study by the study's independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If enrollment is not completed sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 women. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit an NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women. It is our objective to submit the LibiGel NDA to the FDA so that LibiGel may be approved in 2012.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), our licensee, is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur's sales of Elestrin. We maintain the right to receive up to \$140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels, we believe our receipt of such payments unlikely in the near term, if at all.

We license the technology underlying certain of our gel products, including LibiGel and Elestrin, from Antares Pharma, Inc. Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all upfront and milestone payments related to a license and a 4.5 percent royalty on net sales of product by us or a licensee. Bio-T-Gel was developed and is fully-owned by us and licensed to Teva for further development and commercialization. We license the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

Our portfolio of cancer vaccines is designed to stimulate the patient's immune system to fight effectively the patient's own cancer. Multiple Phase II trials of these vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia and breast cancer. We anticipate Phase II trials for prostate cancer to begin in 2011. Four of these vaccines have been granted FDA orphan drug designation. We license our cancer vaccine technology from Johns Hopkins University and The Whitehead Institute for Biomedical Research. Under various agreements, we are required to pay Johns Hopkins University certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the in-licensed technology.

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



Table of Contents

**Summary of 2010 Financial Results and Outlook for 2011**

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our merger with Cell Genesys, Inc., to fund our ongoing business operations and short-term liquidity needs.

We have not introduced commercially any products. Azur, our marketing licensee for Elestrin, commercially launched Elestrin in April 2009. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur's sales of Elestrin. We recognized \$2,306,560 in royalty revenue from sales of Elestrin during the year ended December 31, 2010. The royalty revenue during the year ended December 31, 2010 includes \$152,228 in royalty payments pursuant to our original agreement with Azur, and \$2,150,000 of additional royalty income from payments received as a result of the December 2009 amendment. This royalty revenue amount represents the gross royalty revenue we received from Elestrin through December 31, 2010 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled \$152,228 for the year ended December 31, 2010, is recorded within general and administrative expenses in our statements of operations. Pursuant to a separate agreement with Antares and related to the December 2009 Azur license amendment, we paid Antares an aggregate of \$268,750 in February 2010, which is recorded in licensing expense.

Our business operations to date have consisted mostly of licensing and research and development activities and we expect this to continue for the immediate future. If and when our products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the products ourselves. We currently do not have sufficient resources on a long-term basis to obtain regulatory approval of LibiGel or any of our other products or to complete the commercialization of any of our products for which we have not entered into marketing relationships. As of December 31, 2010, we had \$38.2 million of cash and cash equivalents. In March 2011, we received an additional \$23.8 million in net proceeds from our March 2011 registered direct offering. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. We expect our current cash and cash equivalent to meet our liquidity requirements through at least the next 15 to 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. Exactly how long our current cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel safety study and perhaps more importantly, the number of women we will enroll in the safety study, which number cannot be determined at this time.

We incurred expenses of approximately \$39.7 million on research and development activities during the year ended December 31, 2010, which is a 190 percent increase, compared to 2009, primarily as a result of the conduct of the three LibiGel Phase III clinical studies. In April 2009, we decided to delay screening new subjects for our LibiGel Phase III safety study in order to conserve cash; however, in January 2010, we reinitiated screening and enrollment in the safety study. We anticipate spending on research and development activities approximately \$3.5 million to \$4.5 million per month until enrollment is completed in the safety study. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash available; (2) our development schedule, including the timing and scope of our clinical trials; (3) results of studies, clinical trials and regulatory decisions, including in particular the number of subjects required in our LibiGel safety study; (4) the amount of our clinical recruitment expenditures intended to complete enrollment in our LibiGel safety study; (5) whether we or our licensees are funding the development of our products; and (6) competitive developments.

Our general and administrative expenses for the year ended December 31, 2010 increased 11 percent compared to the year ended December 31, 2009 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and

administrative expenses may fluctuate from year-to-year and

Table of Contents

quarter-to-quarter depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, business development, accounting, corporate governance and other fees and expenses incurred.

We recognized a net loss for the year ended December 31, 2010 of approximately \$46.2 million compared to a net loss of approximately \$47.5 million for the year ended December 31, 2009. This slight decrease was primarily due to the \$29.2 million of non-cash expenses in 2009 related to our merger with Cell Genesys, partially offset by increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for the year ended December 31, 2010 of \$0.70 compared to a net loss per share of \$1.40 for the year ended December 31, 2009. This decrease in net loss per share was the result of a significantly higher weighted average number of shares outstanding during the year ended December 31, 2010, partially offset by the slight increase in net loss as described above. We expect to continue to incur substantial and continuing losses for the next 18 to 24 months. This is true especially as our LibiGel Phase III clinical study program continues.

**Critical Accounting Policies and Estimates**

Our significant accounting policies are described in Note 2 to our financial statements included under the heading Part II. Item 8. Financial Statements and Supplementary Data of this report. The discussion and analysis of our financial statements and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company's most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified the critical accounting policies described below. Although we believe that our 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 Treatment Related to Acquisition of Assets and Liabilities of Cell Genesys***

On October 14, 2009, we completed our legal merger with Cell Genesys, as a result of which we 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 we merged with Cell Genesys was our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for us to access capital prior to and at the time the merger agreement was entered into by both of us in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been our primary method for raising additional financing. We have accounted for our transaction with Cell Genesys under U.S. generally accepted accounting principles as an acquisition of the net assets of Cell Genesys, whereby we have 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, we 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.

In connection with the merger with Cell Genesys, we acquired the rights to in-process research and development of Cell Genesys, as well as associated patents and technology. The estimated fair value of the in-process research and development was charged to expense as it was deemed to have no alternative future use.



Following the completion of the merger, our future net income (loss) reflects charges resulting from the purchase price allocation related to the merger, which includes adjustments to carrying values of the acquired net assets based on the fair value of consideration measured as of the completion of the merger.

Table of Contents*Accounting for Convertible Notes Assumed in Connection with the Cell Genesys Acquisition*

We assumed \$22.0 million principal amount of convertible notes in connection with the Cell Genesys acquisition. We 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 notes recognized in our statements of operations immediately. As a result of this election, we must periodically estimate the fair value of our convertible notes, which requires us to make certain judgments and estimates about appropriate discount rates, our creditworthiness, and assumptions regarding potential conversion of the notes. We believe that our estimates and assumptions are reasonable; however changes in these estimates and assumptions could result in significant differences in the carrying value of the convertible notes. The most sensitive of these assumptions is the discount rate used in the fair value estimate, which was 17% at December 31, 2010, and is based on the median yield to maturity of C and Ca rated debt instruments as of December 31, 2010. A one percentage point increase or decrease in the discount rate would cause the recorded value of the convertible debt to decrease or increase by approximately \$310,000, respectively.

**Results of Operations**

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

	Year Ended December 31,		
	2010	2009	2008
Revenue	\$ 2,474,237	\$ 1,258,054	\$ 3,780,829
Expenses	46,082,598	48,683,608	21,794,471
Research and development	39,705,502	13,680,573	15,789,980
General and administrative	5,940,360	5,373,945	5,124,934
Acquired in-process research and development		9,000,000	
Excess consideration paid over fair value		20,192,194	
Licensing expense	268,750	299,616	836,420
Other (expense) income			
Convertible note fair value adjustment	(1,870,916)	33,163	
Other expense			
Investment impairment charge	(286,000)		
Other expense			
Interest expense	(688,083)	147,025	
Other income	244,479		
Other income			
Interest income	12,665	11,648	588,464
Net loss	\$ (46,196,216)	\$ (47,527,768)	\$ (17,425,178)
Net loss per common share (basic and diluted)	\$ (0.70)	\$ (1.40)	\$ (0.64)
Weighted average number of common shares and common equivalent shares outstanding	65,911,750	33,951,652	27,307,494

*Year Ended December 31, 2010 Compared to Year Ended December 31, 2009*

Revenue increased \$1.2 million in 2010 compared to 2009 primarily as a result of an increase in royalty and licensing revenue during 2010 compared to 2009. Of the \$2.3 million in royalty revenue during 2010, \$2.2 million resulted from our receipt of non-refundable upfront payments from Azur as a result of the December 2009 amendment to our license agreement. Pursuant to a separate agreement with Antares and related to the December 2009 amendment, we paid Antares an aggregate of \$268,750 in February 2010. In addition, during 2010, we recorded royalty revenue of \$152,228 and a corresponding amount of royalty expense, which is recorded within general and administrative expenses in

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

our statements of operations, to reflect the Antares portion of the Elestrin royalty revenues, which revenues were not eliminated as a result of the December 2009 Azur license amendment. In October 2010, we received \$244,479, the maximum per project, after LibiGel qualified for a grant under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

Research and development expenses increased 190 percent in 2010 compared to 2009 primarily as a result of the conduct of the three LibiGel Phase III clinical studies.

General and administrative expenses increased 11 percent in 2010 compared to 2009 primarily as a result of an increase in personnel-related costs and, to a lesser extent, increases in professional fees and other administrative expenses in 2010.

