BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 13, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2011

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

For the transition period from to .

Commission file number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

(847) 478-0500

(Registrant s telephone number, including area code)

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

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

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

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

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

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

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

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

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

one):

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

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

The aggregate market value of the registrant s common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sale price at which the common stock was last sold as of June 30, 2011 (the last business day of the registrant s second fiscal quarter) as reported by The NASDAQ Global Market on that date was approximately $249.9 million.

As of March 12, 2012, 120,826,861 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 definitive Proxy Statement for its 2012 Annual Meeting of Stockholders to be held on May 30, 2012.

Table of Contents

TABLE OF CONTENTS

		Page
PART I		1
ITEM 1.	BUSINESS	1
ITEM 1A.	RISK FACTORS	20
ITEM 1B.	UNRESOLVED STAFF COMMENTS	49
ITEM 2.	PROPERTIES	49
ITEM 3.	LEGAL PROCEEDINGS	49
ITEM 4.	MINE SAFETY DISCLOSURES	50
ITEM 4A.	EXECUTIVE OFFICERS OF THE REGISTRANT	50
PART II		52
ITEM 5.	MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	52
ITEM 6.	SELECTED FINANCIAL DATA	54
ITEM 7.	MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	55
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK	68
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	69
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	101
ITEM 9A.	CONTROLS AND PROCEDURES	101
ITEM 9B.	OTHER INFORMATION	101
PART III		102
ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	102
ITEM 11.	EXECUTIVE COMPENSATION	103
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	103
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	104

ITEM 14.	PRINCIPAL ACCOUNTING FEES AND SERVICES	104
PART IV		105
ITEM 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES	105
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K		108

Table of Contents

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

As used in this report, references to BioSante, the company, we, 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®, GVAX , The Pill-Plus and Elestrin . This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

Table of Contents

PART I

ITEM 1. BUSINESS

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 for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD).

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

- GVAX cancer vaccines a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.

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

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

Our corporate strategy always has included product development of high value medically-needed pharmaceutical products. In light of the recently announced top-line results from our two pivotal LibiGel Phase III efficacy trials described below, we are assessing our corporate strategy. We are determining LibiGel s path forward and potential alternative strategies to utilize the continuing LibiGel Phase III cardiovascular

events and breast cancer safety study. We also have expanded our efforts to explore new product development projects through in-licensing and mergers and acquisitions. In addition, a full review of our GVAX cancer vaccine portfolio is underway.

Our lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. We continue to analyze the data from the two pivotal LibiGel Phase III efficacy trials first reported on December 14, 2011. Initial analysis of the efficacy data from these trials shows that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD. However, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel s results were not shown to be statistically different from placebo. The LibiGel Phase III safety study, which completed enrollment in June 2011, continues and will continue during further analysis of the LibiGel efficacy data and until a final strategic decision has been made. It is our objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study. In the meantime, we have

Table of Contents

instituted certain cost savings measures to minimize the continuing cost of the safety study and our operating expenses overall, including the termination of several of our independent contractor arrangements and a reduction in our total employee headcount. In February 2012, we announced that based upon the eighth unblinded review of 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. At the time of such announcement, 3,656 subjects were enrolled in the safety study resulting in over 5,800 subject-years of exposure. Although we carefully monitor any cardiovascular events or breast cancer experienced by subjects in the safety study, we remain blinded as to whether the events are experienced by subjects in the LibiGel arm or the placebo arm of the study.

Our male testosterone gel is our second FDA approved product. This product was initially developed by us, and then licensed by us to Teva for late stage clinical development. Teva submitted a new drug application (NDA) to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva.

Our GVAX cancer vaccines, which are designed to stimulate a patient s immune system to fight effectively the patient s own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving our GVAX cancer vaccines ongoing, primarily being conducted at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland. The studies are being funded by various sources, including certain foundations and our licensees. Our objective with respect to our GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes seeking additional licensees to fund and develop the cancer vaccines.

BioSante s Primary Product Portfolio

Product	Indication	Early Human Clinical	Late Human Clinical	FDA Approval	Collaborations
LibiGel® (testosterone gel)	Female sexual dysfunction (FSD)				Non-partnered
Male Testosterone Gel	Male hypogonadism				Teva
GVAX Cancer Vaccines	Various cancers				Johns Hopkins
The Pill Plus (birth control with androgen)	Contraception				Pantarhei for oral use Non-partnered for transdermal use

Table of Contents

Product	Indication	Early Human Clinical	Late Human Clinical	FDA Approval	Collaborations
Elestrin (estradiol gel)	Menopausal symptoms				Jazz Pharmaceuticals

Elestrin is our first FDA approved product. Jazz Pharmaceuticals, Inc. (which recently acquired Azur Pharma International II Limited (Azur), our prior 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 sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Jazz Pharmaceuticals 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.

One of our strategic goals has been, and continues to be, 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. In particular, as mentioned above, in light of recently announced results from our two pivotal LibiGel Phase III efficacy trials, we have expanded our exploration of new product development projects through in-licensing and mergers and acquisitions. 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 the products and technologies of others 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.