Table of Contents

We recognized total additional non-cash expenses of \$29.2 million in 2009 related to our merger with Cell Genesys, consisting of \$9.0 million related to the write-off of acquired in-process research and development, and \$20.2 million related to transaction related expenses and additional charges related to the excess of merger consideration over fair values of the net assets acquired. No similar expense was recognized in 2010.

We recognized licensing expense of \$268,750 related to our payment to Antares as a result of the December 2009 Azur license amendment compared to licensing expense of \$299,616 in 2009 as a result of expenses associated with the Azur licensing agreement and the termination of our prior licensing agreement for Elestrin.

The fair value adjustment on our convertible senior notes to increase the recorded liability and corresponding expense was \$1,870,916 in 2010 compared to a fair value adjustment to decrease the recorded liability and corresponding expense of \$33,163 in 2009.

We recorded an investment impairment charge of \$286,000 in 2010 based on our determination that an other-than-temporary impairment had occurred with respect to our investment in Ceregene, Inc. based on a recent third-party investment in Ceregene. No similar investment impairment charge was recognized in 2009.

Interest expense increased \$541,058, or 368 percent, in 2010 compared to 2009 as a result of our convertible senior notes, which we assumed during the fourth quarter of 2009.

Interest income increased \$1,017, or 9 percent, in 2010 compared to 2009 primarily as a result of our higher cash balances and our cash being in a U.S. Treasury portfolio for a portion of 2010 compared to our cash being in a non-interest bearing checking account for the majority of 2009.

***Year Ended December 31, 2009 Compared to Year Ended December 31, 2008***

Revenue decreased 67 percent in 2009 compared to 2008 primarily as a result of our receipt of \$3.4 million from the Azur license of Elestrin in 2008 compared to our receipt of approximately \$1.1 million from Azur in 2009, \$1.0 million of which was a non-refundable payment received as a result of the December 2009 amendment to our license agreement.

Research and development expenses decreased 13 percent in 2009 compared to 2008 primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel safety study to conserve cash.

Our general and administrative expenses increased 5 percent in 2009 compared to 2008 due primarily to a 9 percent or \$111,878 increase in our non-cash, stock option and warrant expense in 2009 compared to 2008. This increase was due to an increase in the number of stock options and warrants granted and the number of stock options and warrants outstanding during 2009 compared to 2008.

We recognized total additional non-cash expenses of \$29.2 million in 2009 related to our merger with Cell Genesys, consisting of \$9.0 million related to the write-off of acquired in-process research and development, and \$20.2 million related to transaction related expenses and additional charges related to the excess of merger consideration over fair values of the net assets acquired. No similar expense was recognized during 2008.

We recognized \$299,616 in licensing expense in 2009 compared to \$836,420 in 2008 due to expenses associated with the Azur licensing agreement and the termination of our prior licensing agreement for Elestrin.

Interest expense was \$147,025 in 2009 compared to no similar expense in 2008 as a result of our convertible senior notes which we assumed during the fourth quarter of 2009.

Table of Contents

Interest income decreased 98 percent in 2009 compared to 2008 primarily as a result of our decision to keep cash and cash equivalents in a 100 percent FDIC-insured non-interest bearing checking account for the majority of 2009 in order to ensure maximum safety of principal the generally lower interest rates available to us at that time.

**Liquidity and Capital Resources**

The following table highlights several items from our balance sheets:

<b>Balance Sheet Data</b>	<b>December 31, 2010</b>		<b>December 31, 2009</b>	
Cash and cash equivalents	\$	38,155,251	\$	29,858,465
Total current assets		40,625,130		31,410,270
Investments		3,405,807		3,626,000
Total assets		44,766,650		36,436,928
Total current liabilities		8,183,327		3,930,117
Convertible senior notes due 2013		17,436,201		16,676,417
Total liabilities		25,619,528		20,606,534
Total stockholders' equity		19,147,122		15,830,394

**Liquidity**

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of \$165,630,644 as of December 31, 2010. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our merger with Cell Genesys, to fund our ongoing business operations and short-term liquidity needs.

During 2010, we raised approximately \$48.5 million, net of offering expenses, through the sale of common stock and warrants, in three separate registered direct offerings. In March 2010, we completed an offering of an aggregate of 10,404,626 shares of our common stock and warrants to purchase an aggregate of 5,202,313 shares of our common stock, resulting in net proceeds of approximately \$17.5 million, after deducting placement agent fees and other offering expenses. In June 2010, we completed an offering of 7,134,366 shares of our common stock and warrants to purchase an aggregate of 3,567,183 shares of our common stock, resulting in net proceeds of approximately \$14.1 million, after deducting placement agent fees and offering expenses. In December 2010, we completed an offering of 10,588,236 shares of our common stock and warrants to purchase an aggregate of 5,294,118 shares of our common stock, resulting in net proceeds of approximately \$16.9 million, after deducting placement agent fees and offering expenses.

As of December 31, 2010, we had \$38.2 million of cash and cash equivalents. In March 2011, we completed an offering of an aggregate of 12,199,482 shares of our common stock and warrants to purchase an aggregate of 4,025,827 shares of our common stock, resulting in net proceeds of approximately \$23.8 million, after deducting placement agent fees and other offering expenses. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III clinical development program. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our LibiGel Phase III clinical development program;
- subject recruitment and enrollment in our current and future clinical studies, including in particular our LibiGel safety study, and the amount of our clinical recruitment expenditures intended to encourage enrollment in such study;
- our ability to license LibiGel or our other products for development and commercialization;
- the cost, timing and outcome of regulatory reviews of our products;

Table of Contents

- the rate of technological advances;
- the commercial success of our products;
- our general and administrative expenses; and
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, and our efforts to continue to evaluate various strategic alternatives available with respect to our products and our company.

If and when our products for which we have not entered into marketing relationships receive FDA approval, we may begin to incur other expenses, including sales and marketing and other expenses if we choose to market the products ourselves. We currently do not have sufficient resources to obtain regulatory approval of LibiGel or any of our other products, to establish our own sales and marketing function or complete the commercialization of any of our products that are not licensed to others for development and marketing. We expect the ongoing LibiGel Phase III clinical development program to continue to require significant resources.

We expect our current cash and cash equivalent to meet our liquidity requirements through at least the next 15 to 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. Exactly how long our current cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel safety study and perhaps more importantly, the number of women we will enroll in the safety study, which number cannot be determined at this time.

As of December 31, 2010, we did not have any existing credit facilities under which we could borrow funds, other than our committed equity financing facility described below. If we are unable to raise additional financing when needed or secure another funding source for our LibiGel Phase III clinical development program, we may need to temporarily slow or delay the program or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product (e.g. one or more of our cancer vaccines) to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

***Committed Equity Financing Facility with Kingsbridge Capital Limited***

In December 2010, we extended the term of our committed equity financing facility with Kingsbridge Capital Limited by one additional year. Under the facility, Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of \$25.0 million or 5,405,840 shares of our common stock through the end of December 2011. We are not obligated to utilize any of the \$25.0 million available under the facility and there are no minimum commitments or minimum use penalties. We have access, at our discretion, to the funds through the sale of newly-issued shares of our common stock. The funds that can be raised under the facility will depend on the then-current



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

price for our common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. We may access capital under the facility by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include a minimum price for our common stock of \$1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of common stock issued or issuable to Kingsbridge; and the continued listing of our common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the facility if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. Other than the issuance of a warrant to purchase 300,000 shares of our common stock at an exercise price of \$4.00 per share in December 2008, attorneys' fees and other direct costs related to the registration of these shares, we did not make any other payments to secure or extend the term of the facility. The facility does not impose any material

Table of Contents

restrictions on our operating or financial activities. During the term of the facility, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to our common stock. As of December 31, 2010, we had not sold any shares to Kingsbridge under the committed equity financing facility.

***Convertible Senior Notes Due November 2011 and May 2013***

As a result of our merger with Cell Genesys, we assumed \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. Contractual interest payments on the convertible senior notes are due on May 1 and November 1 of each year through maturity. Annual interest on the notes is approximately \$0.7 million. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between us and the trustees thereunder, the November 2011 convertible notes are convertible into an aggregate of 24,789 shares of our common stock at a conversion price of \$49.78 per share and the May 2013 convertible notes are convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of \$3.72 per share, in each case subject to adjustments for stock dividends, stock splits and other similar events. The convertible notes are our general, unsecured obligations, ranking equally with all of our existing and future unsecured, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of our subsidiaries. The convertible notes are subject to repurchase by us at each holder's option, if a fundamental change (as defined in the indentures) occurs, at a repurchase price equal to 100 percent of the principal amount of the convertible notes, plus accrued and unpaid interest (and additional amounts, if any) through, but not including, the repurchase date and are subject to redemption for cash by us at any time in the case of the convertible notes due in November 2011 and at any time on or after May 1, 2011, in the case of the convertible notes due in May 2013, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes if the closing price of our common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. The indentures governing the convertible notes, as supplemented by the supplemental indentures, do not contain any financial covenants and do not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indentures.

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

We have elected to record our convertible senior notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, we have adjusted the carrying value of the convertible senior notes to their fair value as of December 31, 2010, with changes in the fair value of the notes occurring since December 31, 2009, reflected in a fair value adjustment in our 2010 statements of operations, and changes in the fair value of the notes occurring from the date we assumed the notes in October 2009 through December 31, 2009 reflected in a fair value adjustment in our 2009 statements of operations. The recorded fair value of the convertible senior notes of an aggregate of \$18,547,333 as of December 31, 2010 differs from their total stated principal amount of \$22,016,000 by \$3,468,667. The recorded fair value of the convertible senior notes of an aggregate of \$16,676,417 as of December 31, 2009 differs from their total stated principal amount of \$22,016,000 by \$5,339,583.

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

Net cash used in operating activities was \$40.1 million for the year ended December 31, 2010 compared to net cash used in operating activities of \$18.4 million for the year ended December 31, 2009 and net cash used in operating

Table of Contents

activities of \$15.5 million for the year ended December 31, 2008. 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 operating activities for 2009 was primarily the result of the net loss for that period. Technology and transaction related expenses and charges of \$29.2 million were incurred as a result of our merger with Cell Genesys in October 2009 but did not result in an operating cash payment by us as we issued shares as consideration for the transaction and cash payments for transaction costs were classified as a financing activity based on the nature of the transaction. Net cash used in operating activities for 2008 was primarily the result of the net loss for that period, and to a lesser extent, an increase in prepaid expenses and other assets related to an increase in our prepaid clinical study related costs, partially offset by an increase in accounts payable and accrued liabilities.

Net cash used in investing activities was \$60,366 for the year ended December 31, 2010 compared to net cash provided by investing activities of \$2.9 million for the year ended December 31, 2009 and net cash provided by investing activities of \$11.3 million for the year ended December 31, 2008. Net cash used in investing activities for 2010 was primarily due to the purchase of capital assets. Net cash provided by investing activities for 2009 and 2008 was primarily due to the redemption of short-term investments, partially offset by purchases of capital assets associated with our LibiGel Phase III clinical development program.

Net cash provided by financing activities was \$48.5 million for the year ended December 31, 2010 compared to \$33.7 million for the year ended December 31, 2009 and \$319,377 for the year ended December 31, 2008. Net cash provided by financing activities in 2010 resulted from the net proceeds to us, after deducting placement agent fees and offering expenses, from the completion of our March, June and December 2010 registered direct offerings. Net cash provided by financing activities for 2009 resulted from a combination of recognizing \$24.7 million in cash acquired as a result of our merger with Cell Genesys and \$11.4 million in net proceeds to us, after deducting placement agent fees and offering expenses, from the completion of our August 2009 registered direct offering, partially offset by \$2.4 million in cash paid for Cell Genesys acquisition-related costs. Net cash provided by financing activities for 2008 resulted from warrant exercises.

***Commitments and Contractual Obligations***

We did not have any material commitments for capital expenditures as of December 31, 2010. We have, however, several financial commitments, including our convertible senior notes, minimum annual lease payments, product development milestone payments to the licensors of certain of our products and payments under our license agreement with Wake Forest University Health Sciences.

The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2010:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible Senior Notes	\$ 22,016,000	\$ 1,234,000	\$ 20,782,000	\$ 0	\$ 0
Interest Payment Obligations Related to Convertible Senior Notes	1,547,490	681,573	865,917	0	0
Operating Lease	1,306,492	353,880	952,612	0	0
	455,000	95,000	185,000	70,000	105,000

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Commitments Under License Agreements with Johns Hopkins University						
Commitments Under License Agreement with Massachusetts Institute of Technology	200,000	50,000	150,000	0	0	
Commitments Under License Agreement with University of California	340,000	20,000	60,000	40,000	220,000	
Commitments Under License Agreement with Wake Forest	720,000	280,000	240,000	120,000	80,000	
Total Contractual Cash Obligations	\$ 26,584,982	\$ 2,714,453	\$ 23,235,529	\$ 230,000	\$ 405,000	

Table of Contents

***Off-Balance Sheet Arrangements***

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

**Recent Accounting Pronouncements**

In March 2010, the Financial Accounting Standard Board (FASB) ratified the consensus reached by the Emerging Issues Task Force on Issue 08-9, which was codified in Accounting Standards Update 2010-17 (ASU 2010-17). ASU 2010-17 establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, for research and development arrangements in which one or more payments are contingent upon achieving uncertain future events or circumstances. ASU 2010-17 is effective for fiscal years beginning on or after June 15, 2010, and will be adopted by us in the fiscal year beginning January 1, 2011. The impact of ASU 2010-17 on our financial position, results of operations and cash flows is dependent on the nature and structure of our future arrangements.

In December 2010, the FASB issued ASU 2010-29, Business Combinations (ASC Topic 805) - Disclosure of Supplementary Pro Forma Information for Business Combinations. This amendment expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. We intend to adopt this guidance in 2011. The adoption of this new guidance will not have a material impact on our financial statements.

**Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

This Item 7A is not applicable to BioSante as a smaller reporting company and has been omitted pursuant to Item 305(e) of SEC Regulation S-K.

Table of Contents

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

<b>Description</b>	<b>Page</b>
<u>Management's Report on Internal Control Over Financial Reporting</u>	55
<u>Report of Independent Registered Public Accounting Firm</u>	56
<u>Report of Independent Registered Public Accounting Firm</u>	57
<u>Balance Sheets as of December 31, 2010 and 2009</u>	58
<u>Statements of Operations for the years ended December 31, 2010, 2009 and 2008</u>	59
<u>Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	60
<u>Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	61
<u>Notes to the Financial Statements for the years ended December 31, 2010, 2009 and 2008</u>	62-84

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 U.S. generally accepted accounting principles.

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, 2010. 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, 2010.

/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

March 16, 2011

Further discussion of our 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, 2010, 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, 2010, 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, 2010 of the Company and our report dated March 16, 2011 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois

March 16, 2011

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, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2011 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois

March 16, 2011

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Balance Sheets****December 31, 2010 and 2009**

	December 31, 2010	December 31, 2009
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 38,155,251	\$ 29,858,465
Accounts receivable		64,645
Prepaid expenses and other assets	2,469,879	1,487,160
	40,625,130	31,410,270
<b>PROPERTY AND EQUIPMENT, NET</b>	<b>635,776</b>	<b>747,979</b>
<b>OTHER ASSETS</b>		
Investments	3,405,807	3,626,000
Deposits	99,937	652,679
	\$ 44,766,650	\$ 36,436,928
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 4,864,217	\$ 2,440,096
Accrued compensation	526,022	529,066
Other accrued expenses	1,681,956	960,955
Current portion of Convertible Senior Notes	1,111,132	
	8,183,327	3,930,117
Long-term Convertible Senior Notes	17,436,201	16,676,417
<b>TOTAL LIABILITIES</b>	<b>25,619,528</b>	<b>20,606,534</b>
<b>STOCKHOLDERS EQUITY</b>		
<b>Capital stock</b>		
Issued and outstanding		
2010 - 391,286; 2009 - 391,286 Class C special stock	391	391
2010 - 81,391,130; 2009 - 53,262,568 Common stock	184,777,375	135,264,431
	184,777,766	135,264,822
Accumulated deficit	(165,630,644)	(119,434,428)
	19,147,122	15,830,394
	\$ 44,766,650	\$ 36,436,928

See accompanying notes to the financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Statements of Operations****Years ended December 31, 2010, 2009 and 2008**

	2010	Year Ended December 31,		2008
		2009		
<b>REVENUE</b>				
Licensing revenue	\$ 115,807	\$	\$ 3,384,091	
Grant revenue	51,870		116,389	65,051
Royalty revenue	2,306,560		1,141,665	34,200
Other revenue				297,487
	<b>2,474,237</b>		<b>1,258,054</b>	<b>3,780,829</b>
<b>EXPENSES</b>				
Research and development	39,705,502		13,680,573	15,789,980
General and administration	5,940,360		5,373,945	5,124,934
Acquired in-process research and development			9,000,000	
Excess consideration paid over fair value			20,192,194	
Licensing expense	268,750		299,616	836,420
Depreciation and amortization	167,986		137,280	43,137
	<b>46,082,598</b>		<b>48,683,608</b>	<b>21,794,471</b>
<b>OTHER</b>				
Convertible note fair value adjustment	(1,870,916)		33,163	
Investment impairment charge	(286,000)			
Interest expense	(688,083)		(147,025)	
Other income	244,479			
Interest income	12,665		11,648	588,464
<b>NET LOSS</b>	<b>\$ (46,196,216)</b>	<b>\$</b>	<b>(47,527,768)</b>	<b>\$ (17,425,178)</b>
<b>Loss per common share:</b>				
Basic	\$ (0.70)	\$	(1.40)	\$ (0.64)
Diluted	\$ (0.70)	\$	(1.40)	\$ (0.64)
<b>Weighted average number of common and common equivalent shares outstanding:</b>				
Basic	65,911,750		33,951,652	27,307,494
Diluted	65,911,750		33,951,652	27,307,494