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;

- 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

Table of Contents

- 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 LibiGel and Elestrin, but not our male testosterone gel, from Antares Pharma, Inc. (Antares). Our license agreement with Antares requires us to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the licensed technology. Our male testosterone gel was developed and is fully-owned by us and licensed to Teva. We license the technology underlying The Pill Plus from Wake Forest University Health Sciences and Cedars-Sinai Medical Center. The financial terms of this license include regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

LibiGel. Our lead product in development has been LibiGel, a once daily transdermal testosterone gel designed to treat FSD, specifically HSDD in postmenopausal 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. During 2011, LibiGel completed two pivotal Phase III efficacy trials, the results of which we announced on December 14, 2011. Although we continue to analyze the data from the two pivotal Phase III efficacy trials, initial analysis of the efficacy data from these trials shows that the trials did not meet the co-primary endpoints of increase in satisfying sexual events or increase in sexual desire or the secondary endpoint of decrease in distress. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD, but the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel s results were not shown to be statistically different from placebo. In light of these results, we currently are evaluating the future of our LibiGel development program, which includes the ongoing Phase III safety study. It is our objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study.

Although generally thought of as being limited to men, testosterone also is important to women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone therapy in women can boost sexual desire, sexual activity and pleasure, increase bone density, raise energy levels and improve mood. According to a study published in the Journal of the American Medical Association, 43 percent of American women between the ages of 18 to 59, or about 40 million women, experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex (low sexual desire). Furthermore, according to a study published in the New England Journal of Medicine, 43 percent of American women between the ages of 57 to 85 experience low sexual desire. Importantly, according to IMS data, approximately two million testosterone prescriptions were written off-label for women in the U.S. in 2010. In addition, according to independent primary market research, approximately 2 million additional prescriptions of compounded testosterone were written off-label for women in the U.S. in 2010. Female sexual dysfunction is defined as a consistent lack of sexual desire, arousal or pleasure. The majority of women with FSD are postmenopausal, experiencing symptoms due to hormonal changes that occur with aging or following surgical menopause.

Although treatment with LibiGel in our Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD, initial analysis of the efficacy data from our Phase III efficacy trials shows that the trials did not meet the co-primary endpoints of increase in satisfying sexual events or increase in sexual desire or the secondary endpoint of decrease in sexual distress. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline; this increase also was significant versus placebo. In this study, the

Table of Contents

effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, in surgically menopausal women distressed by their low sexual desire and activity.

The Phase III safety and efficacy trials were randomized, double-blind, placebo-controlled, multi-center trials of a total of 1,172 menopausal women, exposed to LibiGel or placebo for six months. Subjects in the first trial, called BLOOM-1, who were treated with LibiGel showed an increase of 1.47 days with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.26 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.463. (The smaller the p value, the more strongly the test rejects the null hypothesis, that is, the hypothesis being tested. A p-value of .05 or less rejects the null hypothesis at the 5% level that is, the statistical assumptions used, imply that only 5% of the time would the supposed statistical process produce a finding this extreme if the null hypothesis were true.) In BLOOM 1, there was an increase in the total number of satisfying sexual events of 3.87 from baseline (an increase of 83 percent) in the LibiGel group and in the placebo group there was an increase of 3.52 satisfying sexual events from baseline (an increase of 65 percent) for a p value of 0.698. Subjects in BLOOM-2 who were treated with LibiGel showed an increase of 1.0 day with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.28 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.214. Subjects in BLOOM-1 showed an increase in mean sexual desire of 0.03 over placebo, a p value of 0.672, while subjects in BLOOM-2 demonstrated an increase in mean sexual desire of 0.03 compared to placebo, a p value of 0.48. Subjects in both trials demonstrated a decrease in sexual distress when treated with LibiGel (p=0.569 and p=0.26) compared to baseline.

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

The separate LibiGel Phase III safety study completed enrollment of 3,656 subjects in June 2011. In February 2012, we announced that based upon the eighth unblinded review of safety data from the safety study by the study s independent DMC, 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 enrolled in the safety study. Additional unblinded reviews will be conducted periodically by the DMC. As of the date of the DMC s most recent review, there had been 31 adjudicated cardiovascular (CV) events, a rate of approximately 0.53 percent, and 19 diagnoses of breast cancer, a rate of approximately 0.33 percent, after approximately 5,800 women-years of exposure in the study, or an average of more than 19 months per subject. Although we monitor closely any cardiovascular events or breast cancers experienced by subjects in the safety study, we remain blinded as to whether the CV events are experienced by subjects in the LibiGel arm or the placebo arm of the study.

According to the protocol, the LibiGel Phase III safety study is intended to continue for 12 months of therapy from June 2011, the date the last subject was enrolled before the primary analysis will be conducted. The primary analysis of safety data was targeted for the third quarter of 2012, which will

Table of Contents

not occur if the safety study is terminated early. We intend to continue the LibiGel Phase III safety study during further analysis of the LibiGel efficacy data and until a final strategic decision has been made, which we anticipate should be made during the second quarter of 2012. In the meantime, we have instituted certain cost savings measures to minimize the continuing cost of the safety study.

Male Testosterone Gel. Our once daily transdermal testosterone gel indicated for the treatment of hypogonadism, or testosterone deficiency, in men is our second FDA approved product. Unlike LibiGel and Elestrin, our male testosterone gel is owned by us with no royalty or milestone obligations to any other party.

Our male testosterone gel is subject to a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. Under the agreement, Teva has agreed to develop and market our male testosterone gel for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva, certain milestones and royalties on sales of the product in exchange for rights to develop and market the product. Teva also is responsible under the terms of the agreement for regulatory filings and all manufacturing and marketing associated with the product. Teva submitted a new drug application (NDA) to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva. 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 gel formulated products for men are designed to deliver testosterone without the pain of injections and the physical presence, skin irritation and discomfort associated with transdermal patches. We are aware of four gel testosterone products for men currently on the market in the United States.

***The Pill-Plus*.** The Pill-Plus is based on three issued U.S. patents claiming triple component therapy via any route of administration (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone). The Pill-Plus adds a third component, an androgen, to the normal two component (estrogen and progestogen) oral contraceptive to prevent testosterone deficiency which can result from the estrogen and progestogen components and which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral

Table of Contents

androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousabilty and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to avoid or to improve the symptoms of female sexual dysfunction in oral contraceptive users.

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.

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.

Jazz Pharmaceuticals is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur (which was acquired by Jazz Pharmaceuticals) 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 sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Jazz Pharmaceuticals 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.

Elestrin is also subject to an exclusive agreement with Valeant Pharmaceuticals International, Inc. (which acquired PharmaSwiss SA) for the marketing of Elestrin in Israel. Valeant Pharmaceuticals will be responsible for regulatory and marketing activities in Israel. Israeli authorities have approved Elestrin and plans for marketing Elestrin in Israel are under consideration.

***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

7

Table of Contents

common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. No recent investments have been made and none are expected in the foreseeable future.

Description of Our GVAX Cancer Vaccines and Other Technologies

GVAX Cancer Vaccine Technology. Our GVAX 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.

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 primarily as non patient-specific, or allogeneic, vaccines. Our GVAX cancer vaccines are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies involving our GVAX cancer vaccines ongoing, primarily being conducted at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland. The studies are being funded by various sources, including certain foundations and our licensees.

In June 2011, we announced that the FDA s clinical hold on our GVAX prostate cancer vaccine for the treatment of prostate cancer was lifted by the FDA. Manufacturing of new GVAX prostate cancer vaccine is complete, and planning for a new Phase II clinical trial, funded by others, at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center is underway.

In March 2011, we licensed aspects of our GVAX pancreas cancer vaccine and GVAX prostate cancer vaccine to Aduro BioTech, a clinical-stage immunotherapy company, solely for use in combination with Aduro s proprietary vaccine platform based on Listeria monocytogenes (Lm). Under the agreement, we are entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using our GVAX cancer vaccine technology in combination with Aduro s vaccines.

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

In February 2012, we announced the presentation of results from a Phase Ib clinical study that show our GVAX pancreas cancer vaccine increased the median survival of pancreatic cancer patients with previously treated, locally advanced or metastatic pancreatic adenocarcinoma

(PDA), from 3.3 months when treated with ipilimumab (IPI; Yervoy; BMS), to 5.5 months on the combination of IPI

Table of Contents

plus GVAX Pancreas, an increase of more than 60 percent. In addition, the IPI/GVAX pancreas combination demonstrated an increase in one year survival, from 7 percent to 27 percent. A new multicenter clinical study is planned to begin this year.

Our objective with respect to our GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes seeking additional licensees to fund and develop the cancer vaccines.

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.

Sales and Marketing

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 Jazz Pharmaceuticals, Jazz Pharmaceuticals has agreed to use commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States, and under our agreement with Teva, Teva has agreed to use commercially reasonable efforts to market our male testosterone gel in 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.

Research and Product Development

We historically have spent a significant amount of our financial resources on product development activities, with the largest portion being spent on clinical studies for LibiGel. We spent approximately $44.2 million in 2011, $39.7 million in 2010 and $13.7 million in 2009 on research and product development activities. We spent an average of approximately $3.7 million per month on our research and product development activities during 2011, the substantial majority of which was spent on our LibiGel Phase III clinical studies. The amount of our research and product development expenses for 2012 will depend significantly upon whether we continue our LibiGel Phase III safety study and if we in-license or otherwise acquire additional products and technologies requiring additional product development.

Table of Contents

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 development in accordance with FDA and other appropriate regulations.

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 and Elestrin, but not our male testosterone 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, although with respect to LibiGel, a new U.S. patent covering the method of use of LibiGel for treating FSD and HSDD was issued, which will expire in December 2028. In addition, we have other patents pending, which, if issued, may expire later than 2028. Our male testosterone gel was developed and is fully-owned by us and not covered under the Antares license.

GVAX Cancer Vaccine Technology. We own development and commercialization rights to our GVAX cancer vaccine technology as a result of our merger with Cell Genesys in October 2009. The patent estate covering our cancer vaccine technology is licensed exclusively to BioSante from Johns Hopkins University and The Whitehead Institute for Biomedical Research. 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 50 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.

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

Table of Contents

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.

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 Jazz Pharmaceuticals in the U.S., we transferred the Elestrin trademark in the U.S. to Jazz Pharmaceuticals). In addition, we own common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, GVAX , THE PILL-PLUS , ELESTRIN , BIO-E-GEL® and LIBIGEL-E/T . 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 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. 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 our gel products. 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 products, Elestrin and our male testosterone gel, 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 and potentially on cost. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market and may result in certain marketing exclusivity as per federal legislation. Acceptance by physicians and

Table of Contents

other health care providers, including managed care groups, also is critical to the success of a product versus competitor products.