See accompanying notes to the financial statements.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Statements of Stockholders Equity****Years ended December 31, 2010, 2009 and 2008**

	Class C Special Shares		Common Stock		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount		
<b>Balance, January 1, 2008</b>	<b>391,286</b>	<b>\$ 391</b>	<b>26,794,607</b>	<b>\$ 84,206,583</b>	<b>\$ (54,481,482)</b>	<b>\$ 29,725,492</b>
Issuance of common shares Warrant exercises - various			248,157	379,720		379,720
Stock option expense				1,102,444		1,102,444
Stock warrant expense				104,284		104,284
Credit equity financing facility				(60,343)		(60,343)
Net loss					(17,425,178)	(17,425,178)
<b>Balance, December 31, 2008</b>	<b>391,286</b>	<b>\$ 391</b>	<b>27,042,764</b>	<b>\$ 85,732,688</b>	<b>\$ (71,906,660)</b>	<b>\$ 13,826,419</b>
Stock option expense				1,254,503		1,254,503
Stock warrant expense				64,103		64,103
Registered direct offering of common shares and warrants, net			6,000,000	11,352,751		11,352,751
Issuance of common shares pursuant to Cell Genesys, Inc. transaction			20,219,804	36,800,043		36,800,043
Credit equity financing facility				60,343		60,343
Net loss					(47,527,768)	(47,527,768)
<b>Balance, December 31, 2009</b>	<b>391,286</b>	<b>\$ 391</b>	<b>53,262,568</b>	<b>\$ 135,264,431</b>	<b>\$ (119,434,428)</b>	<b>\$ 15,830,394</b>
Issuance of common shares Stock option exercise			1,334	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			28,127,228	48,452,644		48,452,644
Net loss					(46,196,216)	(46,196,216)
<b>Balance, December 31, 2010</b>	<b>391,286</b>	<b>\$ 391</b>	<b>81,391,130</b>	<b>\$ 184,777,375</b>	<b>\$ (165,630,644)</b>	<b>\$ 19,147,122</b>

See accompanying notes to the financial statements.

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

Years ended December 31, 2010, 2009 and 2008

	2010	Year Ended December 31, 2009	2008
<b>CASH FLOWS (USED IN) OPERATING ACTIVITIES</b>			
Net loss	\$ (46,196,216)	\$ (47,527,768)	\$ (17,425,178)
Adjustments to reconcile net loss to net cash (used in) operating activities			
Acquired in-process research and development		9,000,000	
Excess consideration paid over fair value		20,192,194	
Depreciation and amortization	167,986	137,280	43,137
Employee and director stock-based compensation	992,757	1,254,503	1,102,444
Stock warrant expense - noncash	65,529	64,103	104,284
Loss on disposal of equipment	4,583		
Investment impairment charge	286,000		
Other non-cash items	(65,807)	60,739	
Convertible note fair value adjustment	1,870,916	(33,163)	
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	(429,977)	(316,101)	(1,330,491)
Accounts receivable	64,645	285,838	(215,209)
Accounts payable and accrued liabilities	3,142,078	(1,548,535)	2,194,173
Deferred revenue			(9,091)
<b>Net cash used in operating activities</b>	<b>(40,097,506)</b>	<b>(18,430,910)</b>	<b>(15,535,931)</b>
<b>CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES</b>			
Redemption of short term investments		3,026,334	11,979,642
Proceeds from sale of fixed assets	3,075		
Purchase of fixed assets	(63,441)	(165,724)	(651,116)
<b>Net cash (used in) provided by investing activities</b>	<b>(60,366)</b>	<b>2,860,610</b>	<b>11,328,526</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>			
Cash paid for transaction related costs		(2,431,252)	
Cash received in transaction		24,746,346	
Credit equity financing facility			(60,343)
Proceeds from common stock option exercises	2,014		
Proceeds from common stock warrant exercises			379,720
Proceeds from issuance of common stock by registered direct offerings	48,452,644	11,352,751	
<b>Net cash provided by financing activities</b>	<b>48,454,658</b>	<b>33,667,845</b>	<b>319,377</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>			
	8,296,786	18,097,545	(3,888,028)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>			
	29,858,465	11,760,920	15,648,948
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 38,155,251</b>	<b>\$ 29,858,465</b>	<b>\$ 11,760,920</b>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION</b>			

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Interest paid, including acquired accrued interest	\$	688,000	\$	248,388	\$
<b>Noncash Investing and Financing Activities:</b>					
Investment - non-cash	\$	65,807	\$		\$
Liabilities acquired through Cell Genesys transaction	\$		\$	18,487,298	\$
Shares issued for Cell Genesys transaction	\$		\$	36,800,043	\$
Investment aquired through Cell Genesys transaction	\$		\$	3,486,000	\$
Other assets acquired in Cell Genesys transaction	\$		\$	293,658	\$
Purchase of fixed assets on account, non-cash investing activity	\$		\$		\$ 152,019

See accompanying notes to the financial statements.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**1. DESCRIPTION OF BUSINESS**

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. The Company's lead products include LibiGel (transdermal testosterone gel) in Phase III clinical development by the Company under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD), and Elestrin (estradiol gel) developed through FDA approval by the Company, indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, currently marketed in the U.S. Other products in development are Bio-T-Gel, a testosterone gel for male hypogonadism, which is licensed to Teva Pharmaceuticals, and an oral contraceptive in Phase II clinical development using the Company's patented technology. Also in development is a portfolio of cancer vaccines, several of which are currently in Phase II clinical trials at minimal cost to the Company. Four of these vaccines have been granted FDA orphan drug designation. The Company also is developing its calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as well as seeking opportunities for its other technologies.

On October 14, 2009, the Company acquired 100 percent of the common stock of Cell Genesys, Inc. (Cell Genesys) in a direct merger transaction, with the Company being the surviving corporation. The primary reason the Company merged with Cell Genesys was the Company's need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for the Company to access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been the Company's primary method for raising additional financing. Effective October 14, 2009, the balance sheet and net loss of the Company reflect the purchase price allocation and charges resulting from the purchase price allocation related to the merger, which included adjustments to carrying values of the acquired net assets based on their estimated fair values as of that date.

**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.

*Reclassifications*

Certain amounts in the 2009 and 2008 financial statements have been reclassified to conform to their presentation in the 2010 financial statements. Specifically, in the balance sheet, Due to

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

licensor - Antares of \$18,033 has been combined into other accrued expenses as of December 31, 2009. Similarly, in the statement of cash flows, the changes related to Due to licensor Antares in the amounts of \$12,640 and \$4,330 for the years ended December 31, 2009 and 2008, respectively, have been combined into the Accounts payable and accrued liabilities line item within the net cash used in operating activities section. Also, in the statement of cash flows for the year ended December 31, 2008, the amount of \$319,377 for Proceeds from the sale or conversion of shares, net in the net cash provided by financing activities has been separated into two line items; (1) proceeds from common stock warrant exercises of \$379,720 and (2) credit equity financing facility of (\$60,343).

*Cash and Cash Equivalents*

The Company generally considers all instruments with original maturities of three months or less to be cash equivalents. Certain investments that could meet the definition of a cash equivalent are classified as investments due to the nature of the account in which the investment is held and the Company's intended use of the investment. Interest income on invested cash balances is recognized on the accrual basis as earned.

As of December 31, 2010, all of the Company's cash and cash equivalents resided in either a 100 percent FDIC-insured non-interest bearing checking account, a U.S. Treasury money market fund or a certificate of deposit. As of December 31, 2009, all of the Company's cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account in order to ensure maximum safety of principal.

*Short-Term Investments*

Short-term investments are classified as available for sale under the provisions of Accounting Standards Codification (ASC) 320. Accordingly, short-term investments are reported at fair value, with any related unrealized gains and losses included as a separate component of stockholders equity, net of applicable taxes. Realized gains and losses and interest and dividends are included in interest income. Realized gains and losses are recorded based upon the specific identification method. At December 31, 2010 and 2009, the Company did not own any short-term investments. Accordingly, there were no gains or losses recorded in accumulated other comprehensive income as of December 31, 2010 or December 31, 2009, and there were no realized gains or losses included in earnings as the result of sales of available for sale securities for the years ended December 31, 2010, December 31, 2009 or December 31, 2008.

*Fair Value of Financial Instruments*

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

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 15, Fair Value Measurements.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

*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 years for software and 10 years for laboratory 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 assumed two series of convertible senior note obligations with an aggregate principal balance of \$22,016,000, which contain certain redemption, repurchase and conversion adjustment features as a result of its transaction with Cell Genesys. The Company has made an irrevocable election to account for these debt instruments at fair value commencing from the date of the merger, resulting in recognition of a single liability for each of the two series of convertible senior notes which is reported at fair value at each reporting date. Subsequent changes in the carrying value of the notes are reflected in fair value adjustment in the accompanying statements of operations. See Note 7, Convertible Senior Notes for a description of these financial liabilities.