With regard to our GVAX cancer vaccine technology and other related 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 vaccine for prostate cancer. VaxOnco Inc., Agenus Inc., Oncothyreon Inc., GlaxoSmithKline and Boerhinger 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.

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

Table of Contents

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 two types of applications used for obtaining FDA approval of new non-biological drug products, other than a generic product:

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

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

- 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

Table of Contents

- 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 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.

Table of Contents

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

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

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

Table of Contents

including additional preclinical testing or clinical trials. Even if such information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

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

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. The Hatch-Waxman Act provides five years of marketing exclusivity if the product is a new chemical entity not previously approved.

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

16

Table of Contents

request for more information is rendered in 60 days. NDAs 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 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.

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 54 employees as of December 31, 2011, including 41 in product development and 13 in management or administrative positions. We also engage independent contractors from time to time on an as needed, project by project, basis. During 2011, we were receiving services from several independent contractors, most of whom were assisting us with our LibiGel Phase III clinical development program. In January 2012, in order to reduce our operating expenses, we terminated several of our independent contractor arrangements and reduced our total employee headcount. As of March 13, 2012, we had 48 employees, including 36 in product development and 12 in management or administrative positions. None of our employees is covered by a collective bargaining agreement.

Our success is dependent upon the efforts of a relatively small management team and staff. We have little or no redundancy of personnel in key development areas, including clinical, regulatory,

Table of Contents

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

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, 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 of these words, other words and terms of similar meaning and the use of future dates. These forward-looking statements may be contained in this section, the notes to 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:

- the status of our LibiGel Phase III clinical development program and the timing of our decision whether to continue our LibiGel Phase III safety study;

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

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

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

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

- 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

Table of Contents

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 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 (SEC).

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. 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.

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.

Table of Contents

ITEM 1A. RISK FACTORS

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

Risks Related to Our Financial Condition and Future Capital Requirements

Our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that in light of such data, we may terminate our LibiGel Phase III clinical development program, which could impact negatively our ability to obtain future funding and enter into strategic transactions.

Our lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. Initial analysis of the efficacy data from our two pivotal LibiGel Phase III efficacy trials shows that the trials did not meet the co-primary or secondary endpoints. Although the results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel s results were not shown to be statistically different from placebo. The LibiGel Phase III safety study continues and will continue during further analysis of the LibiGel efficacy data and until a final strategic decision has been made. It is our objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study. It is possible that we may terminate our LibiGel Phase III clinical development program, including the Phase III safety study, which, among other things, could harm our ability to obtain future funding and enter into strategic transactions. Even if we decide to continue the LibiGel Phase III safety study, we may have difficulty obtaining future funding and entering into strategic transactions.

We have not generated significant revenues and do not expect to in the near future. We have a history of operating losses, expect continuing losses and may never become profitable.

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. 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, or acquire additional new products that generate or have the potential to generate revenues. Because of the numerous risks and uncertainties associated with our and our strategic partners product development programs and our ability to acquire additional new products, we are unable to predict when we will be able to generate significant revenue or become profitable, if at all. We incurred a net loss of $51.6 million for the year ended December 31, 2011 and as of December 31, 2011, our accumulated deficit was $217.2 million. We expect to continue to incur substantial and continuing losses for the foreseeable future. These losses may increase as we explore strategic alternatives and if we enter into a strategic transaction. Even if our approved products, products in development or any additional new products we may acquire or in-license 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 technologies in order to achieve or sustain future profitability.

Table of Contents

Because we have no source of significant recurring revenue, we must depend on financing or partnering to sustain our operations. We may need 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, if we decide to continue our LibiGel Phase III safety study or if we in-license additional new products that require further development, we may need additional capital. 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 if we decide to continue our LibiGel Phase III safety study or if we in-license additional new products that require further development;

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

- our ability to obtain value from our current products and technologies and our ability to out-license our products and technologies to third parties for development and commercialization and the terms of such out-licensings;

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

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

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

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

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

- the outstanding principal amount of our 3.125% convertible senior notes due May 1, 2013 (convertible senior notes) that are scheduled to mature and become due and payable on May 1, 2013 and our ability to avoid a fundamental change or an event of default under the

indenture governing such notes, which may cause such notes to become due and payable prior to their maturity date on May 1, 2013;

- our operating expenses;

- the resolution of pending litigation; 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 evaluate various strategic alternatives available with respect to our products and our company.

Our future capital requirements and projected expenditures are based upon numerous assumptions and subject to many uncertainties, and actual requirements and expenditures may differ significantly from

Table of Contents

our projections. To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. We may need to raise additional capital to fund our operations. As of December 31, 2011, we had $57.2 million of cash and cash equivalents. We do not have any existing credit facilities under which we may borrow funds. 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 safety study if we decide to continue such study. As of March 12, 2012, we had $11.8 million in principal amount of convertible senior notes outstanding that mature on May 1, 2013. Assuming we continue our LibiGel Phase III safety study, we expect our cash and cash equivalents as of December 31, 2011 to meet our liquidity requirements through mid 2013. If we terminate our LibiGel Phase III safety study and assuming we do so during the second quarter of 2012 and assuming no other corporate product development and activities, we expect our cash and cash equivalents to meet our liquidity requirements through late 2014. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier in order to create a cash cushion and take advantage of favorable financing conditions. The announcement of the results of our LibiGel Phase III efficacy trials has significantly depressed the trading price of our common stock and if we terminate our LibiGel Phase III safety study, the trading price of our common stock could be depressed further and harm our ability to raise additional capital. 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 investors are not confident in the future value of our company, we lose the NASDAQ listing of our common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to cut our operating costs further or we may be forced to explore other strategic alternatives, such as selling or merging our company or winding down our operations and liquidating our company. In such case, our stockholders could lose some or all of their investment.

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. In addition, the issuance of any equity securities could be at a discount to the market pice.

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

As an alternative to raising additional financing by issuing additional equity or debt securities, we may choose to license one or more of our products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under 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

As a result of our merger with Cell Genesys, we have substantial indebtedness, in the form of convertible senior notes, which notes we may not be able to pay when they become due and payable on May 1, 2013, or earlier if we experience a fundamental change or an event of default under the indenture governing such notes.

As a result of our merger with Cell Genesys, we assumed $22.0 million aggregate principal amount of convertible senior notes, $11.8 million of which remain outstanding as of March 12, 2012. The annual interest payment on these notes is approximately $0.4 million. At maturity, on May 1, 2013, the entire then remaining aggregate outstanding principal amount of our convertible senior notes will become due and payable. In addition, upon the occurrence of a fundamental change , holders of our convertible senior notes may require us to purchase their notes prior to the May 1, 2013 maturity date. A fundamental change includes a significant change in our ownership; the first day the majority of our board of directors does not consist of continuing directors; the consummation of certain recapitalizations, reclassifications, or changes of common stock, share exchanges or consolidations or mergers; or the termination of trading of our common stock (which will be deemed to have occurred if our common stock is neither listed for trading on a United States national securities exchange nor any United States system of automated dissemination of quotations of securities prices or traded in over-the-counter securities markets). Additionally, the aggregate principal amount of the outstanding convertible senior notes will become due and payable upon an uncured or unwaived event of default. We do not have any significant source of revenues; and thus, although we intend to seek additional financing to support our operations and pay the aggregate outstanding principal amount of our convertible senior notes, it is possible that we may not have sufficient funds to pay the aggregate principal amount of our then outstanding convertible senior notes when they mature on May 1, 2013, or become due and payable earlier if we were to experience a fundamental change or an event of default under the indenture governing such notes.

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

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

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

In February 2012, we entered into privately-negotiated securities exchange agreements with one of the holders of our convertible senior notes pursuant to which we issued an aggregate of approximately 11.2 million shares of our common stock to the note holder in exchange for cancellation of an aggregate of $9.0 million principal amount of our convertible senior notes, including accrued and unpaid interest.

Table of Contents

As a result of such exchange, an aggregate of $11.8 million principal amount of the convertible senior notes remained outstanding as of March 12, 2012. From time to time, we may again purchase, exchange or restructure our outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of our company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, our available cash and cash equivalents, our liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of our stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of our existing stockholders and/or decrease our cash balance. A significant decrease in our cash balance may impair our ability to execute strategic alternatives or leave us without sufficient cash remaining for operations.

We are subject to pending purported securities class action litigation, which could divert management s attention, harm our business and/or reputation and result in significant liabilities, as well as harm our ability to raise additional financing.

As described in more detail under Item 3. Legal Proceedings of this report, we, along with our President and Chief Executive Officer, are defendants in purported securities class action litigation, alleging that certain of our disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of our securities resulting in violations of Section 10(b), Rule 10b-5 and Section 20(a) of the Securities Exchange Act of 1934, as amended. The plaintiffs seek to represent a class of persons who purchased our securities during the period, depending on the complaint, between as early as February 8, 2010 to December 15, 2011 and seek unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. While we believe the actions are without merit and intend to defend the actions vigorously, additional lawsuits may be filed and, at this time because the litigation is in its early stages, we are unable to predict the outcome of the lawsuits, the possible loss or range of loss, if any, associated with the resolution of the lawsuits or any potential effect they may have on our company or our operations. Such litigation, however, could divert management s attention, harm our business and/or reputation and result in significant liabilities, as well as harm our ability to raise additional financing.

If we fail to continue to meet all applicable NASDAQ Global Market requirements and The NASDAQ Stock Market determines to delist our common stock, the delisting could affect adversely the market liquidity of our common stock, impair the value of your shares and harm our ability to raise additional financing.

Our common stock currently is listed on The NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On January 31, 2012, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market under NASDAQ Listing Rule 5450(a)(1). The notification letter stated that pursuant to NASDAQ Listing Rule 5810(c)(3)(A), we will be afforded 180 calendar days, or until July 30, 2012, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance by July 30, 2012, we may transfer our common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if we meet the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, we also would need to provide

Table of Contents

NASDAQ written notice of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not indicate our intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for us to cure the deficiency, we will not be eligible for the second 180-day grace period and our common stock will be subject to delisting, which delisting determination we may appeal to a hearings panel at that time. The closing bid price of our common stock on The NASDAQ Global Market was $0.74 on March 12, 2012.