*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.

*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 there is an antidilutive effect on loss per share.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

*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 has also 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 remeasured until the counterparty's performance under the arrangement is complete. Warrants of this nature to purchase an aggregate of 180,000 and 180,000 shares of the Company's common stock were issued in 2010 and 2009, respectively.

*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 or upon the occurrence of certain regulatory actions, such as the filing of a regulatory application or the receipt of a regulatory approval. 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.

*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, 2010 and 2009.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

*Investments*

The investments balance of \$3,405,807 as of December 31, 2010 and \$3,626,000 as of December 31, 2009 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 recent third-party investment in Ceregene.

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*

In March 2010, the Financial Accounting Standard Board (FASB) ratified the consensus reached by the Emerging Issues Task Force on Issue 08-9, which was codified in Accounting Standards Update 2010-17 (ASU 2010-17). ASU 2010-17 establishes a revenue recognition model for contingent consideration that is payable upon the achievement of an uncertain future event, referred to as a milestone, for research and development arrangements in which one or more payments are contingent upon achieving uncertain future events or circumstances. ASU 2010-17 is effective for fiscal years beginning on or after June 15, 2010, and will be adopted by the Company in the fiscal year beginning January 1, 2011. The impact of ASU 2010-17 on the Company's financial position and operations is dependent on the nature and structure of the Company's future arrangements.

In December 2010, the FASB issued ASU 2010-29, Business Combinations (ASC Topic 805) - Disclosure of Supplementary Pro Forma Information for Business Combinations. This amendment expands the supplemental pro forma disclosures to include a description of the nature and amount of material, nonrecurring pro forma adjustments directly attributable to the business combination included in the reported pro forma revenue and earnings. This amendment is effective prospectively for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010. Early adoption is permitted. The Company intends to adopt this guidance in 2011. The adoption of this new guidance will not have a material impact on the Company's financial statements.



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**3. LIQUIDITY AND CAPITAL RESOURCES**

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

To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs. During 2010, the Company completed three registered direct offerings resulting in net proceeds of approximately \$48.5 million as more fully described in Note 9, Stockholders' Equity. As of December 31, 2010, the Company had \$38.2 million of cash and cash equivalents. In March 2011, the Company completed an offering of an aggregate of 12,199,482 shares of our common stock and warrants to purchase an aggregate of 4,025,827 shares of our common stock, resulting in net proceeds of approximately \$23.8 million, after deducting placement agent fees and other offering expenses. See Note 16, Subsequent Event .

Absent the receipt of any additional significant licensing income or financing, the Company expects its cash and cash equivalents balance to decrease as the Company continues to use cash to fund its operations, including in particular its LibiGel Phase III clinical development program. The Company expects its cash and cash equivalents to meet its liquidity requirements through at least the next 15 to 18 months. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier. Exactly how long the Company's cash resources will last will depend upon several factors, including the pace and timing of enrollment in the LibiGel safety study and perhaps more importantly, the number of women the Company will enroll in the safety study, which number cannot be determined at this time. According to the study's protocol, the minimum number of enrolled women is 2,500 women and the maximum number is 4,000 women. The greater the number of enrolled women, the more the Company will be required to use its cash to conduct the study. As of the end of February 2011, approximately 2,900 women were enrolled in the safety study. The number of women enrolled in the LibiGel safety study will be determined based on statistical methods contained in the study's FDA-agreed protocol as analyzed by the study's independent Data Monitoring Committee (DMC).

As of December 31, 2010, the Company did not have any existing credit facilities under which it could borrow funds, other than the Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at the Company's sole discretion, up to the lesser of \$25.0 million or 5,405,840 shares of the Company's common stock. The term of the CEFF runs through December 2011. The Company may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of the



Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****3. LIQUIDITY AND CAPITAL RESOURCES (continued)**

Company's common stock during the applicable pricing period. As of December 31, 2010, the Company had not sold any shares to Kingsbridge under the CEFF. For additional information regarding the CEFF, see Note 9, "Stockholders' Equity."

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

**4. ACQUISITION OF NET ASSETS OF CELL GENESYS**

On October 14, 2009, the Company acquired 100 percent of the common stock of Cell Genesys in a direct merger transaction. The merger was accounted as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys were recorded by the Company as of the completion of the merger based on their estimated fair values. As Cell Genesys had ceased substantially its operations prior to the date of the transaction, the merger was not considered to be a business combination, and the allocation of the purchase price did not result in recognition of goodwill. The total purchase price is allocated to the acquired assets and assumed liabilities of Cell Genesys based on their estimated relative fair values as of the merger closing date. The table below displays the purchase price of the merger.

Fair value of BioSante common stock issued (20,219,804 shares)	\$	36,800,043
Transaction costs of BioSante		2,431,252
Total purchase price	\$	39,231,295

The total purchase price was allocated as follows:

Cash	\$	24,746,346
Investment in Ceregene		3,486,000
In process research and development		9,000,000
Receivables, equipment and other assets		293,658
Accounts payable and accrued liabilities		1,777,323
Convertible senior notes		16,709,580
Total net assets acquired	\$	19,039,101

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

In addition to the \$24.7 million in cash acquired, the Company obtained, as a result of the merger, the rights to all in-process research and development of Cell Genesys, which included a portfolio of cancer vaccines and other technologies. The \$9.0 million value attributed to this portfolio was expensed as of the date of the acquisition as acquired in-process technology, as it was considered to have no alternative future use. The \$20.2 million representing the premium of the total value of consideration in excess of fair values of the net assets acquired was also expensed as of the date of the acquisition.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**4. ACQUISITION OF NET ASSETS OF CELL GENESYS (continued)**

In addition, as a result of the merger, the Company assumed \$1.2 million in principal amount of outstanding 3.125% convertible senior notes due in November 2011 and \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013 issued by Cell Genesys. As a result of the merger and in accordance with the terms of the indentures governing such notes as supplemented by supplemental indentures entered into between the Company and the trustees thereunder, the November 2011 convertible notes became convertible into an aggregate of 24,789 shares of the Company's common stock at an initial conversion price of \$49.78 per share and the May 2013 convertible notes became convertible into an aggregate of 5,586,559 shares of the Company's common stock at a conversion price of \$3.72 per share, in each case subject to adjustments for stock dividends, stock splits, and other similar events. For more details see Note 7, Convertible Senior Notes.

**5. LICENSE AGREEMENTS**

*Gel Products*

The Company licensed the technology underlying LibiGel, Elestrin and certain of its other gel products, other than Bio-T-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 and as such, the Company owed Antares \$0 as of December 31, 2010 and \$18,033 as of December 31, 2009 pursuant to this agreement. The patents covering the formulations used in these gel products are expected to expire in 2022. Bio-T-Gel was developed and is fully-owned by the Company and is not covered under the Antares license.

*The Pill Plus*

The Company licensed the technology underlying its triple component contraceptive, or The Pill Plus, from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently is marketed. The patents covering the technology underlying The Pill Plus are expected to expire in 2016.

*CaP Technology*

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California (the University), which agreement subsequently has been amended, pursuant to which the University has granted the Company an exclusive license to seven United States patents owned by the University, including rights to sublicense such patents, in fields of use pertaining to vaccine adjuvants and drug delivery systems. The last of the expiration dates for these patents is 2014. The University of California also has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan. The



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**5. LICENSE AGREEMENTS (continued)**

license agreement requires the Company to pay royalties to the University based on a percentage of the net sales of any products the Company sells or a licensee sells incorporating the licensed technology until expiration of the licensed patents.

*Cancer Vaccine Technology*

The Company owns development and commercialization rights to its cancer vaccine technology as a result of its transaction with Cell Genesys. The original core patent applications covering the cancer vaccine technology were licensed exclusively to Cell Genesys from Johns Hopkins University and The Whitehead Institute for Biomedical Research in 1992. Rights to additional patents and patent applications were licensed from Johns Hopkins University in 2001. The patents are expected to expire between 2012 and 2026. Under the various agreements, the Company is required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research 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.

*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, 2010 and 2009 consists of the following:

	2010		2009
Computer equipment	\$ 417,840	\$	432,625
Office equipment	163,653		143,548
Laboratory and equipment	500,130		518,775
	<b>1,081,623</b>		<b>1,094,948</b>

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Accumulated depreciation and amortization	(445,847)	(346,969)
	\$ 635,776	\$ 747,979

There was no construction in progress as of December 31, 2010 or December 31, 2009.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**7. CONVERTIBLE SENIOR NOTES**

As a result of the Company's merger with Cell Genesys, the Company assumed liabilities related to two series of convertible senior notes of Cell Genesys. The conversion features of the convertible senior notes were adjusted for the exchange ratio used in the merger, as described in Note 4, Acquisition of Net Assets of Cell Genesys. The terms of the convertible senior notes are as follows:

- \$20,782,000 principal amount of 3.125% Convertible Senior Notes due May 1, 2013 (the 2013 Notes), exchangeable at the option of the holder or upon certain specified events into an aggregate of 5,586,559 shares of the Company's common stock at a conversion price of \$3.72 per share. The Company has the right to redeem the 2013 Notes for cash as a whole or in part after May 1, 2011. The Company may be obligated to redeem the 2013 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.
- \$1,234,000 principal amount of 3.125% Convertible Senior Notes due November 1, 2011 (the 2011 Notes and collectively with the 2013 Notes, the Notes), exchangeable at the option of the holder or upon certain specified events into an aggregate of 24,789 shares of the Company's common stock at a conversion price of \$49.78 per share. The Company has the right to redeem the 2011 Notes for cash as a whole or in part after November 1, 2009. The Company may be obligated to redeem the 2011 Notes prior to their stated maturity if there is an occurrence of a fundamental event, as described in the indentures.

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

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of December 31, 2010, with changes in the fair value of the Notes occurring since December 31, 2009, 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 \$18,547,333 and \$16,676,417 as of December 31, 2010 and 2009, respectively, differs from their total stated principal amount of \$22,016,000 by \$3,468,667 and \$5,339,583 as of December 31, 2010 and 2009, respectively. The Company recorded fair value adjustments of (\$1,870,916) and \$33,163 related to the convertible senior notes for the years ended December 31, 2010 and 2009, respectively, to increase its recorded liability and corresponding expense in 2010 and reduce its recorded liability and corresponding expense in 2009.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****7. CONVERTIBLE SENIOR NOTES (continued)**

For the year ended December 31, 2010, approximately \$184,000 of the fair value adjustment was attributable to the change in instrument specific credit risk. There was no significant change in the fair value of the convertible senior notes due to a change in instrument specific credit risk for the year ended December 31, 2009. The change in the aggregate fair value of the Notes due to instrument specific credit risk was estimated by calculating the difference between the December 31, 2010 fair value of the Notes as recorded and what the fair value of the convertible notes would have been on December 31, 2010 if the December 31, 2009 discount rate continued to be used in the calculation. The instrument specific credit risk for the year ended December 31, 2010 has increased the fair value of the Notes as market borrowing rates have decreased for similarly rated companies and are estimated to have decreased for the Company as well, indicating a lower credit spread assuming no significant changes in the risk-free borrowing rate.

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

The assumptions as of December 31, 2010 were:

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

The assumptions as of December 31, 2009 were:

	2013 Notes	2011 Notes
Average risk-free rate	1.7%	1.1%
Volatility of BioSante common stock	81.4%	89.8%
Discount rate for principal payments in cash	17.6%	17.6%

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

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

The following table represents the scheduled maturities of required principal payments by year related to the convertible senior notes at December 31, 2010:

2011		1,234,000
2012		
2013		20,782,000
Total	\$	22,016,000

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****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 only periods subject to examination by the major tax jurisdictions where the Company does business are the 2007 through 2010 tax years. The Company determined there are no uncertain tax positions existing as of December 31, 2010 or 2009.

The components of the Company's net deferred tax asset at December 31, 2010 and 2009 were as follows:

	2010	2009
Net operating loss carryforwards	\$ 46,071,206	\$ 29,856,745
Tax basis in intangible assets	4,452,360	3,618,489
Deferred financing costs for tax	7,001,619	7,622,553
Research & development credits	5,796,148	4,242,829
Stock option expense	2,310,405	1,935,640
Other	25,955	109,356
	<b>65,657,693</b>	47,385,612
Valuation allowance	<b>(65,657,693)</b>	(47,385,612)
	\$	\$

The presentation of the net deferred tax assets as of December 31, 2009 has been corrected to remove a deferred tax asset for convertible senior notes of \$6,295,348 that had been previously presented, and correspondingly reduce the valuation allowance by the same amount. There was no effect on the total net deferred tax assets or net loss.

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2010, the Company had approximately \$123,401,000 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 2018-2030. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, generate 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, the amount management believes is more likely than not to be realized. Additionally, the Company has provided a full valuation allowance against \$5,796,148 of research and development credits, which are available to reduce future income taxes, if any, through the year 2030.

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:

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

	<b>2010</b>	<b>2009</b>	<b>2008</b>
Tax at U.S. federal statutory rate	\$ (15,937,695)	\$ (16,397,080)	\$ (6,030,952)
State taxes, net of federal benefit	(1,501,377)	(1,544,652)	(568,133)
Research and development credits	(966,941)	(515,235)	(526,196)
Other, net	133,932	17,718	(2,998)
Change in valuation allowance	18,272,081	18,439,249	7,128,279
	\$	\$	\$

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**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, 2010 or 2009.

There were 391,286 shares of class C special stock issued and outstanding as of December 31, 2010 and 2009. 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 \$2.50 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 81,391,130 and 53,262,568 shares of common stock issued and outstanding as of December 31, 2010 and 2009, 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.

*Registered Direct Offerings*

On March 8, 2010, the Company completed a registered direct offering of an aggregate of 10,404,626 shares of its common stock and warrants to an aggregate of 5,202,313 shares of its common stock, at a purchase price of \$1.73 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 \$2.08 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 208,093 shares of the Company's common stock at an





Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**9. STOCKHOLDERS EQUITY (continued)**

exercise price of \$2.16, which warrants are exercisable beginning on September 8, 2010 and will expire on June 9, 2014.

On June 23, 2010, the Company completed an offering of 7,134,366 shares of its common stock and warrants to purchase an aggregate of 3,567,183 shares of its common stock at a purchase price of \$2.1025 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 are exercisable immediately, have an exercise price of \$2.45 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 214,031 shares of the Company's common stock at an exercise price of \$2.63 per share, which warrants are exercisable immediately and will expire on June 9, 2015.

On December 31, 2010, the Company completed an offering of 10,588,236 shares of its common stock and warrants to purchase an aggregate of 5,294,118 shares of its common stock at a purchase price of \$1.70 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 are exercisable immediately, have an exercise price of \$2.00 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 317,647 shares of the Company's common stock at an exercise price of \$2.125, which warrants are exercisable immediately and will expire on June 9, 2015.

*Acquisition of Net Assets of Cell Genesys*

In October 2009, the Company acquired Cell Genesys in a direct merger. As a result of the merger, each share of common stock of Cell Genesys issued and outstanding immediately prior to the effective time of the merger was converted into the right to receive 0.1828 of a share of the Company's common stock. In the aggregate, the Company issued approximately 20.2 million shares of its common stock to former Cell Genesys stockholders in connection with the merger. All options to purchase shares of Cell Genesys common stock, other than certain designated options held by certain of Cell Genesys's former officers (Assumed Options), became fully vested and exercisable until immediately prior to the effective time of the merger. At the effective time of the merger, such unexercised options other than the Assumed Options terminated. The Assumed Options were assumed by the Company and will remain outstanding following the merger, but converted into and became options to purchase shares of the Company's common stock on terms substantially identical to those in effect prior to the merger, except for adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, the Assumed Options converted into options to purchase an aggregate of 234,429 shares of the Company's common stock at a weighted average exercise price of \$19.73 per share. All warrants to purchase shares of Cell Genesys common stock which by their terms survived the merger (Assumed Warrants) were assumed by the Company, but were converted into and became warrants to purchase shares of the Company's common stock on terms substantially identical to those in effect prior to the merger, except for



Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**9. STOCKHOLDERS EQUITY (continued)**

adjustments to the underlying number of shares and the exercise price based on the 0.1828 exchange ratio. As a result of the merger, these Assumed Warrants converted into warrants to purchase an aggregate of 395,246 shares of the Company's common stock at a weighted average exercise price of \$39.27 per share.

For additional discussion regarding the merger with Cell Genesys and the assets and liabilities acquired, see Note 4, Acquisition of Net Assets of Cell Genesys.

*Convertible Senior Notes*

See the Acquisition of Net Assets of Cell Genesys section of this Note 9 and see Note 7, Convertible Senior Notes for information regarding the convertible senior notes assumed in the Cell Genesys merger.