While we intend to engage in efforts to regain compliance, and thus maintain our listing on The NASDAQ Global Market, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above or keep our listing on The NASDAQ Global Market or transfer our listing to The NASDAQ Capital Market. Stocks trading on The NASDAQ Capital Market rather than The NASDAQ Global Market tend to be more volatile and less liquid as trading volumes are generally significantly lower on The NASDAQ Capital Market than The NASDAQ Global Market. Furthermore, if we fail to meet all applicable NASDAQ Stock Market requirements and NASDAQ determines to delist our common stock, the delisting could decrease substantially trading in our common stock, affect adversely the market liquidity of our common stock, decrease the trading price of our common stock, increase the volatility of our stock price, decrease analyst coverage of our common stock, decrease investor demand and information available concerning trading prices and volume of our common stock, make it more difficult for investors to buy or sell shares of our common stock and harm our ability to obtain additional financing on acceptable terms, if at all.

In addition, if our common stock were to be delisted from The NASDAQ Stock Market, and our trading price remained below $5.00 per share, trading in our common stock also might become subject to the requirements of certain rules promulgated under the Securities Exchange Act of 1934, as amended, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a penny stock (generally, any equity security not listed on a national securities exchange that has a market price of less than $5.00 per share, subject to certain exceptions). Many brokerage firms are reluctant to recommend low-priced stocks to their clients. Moreover, various regulations and policies restrict the ability of stockholders to borrow against or margin low-priced stocks, and declines in the stock price below certain levels may trigger unexpected margin calls. Additionally, because brokers commissions on low-priced stocks generally represent a higher percentage of the stock price than commissions on higher priced stocks, the current price of our common stock can result in an individual stockholder paying transaction costs that represent a higher percentage of total share value than would be the case if the price of our common stock were higher. This factor also may limit the willingness of institutions to purchase our common stock. Finally, the additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from facilitating trades in our common stock, which could severely limit the market liquidity of the stock and the ability of investors to trade our common stock.

If we decide to terminate our LibiGel Phase III clinical development program, we may incur significant costs, which could affect adversely our operating results and financial condition.

If we decide to terminate our LibiGel Phase III clinical development program, including the Phase III safety study, we may terminate the employment of several of our employees, whose duties entail the coordination of our safety study, in order to cut costs and decrease our operating expenses. We also may decide to take other actions to reduce our operating expenses. Such actions likely would affect adversely our operating results at least in the near term and could result in significant cash outlays. In connection with such cost savings measures if we decide to undertake them, we may experience:

- higher costs than we anticipated;

Table of Contents

- difficulties in completing our cost savings measures within the budgeted time;

- diversion of our management s time and attention from other business concerns; and

- lower than expected future benefits due to unforeseen or changing business conditions.

If we experience any or all of the foregoing, our operations and financial results could be affected adversely.

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

Acquisitions often involve known and unknown risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. In October 2008, in view of the termination of both its VITAL-1 and VITAL-2 Phase III clinical trials, Cell Genesys discontinued further development of its GVAX 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, and no new liabilities have arisen to date it is possible that undisclosed, contingent or other liabilities or problems may arise, which could have an adverse effect on our business, operating results and financial condition.

Risks Related to Our Business

Our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that in light of such data, we may decide to terminate our LibiGel Phase III clinical development program, which could harm our business and further disappoint our stockholders and cause our stock price to decrease.

Our lead near term product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved product. Initial analysis of the efficacy data from our two pivotal LibiGel Phase III efficacy trials shows that the trials did not meet the co-primary or secondary endpoints. The LibiGel Phase III safety study continues and will continue until a final strategic decision has been made. It is our objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study. If we decide to terminate our LibiGel Phase III clinical development program, including the LibiGel Phase III safety study, our decision could harm our business, further disappoint our stockholders and cause our stock price to decline.

If we choose to acquire or invest in new businesses, products or technologies, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

At this time we are seeking to acquire or invest in other businesses, products or technologies. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;

Table of Contents

- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of additional debt;

- the assumption of significant liabilities;

- increased operating costs and losses;

- financing obtained on unfavorable terms;

- large one-time expenses; and

- the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges.

Any of these factors could materially harm our business, operating results, financial condition and stock price.

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

We may explore the possibility of reallocating our resources towards other products and technologies in our current product portfolio or any additional new products and technologies that we may acquire or in-license. We cannot guarantee that any such allocation would result in the identification and successful development of one or more approved and commercially viable products. The development of products and technologies is subject to a number of risks and uncertainties, including but not limited to:

Table of Contents

- the time, costs and uncertainty associated with the clinical testing required to demonstrate the safety and effectiveness of our products and obtain regulatory approvals;

- the ability to raise sufficient funds to fund the research and development of our products;

- the ability to find third party strategic partners to assist or share in the costs of product development, and potential dependence on such strategic partners, to the extent we rely on them for future sales, marketing or distribution;

- the ability to protect the intellectual property rights associated with our products;

- litigation;

- competition;

- ability to comply with ongoing regulatory requirements;

- government restrictions on the pricing and profitability of products in the United States and elsewhere; and

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

Although our male testosterone gel recently was approved by the FDA, we are uncertain as to when Teva will begin to market and sell our male testosterone gel and thus when we would begin to receive royalties from such sales in light of Teva s settlement agreement with a subsidiary of Abbott Laboratories.

Our male testosterone gel initially was developed by us, and then licensed by us to Teva for late stage clinical development. Teva submitted a New Drug Application, which NDA was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. In its NDA filing, Teva asserted that the male testosterone gel subject to the NDA does not infringe any patent listed in the FDA Orange Book related to Abbott Laboratories testosterone gel for men. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011;

however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva.

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

Several of our products are in the human clinical development stages and will require further development, preclinical and clinical testing and investment prior to obtaining required regulatory approvals and commercialization in the United States and abroad. Other than Elestrin and our male testosterone gel, none of our products has been approved by the FDA or other regulatory authorities, and accordingly none of our products have been introduced commercially and most are not expected to be for several years and likely more, if at all. Some of our products are not in active development. We currently

Table of Contents

are evaluating whether to continue our LibiGel clinical development program. 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 marketed successfully 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 very lengthy and expensive, and approval never is certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development eventually are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, 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 or other entities, 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. Depending on the stage of development, may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

Table of Contents

After we have conducted pre-clinical studies in animals, if required, we must demonstrate that our products are safe and effective for use in the target human population 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. As an example, our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary endpoints of increase in satisfying sexual events and increase in desire and the secondary endpoint of decrease in distress even though treatment with LibiGel in our Phase II clinical trial significantly increased satisfying sexual events and showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline and a significant increase versus placebo. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent us from submitting for regulatory approval of our products. With respect to LibiGel, we still are deciding whether to continue to pursue our LibiGel clinical development program.

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;
- new or additional trials or studies that are designed differently in order to increase the chances of demonstrating efficacy or safety;
- adverse medical events or side effects in treated subjects;
- lack of effectiveness of the product being tested; and
- lack of funding.

Delays in 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.

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

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

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

Table of Contents

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

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

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

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 the price of our common stock 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 submission of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in 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 affected adversely and materially and the price of our common stock could decline. As an example, prior to our receipt of the results from our two pivotal LibiGel Phase III efficacy trials in December 2011, our objective with respect to LibiGel was to submit an NDA in 2012. This is no longer a realistic objective of ours in light of the fact that our two pivotal LibiGel Phase III efficacy trials did not meet the co-primary and secondary endpoints, and it is possible that in light of such data, we may decide to terminate our LibiGel Phase III clinical development program entirely.

We also disclose from time to time projected financial information, including our cash position and anticipated cash 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 our products are smaller than we anticipate, then our future revenues and business may be affected adversely.

From time to time, we disclose estimated market opportunity data for our products and products in development. Although we believe we have a reasonable basis for our market opportunity estimates, our estimates may prove to be incorrect. If the market opportunities for our products are smaller than we

Table of Contents

anticipate, our anticipated revenues from the sales or licensure of such products will be lower than we anticipate.

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

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

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

If clinical studies for our products are terminated, 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 or prevent 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, suspend or terminate those studies or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or cause us to suspend 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:

Table of Contents

- 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 or recommend stopping our clinical studies prior to completion. Our clinical studies for our products in development may not begin as planned, may need to be amended, suspended or terminated and may not be completed on schedule, if at all. This is particularly true if we no longer believe we can obtain regulatory approval for a particular product or if we no longer have the financial resources to dedicate to a clinical development program for a particular product.

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 required contractually 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.

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

Table of Contents

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 help develop and commercialize our products in development. 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 obtain required approvals for and 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 a strategic relationship with Jazz Pharmaceuticals with respect to Elestrin, with Teva with respect to our male testosterone gel, with Pantarhei Science with respect to The Pill Plus and with several third parties with respect to our GVAX cancer vaccines. We currently do not have a strategic partner for LibiGel, although we may not need a strategic partner for LibiGel if we decide to terminate the LibiGel Phase III clinical development program.

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 if we decide to continue the LibiGel Phase III clinical development program, and any additional

Table of Contents

new products we may acquire or in-license. We face significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic relationships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If we are unable to negotiate additional strategic relationships for our products, 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 would then 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 and any additional new products we may acquire or in-license 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, 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.

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

Table of Contents

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 harm 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 strategic relationships with Jazz Pharmaceuticals with respect to Elestrin, with Teva with respect to our male testosterone gel and with Pantarhei Science with respect to The Pill Plus and several third parties with respect to our GVAX cancer vaccines.

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 affect adversely 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 delay research and development programs or commercialization of a partnered product;

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

Table of Contents

As an example, our male testosterone gel was developed initially by us and then licensed to Teva for late stage clinical development. Teva submitted an NDA for our male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva.

Although we maintain the right to receive sales-based milestones of up to $140 million, our ability to receive these milestones is dependent upon Jazz Pharmaceuticals ability to market and sell Elestrin, and based on Elestrin sales during 2011, we believe it is unlikely that we will receive any sales-based milestone payments from Jazz Pharmaceuticals in the foreseeable future, or at all.

Jazz Pharmaceuticals, Inc. (which acquired Azur) 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 sales of Elestrin. We continue to recognize certain royalty revenue from sales of Elestrin; however, such revenue is offset by our corresponding obligation to pay royalties to Antares, from whom we licensed the technology underlying our Elestrin product. We maintain the right to receive up to $140 million in sales-based milestone payments from Jazz Pharmaceuticals if Elestrin reaches certain predefined sales per calendar year. We cannot assure you that Jazz Pharmaceuticals will be successful in marketing Elestrin, Elestrin will be accepted widely in the marketplace or that Jazz Pharmaceuticals will remain focused on the commercialization of Elestrin, especially if Jazz Pharmaceuticals does not experience significant Elestrin sales. Based on current sales of Elestrin, we believe it is unlikely that we will receive any sales-based milestone payments from Jazz Pharmaceuticals in the foreseeable future, or at all.