*Committed Equity Financing Facility*

In December 2008, the Company entered into a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at the Company's sole discretion, up to the lesser of \$25.0 million or 5,405,840 shares of the Company's common stock. In December 2010, the parties extended the term of the CEFF until December 2011. The Company may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of the Company's common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for the Company's common stock of \$1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of common stock issued or issuable to Kingsbridge; and the continued listing of the Company's common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting the Company's business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides the Company notice of such material and adverse event. As of December 31, 2010, the Company had not sold any shares to Kingsbridge under the CEFF.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****9. STOCKHOLDERS EQUITY (continued)***Warrants*

As of December 31, 2010, warrants to purchase 19,418,590 shares of the Company's common stock were outstanding, as follows, of which, all but 180,000 were exercisable as of December 31, 2010:

<b>Issue Date</b>	<b>Amount</b>	<b>Exercise Price</b>	<b>Expiration</b>
July 21, 2006	853,292	\$ 2.75	October 21, 2011
May 15, 2008	66,667	\$ 4.78	May 14, 2011
December 15, 2008	300,000	\$ 4.00	June 14, 2014
July 21, 2009	180,000	\$ 2.00	July 20, 2012
August 13, 2009	2,400,000	\$ 2.50	August 12, 2014
August 13, 2009	240,000	\$ 2.50	June 9, 2014
October 14, 2009	395,246	\$ 39.27	April 1, 2012
March 8, 2010	5,202,313	\$ 2.08	September 8, 2015
March 8, 2010	208,093	\$ 2.16	June 9, 2014
June 23, 2010	3,567,183	\$ 2.45	June 23, 2015
June 23, 2010	214,031	\$ 2.63	June 9, 2015
November 22, 2010	180,000	\$ 2.00	November 21, 2013
December 30, 2010	5,294,118	\$ 2.00	December 30, 2015
December 30, 2010	317,647	\$ 2.125	June 9, 2015

During 2010, the Company issued warrants to purchase 14,803,385 shares of the Company's common stock in connection with registered direct offerings as described above, and warrants to purchase 180,000 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 763,750 shares of the Company's common stock expired unexercised.

During 2009, the Company issued warrants to purchase 2,640,000 shares of the Company's common stock in connection with a registered direct offering, warrants to purchase 395,246 shares of the Company's common stock in connection with the Cell Genesys merger, and warrants to purchase 180,000 shares of the Company's common stock as compensation for investor relations services as described below. During 2009, no warrants were exercised and warrants to purchase 534,996 shares of the Company's common stock expired unexercised.

During 2008, the Company issued warrants to purchase 300,000 shares of the Company's common stock in connection with the CEFF, and warrants to purchase 80,000 shares of the Company's common stock as compensation for investor relations services as described below. Warrants to purchase an aggregate of 176,614 shares of common stock were exercised for total cash proceeds of \$379,720. Warrants to purchase

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

an aggregate of 71,543 shares of common stock were exercised on a cashless basis, for which warrants to purchase 74,957 shares of common stock were cancelled by the Company in payment of the exercise price for the exercised warrants. During 2008, warrants to purchase 500 shares of the Company's common stock expired unexercised.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**Notes to the Financial Statements**

**December 31, 2010**

**9. STOCKHOLDERS EQUITY (continued)**

In 2010, 2009 and 2008, the Company issued warrants to purchase 180,000, 180,000 and 80,000 shares of the Company's common stock, respectively, in consideration for various investor relations services. The warrants became exercisable on a ratable basis over a twelve-month period. With respect to the warrants issued in 2008, the Company terminated its relationship with the investor relations firm effective March 31, 2009, at which time 66,667 of the warrants were exercisable, and such warrants remain outstanding at December 31, 2010. 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, 2010, 2009 and 2008, the Company recorded \$65,529, \$64,103 and \$104,284, respectively, in non-cash general and administrative expense pertaining to consultant warrants.

**10. STOCK-BASED COMPENSATION**

As of December 31, 2010, 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. 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, 2010, 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 4,000,000 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, 1,334 shares had been issued and 1,660,916 shares were subject to outstanding stock options as of December 31, 2010. Outstanding employee stock options generally vest over a period of three years and for more recent 2011 grants, four years, and have 10-year contractual terms. Upon exercise of an option, the Company issues new shares. 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. None of these options were outstanding as of December 31, 2010. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan and the 2008 Plan was \$992,757, \$1,254,503 and \$1,102,444 for the years ended December 31, 2010, 2009 and 2008, respectively. No income tax benefit was recognized in the Company's statements of operations for stock-based compensation arrangements due to the Company's net loss position.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**10. STOCK-BASED COMPENSATION (continued)**

The weighted average fair value of the options at the date of grant for options granted during 2010, 2009 and 2008 was \$1.11, \$1.04 and \$2.41, 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:

	2010	2009	2008
Expected option life (years)	6.00	6.00	6.00
Risk-free interest rate	2.42%	2.74%	3.45%
Expected stock price volatility	76.05%	76.75%	67.63%
Dividend yield			

The Company uses the simplified method to estimate the life of options meeting certain criteria. 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.

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:

	2010	2009	2008
Research and development	\$ 325,208	\$ 361,773	\$ 356,287
General and administrative	667,549	892,730	746,157
Total stock-based compensation expense	\$ 992,757	\$ 1,254,503	\$ 1,102,444

A summary of activity under the Plans during the year ended December 31, 2010 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2009	3,006,120	\$ 4.24
Granted	758,750	\$ 1.64
Exercised	1,334	\$ 1.51
Forfeited or expired	46,100	\$ 1.57
Outstanding December 31, 2010	3,717,436	\$ 3.69
<i>(weighted average contractual term)</i>	6.74	



Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

Exercisable at December 31, 2010	2,228,853	4.91
<i>(weighted average contractual term)</i>	<i>5.46</i>	

The aggregate intrinsic value of the Company's outstanding and exercisable options as of December 31, 2010 was \$162,892 and \$36,248, respectively. Substantially all outstanding options are expected to vest.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**10. STOCK-BASED COMPENSATION (continued)**

As of December 31, 2010, there was \$914,412 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 1.81 years.

The intrinsic value of options exercised during the years ended December 31, 2010 was \$974. No stock options were exercised during 2009 or 2008. 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, 2010, 2009 and 2008 was \$764,921, \$788,461 and \$659,898, 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 IRS limitation. Under the 401(k) Plan, the Company can make discretionary matching contributions. Company contributions expensed in 2010, 2009 and 2008 totaled \$179,349, \$117,969 and \$108,019, 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 2011, 2012 and 2013 are \$353,880, \$421,910 and \$454,270, respectively.

Rent expense amounted to \$338,588, \$325,093 and \$277,370 for the years ended December 31, 2010, 2009 and 2008, respectively.

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****13. COMMITMENTS***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 2010, 2009 and 2008, the Company paid or accrued \$152,228, \$63,749 and \$21,830, respectively, to Antares as a result of royalties generated by Elestrin revenues. Pursuant to a separate agreement with Antares and related to the December 2009 Azur license amendment, the Company paid Antares an aggregate of \$268,750 in February 2010, which is recorded in licensing expense. In 2008, the Company also paid \$462,500 to Antares as a result of the Azur license of Elestrin.

*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 include 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 include 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.

Future minimum maintenance payments due under this agreement are as follows:

<b>Year</b>	<b>Minimum Amount Due</b>
2011	80,000
2012	80,000
2013	80,000
2014	80,000
2015	80,000
Thereafter	120,000

Under the terms of the license agreement with the Wake Forest University Health Sciences and Cedars-Sinai Medical Center, the Company has the right to terminate the license at any time.

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.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**14. FAIR VALUE MEASUREMENTS**

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

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

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

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

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

Financial assets and liabilities recorded at fair value on a recurring basis as of December 31, 2010 and 2009 are classified in the table below in one of the three categories described above:

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

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

In addition, as of September 30, 2010, the Company recorded an impairment of \$286,000 to reduce its investment in Ceregene to its estimated fair value of \$3,200,000, which was based on a recent third party investment in Ceregene. The fair value measurement is based on level 2 measurements. The market based valuation technique was used to measure fair value as of September 30, 2010 due to the availability of information, compared to the income based valuation technique at inception. As of December 31, 2010, the investment continues to be recorded at \$3,200,000.

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**  
**Notes to the Financial Statements**  
**December 31, 2010**

**14. FAIR VALUE MEASUREMENTS (continued)**

Description	December 31, 2009 Balance	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities:</b>				
2011 Senior Notes	\$ 974,579		\$ 974,579	
2013 Senior Notes	15,701,838		15,701,838	
Total liabilities	\$ 16,676,417		\$ 16,676,417	

The Company made an election to record the values of the 2011 and 2013 Senior Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earnings immediately pursuant to ASC 825. The fair values of the 2011 and 2013 Senior 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.

The table below presents a reconciliation of the level 3 fair value measurements, which are based on significant unobservable inputs, during 2009, which relate to the auction rate securities previously held by the Company. There were no recurring level 3 fair value measurements during 2010.

	Fair Value Measurements Using Significant Unobservable Inputs Auction Rate Securities	Fair Value Measurements Using Significant Unobservable Inputs Put Asset Related to Auction Rate Securities
January 1, 2009	\$ 2,534,820	\$ 465,180
Transfers into Level 3		
Purchases, redemptions, issuances or settlements	(2,534,820)	(465,180)
Total gains or (losses) (realized/unrealized) included in net loss		
December 31, 2009	\$	\$

Table of Contents**BIOSANTE PHARMACEUTICALS, INC.****Notes to the Financial Statements****December 31, 2010****15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

Selected quarterly data for 2010 and 2009 is as follows:

	<b>2010</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Revenue	\$ 2,279,874	\$ 8,657,606	\$ 9,716,091	\$ 11,904,935
Research and development expenses	9,426,870	1,540,200	1,534,417	1,367,491
General and administrative expenses	1,498,252	268,750	(8,959,419)	(10,240,352)
Licensing expense	268,750	(10,240,352)	(11,240,177)	(13,168,413)
Operating loss	(8,959,419)	(10,240,352)	(11,240,177)	(13,168,413)
Net loss	(10,540,419)	(10,794,351)	(11,589,711)	(13,271,735)
Loss per share:				
Basic and diluted	\$ (0.19)	\$ (0.17)	\$ (0.16)	\$ (0.18)

	<b>2009</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Revenue	\$ 68,428	\$ 115,163	\$ 10,492	\$ 1,063,971
Research and development expenses	3,072,240	3,493,576	3,371,217	3,743,540
General and administrative expenses	1,029,202	1,208,956	1,506,056	1,629,731
Acquisition related charges			1,470,467	27,721,727
Licensing expense				299,616
Operating loss	(4,062,260)	(4,620,701)	(6,370,556)	(33,630,091)
Net loss	(4,050,612)	(4,620,701)	(6,370,556)	(32,485,899)
Loss per share:				
Basic and diluted	\$ (0.15)	\$ (0.17)	\$ (0.21)	\$ (0.84)

**16. SUBSEQUENT EVENT**

On March 8, 2011, the Company completed an offering of 12,199,482 shares of its common stock and warrants to purchase an aggregate of 4,025,827 shares of its common stock at a purchase price of \$2.0613 per share to institutional investors for gross proceeds of \$25.1 million. The offering resulted in net proceeds to the Company of approximately \$23.8 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of \$2.25 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 243,990 shares of the Company's common stock at an exercise price of \$2.58, which warrants are exercisable immediately and will expire on June 9, 2014. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities.





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**

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

**Management's Report on Internal Control Over Financial Reporting**

Our 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, our independent registered public accounting firm, regarding the effectiveness of our internal control over financial reporting is included in this report in Item 8, under the heading "Report of Independent Registered Public Accounting Firm."

**Change in Internal Control Over Financial Reporting**

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. OTHER INFORMATION**

Not applicable.

Table of Contents

**PART III**

---

**Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

**Directors**

The information in the Proposal No. 1 Election of Directors section of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

**Executive Officers**

The information concerning our executive officers is included in this report under Item 4a, Executive Officers of the Registrant and is incorporated in this report by reference.

**Section 16(a) Beneficial Ownership Reporting Compliance**

The information in the Stock Ownership Section 16(a) Beneficial Ownership Reporting Compliance section of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

**Code of Conduct and Ethics**

Our Code of Conduct and Ethics applies to all of our employees, officers and directors, including our principal executive officer and principal financial officer, and meets the requirements of the Securities and Exchange Commission. A copy of our Code of Conduct and Ethics is filed as an exhibit to this report. We intend to satisfy the disclosure requirements of Item 5.05 of Form 8-K regarding amendments to or waivers from any provision of our Code of Conduct and Ethics by posting such information on our corporate website located at [www.biosantepharmaceutical.com](http://www.biosantepharmaceutical.com).

**Changes to Nomination Procedures**

During the fourth quarter of 2010, we made no material changes to the procedures by which stockholders may recommend nominees to the Board of Directors, as described in our most recent proxy statement.

**Audit Committee Matters**

The information in the Corporate Governance Audit and Finance Committee section of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

Table of Contents**Item 11. EXECUTIVE COMPENSATION**

The information in the Executive Compensation and the Director Compensation sections of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

**Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS****Stock Ownership**

The information in the Stock Ownership section of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders and is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table and notes provide information about shares of our common stock that may be issued under all of our equity compensation plans as of December 31, 2010. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan are within the discretion of the Compensation Committee of our Board of Directors and our 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	3,483,007(1)(2) \$	2.61	2,337,750(3)
Equity compensation plans not approved by security holders	234,429 \$	19.73	0

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

<b>Total</b>	3,717,436	\$	3.69	2,337,750
--------------	-----------	----	------	-----------

---

(1) Amount includes shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2010 under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the 2008 Plan ) and the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the 1998 Plan ).

(2) Excludes options assumed by us in connection with our merger with Cell Genesys, Inc. As of December 31, 2010, a total of 234,429 shares of our 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 \$19.73 per share and they have an average weighted life remaining of 5.4 years. All of the options assumed and outstanding in connection with our merger with Cell Genesys were exercisable as of December 31, 2010. No additional options, restricted stock units or other equity incentive awards may be granted under the assumed Cell Genesys, Inc. plans.

Table of Contents

(3) As of December 31, 2010, these shares remain available for future issuance under the 2008 Plan. Under the terms of the 2008 Plan, any shares of our common stock subject to outstanding awards under the 1998 Plan as of the approval of the 2008 Plan by our stockholders on June 11, 2010 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.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information in the Related Party Relationships and Transactions and Corporate Governance Director Independence sections of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated in this report by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

**Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information in the Audit-Related Matters Audit, Audit-Related, Tax and Other Fees and Audit-Related Matters Pre-Approval Policy and Procedures of our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders is incorporated herein by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.



Table of Contents

**PART IV**

---

**Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Our 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. (filed herewith).
  
- D. Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes (filed herewith).
  
- E. BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)).

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

F. Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)).

G. Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)).

H. 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)).

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

### Table of Contents

- I. 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)).
- J. 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)).
- K. 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)).
- L. 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)).
- M. 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)).
- N. Description of Non-Employee Director Compensation Arrangements (filed herewith).
- O. 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)).
- P. 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: March 16, 2011

BIOSANTE PHARMACEUTICALS, INC.

By */s/ STEPHEN M. SIMES*  
 Stephen M. Simes  
*Vice Chairman, President and Chief Executive Officer*  
*(Principal Executive Officer)*

By */s/ PHILLIP B. DONENBERG*  
 Phillip B. Donenberg  
*Senior Vice President of Finance, Chief Financial*  
*Officer and Secretary (Principal Financial and*  
*Accounting Officer)*

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
<i>/S/ STEPHEN M. SIMES</i> Stephen M. Simes	Vice Chairman, President and Chief Executive Officer	March 16, 2011
<i>/S/ LOUIS W. SULLIVAN, M.D.</i> Louis W. Sullivan, M.D.	Chairman of the Board	March 16, 2011
<i>/S/ FRED HOLUBOW</i> Fred Holubow	Director	March 16, 2011
Peter Kjaer	Director	March __, 2011
<i>/S/ ROSS MANGANO</i> Ross Mangano	Director	March 16, 2011
<i>/S/ JOHN T. POTTS, JR., M.D.</i> John T. Potts, Jr., M.D.	Director	March 16, 2011

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 10-K

/S/ EDWARD C. ROSENOW, III, M.D.  
Edward C. Rosenow, III, M.D.

Director

March 16, 2011

/S/ STEPHEN A. SHERWIN, M.D.  
Stephen A. Sherwin, M.D.

Director

March 16, 2011

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**

**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K**

**FOR THE YEAR ENDED DECEMBER 31, 2010**

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
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)
2.1	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

Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
		the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
3.2	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 October 20, 2004, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to Cell Genesys's Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on December 29, 2004 (File No. 000-19986)
4.2	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of October 20, 2004, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2011	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
4.3	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)
4.4	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)
4.5	Form of Warrant dated as of July 21, 2006 issued by BioSante Pharmaceuticals, Inc. to each of the Subscribers Party to the Subscription Agreements dated July 7, 2006	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 24, 2006 (File No. 001-31812)
4.6	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

Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
		the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
4.7	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)
4.8	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)
4.9	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)
4.10	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)
4.11	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)
4.12	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)
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



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

### Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b> (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.	Filed herewith
10.4	Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes	Filed herewith
10.5	BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)
10.6	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)
10.7	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. 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 11, 2010 (File No. 001-31812)
10.8	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)

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

## Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
10.9	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)
10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.15	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)

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

### Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.16	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)

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

### Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.23	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)
10.24	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)
10.25	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)
10.26	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)
10.27	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.28	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.29	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)
10.30	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.31	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith

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

### Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
10.32	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Filed herewith
10.33	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.34	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (3)	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)
10.35	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (3)	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)
10.36	Form of Subscription Agreement dated as of July 7, 2006 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement	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 10, 2006 (File No. 001-31812)
10.37	Form of Subscription Agreement dated as of May 25, 2007 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 25, 2007 (File No. 001-31812)
10.38	Common Stock Purchase Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	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 18, 2008 (File No. 001-31812)
10.39	Amendment No. 1 to Common Stock Purchase Agreement dated as of March 24, 2010 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.39 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)

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

### Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
10.40	Amendment No. 2 to Common Stock Purchase Agreement dated as of December 15, 2010 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	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 23, 2010 (File No. 001-31812)
10.41	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)
10.42	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)
10.43	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)
10.44	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)
10.45	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)
10.46	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)

Table of Contents

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
10.47	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 10.1 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)
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

---

(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 sought with respect to designated portions of this document.

(3) 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.