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

The commercial success of our products in development, if they receive the required FDA or other regulatory approvals, and the commercial success of our male testosterone gel, which recently received FDA approval, are dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products, if approved for commercial sale with respect to our products in development, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials with respect to our products in development;
- the existence, prevalence and severity of any side effects;
- the availability of competitive or alternative treatments and potential or perceived advantages or disadvantages compared to competitive or alternative treatments;

- the timing of market entry relative to competitive treatments;

- relative convenience, product dependability and ease of administration;

Table of Contents

- 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 Jazz Pharmaceuticals, the U.S. development and marketing rights to our male testosterone gel to Teva. 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, obtain required regulatory approvals 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 affect adversely the commercial success of our products.

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

- private health insurers;

- health maintenance organizations;

- pharmacy benefit management companies;

- government health administration authorities; and

- other healthcare-related organizations.

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

Table of Contents

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

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

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

We have no manufacturing experience or manufacturing capabilities for the production of our products for our clinical studies or, if approved, 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 or compromised, and with respect to our approved products, our future revenue from royalties and milestone payments could be affected adversely.

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 affected adversely 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 are dependent upon key employees and the limited use of independent contractors, the loss of some of which could affect adversely our operations.

Our success is dependent upon the efforts of a relatively small management team and staff. We also engage independent contractors from time to time on an as needed, project by project, basis. In January 2012, in order to reduce our operating expenses, we terminated several of our independent contractor arrangements and reduced our total employee headcount. If we decide to terminate our LibiGel clinical development program, including the LibiGel Phase safety study, we likely will terminate additional independent contractor arrangements and further reduce our total employee headcount. Such reductions in force, combined with our future business prospects and financial condition, put us at risk of

losing key personnel who we will need going forward to implement our business strategies. We have no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. We have employment arrangements in place with our executive and other officers, but none of these executive and other officers is bound legally to remain employed with us for any specific term. We do not have key man life insurance policies covering our executive and other officers or any of our other

Table of Contents

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

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.

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

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

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to assess the effectiveness of our internal control over financial reporting and to provide a report by our registered independent public accounting firm addressing the effectiveness of our internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If we are unable to assert that our internal control over financial reporting is effective (or if our registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or they issue

41

Table of Contents

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 stock price.

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

We are subject to changing rules and regulations of federal and state governments as well as the stock exchange on which our common stock is listed. These entities, including the SEC and The NASDAQ Stock Market, continue to issue new requirements and regulations in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act, 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 and NASDAQ 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.

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

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

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 or our strategic partners introduce commercially may not be successful.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than 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, operating results and financial position, and the market value of our common stock could decline.

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

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

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 affect adversely our ability to enter into strategic arrangements for the development and commercialization of our products, and as a result may harm our business.

Table of Contents

Risks Related to Our Intellectual Property

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

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

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

We have licensed some of our products to third parties, including Jazz Pharmaceuticals, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and Valeant Pharmaceuticals. All of these parties, except for Jazz Pharmaceuticals, 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. Any breach of our agreements 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. As an example, our male testosterone gel was initially developed by us, and then licensed to Teva for late stage clinical development and commercialization. Teva submitted an NDA for our male testosterone gel that was approved by the FDA in February 2012. Subsequent to Teva s NDA submission, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. The Teva/Abbott Laboratories patent infringement litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva.

Table of Contents

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

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

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

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

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

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

- Litigation also may be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may affect adversely 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

Table of Contents

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 and the new U.S. patent covering the method of use of LibiGel for treating FSD and HSDD will expire in December 2028. 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, if we decide to pursue regulatory approval for LibiGel. 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 affect adversely our operating results and financial condition.

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

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause product development delays;

- require us to develop non-infringing technology; or

Table of Contents

- require us to enter into royalty or licensing agreements.

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

Risks Related to Our Common Stock

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

The price of our common stock has fluctuated in the past and it is likely that the price of our common stock will continue to fluctuate in the future. During 2011, the sale price of our common stock ranged from $0.38 per share to $4.02 per share. 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 addition, as our convertible senior notes are convertible into shares of our common stock, volatility or depressed prices of our common stock could have a similar effect on the trading price of the notes. Interest rate fluctuations also can affect the price of our convertible senior notes. In particular, the market price of our common stock and our convertible senior notes may fluctuate significantly due to a variety of factors, including:

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

- 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 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;

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

Table of Contents

- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- our cash and cash equivalents and our need and ability to obtain additional financing;
- equity sales by us to fund our operations or restructure our outstanding convertible senior notes;
- changes in laws or regulations applicable to our products;
- the resolution of pending litigation;
- 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 in subsequent 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 currently are subject to such litigation as described elsewhere in this report. 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.

Future exercises by holders of warrants and options and conversions by holders of our convertible senior notes and other issuances of additional securities could substantially dilute our common stock.

As of March 1, 2012, we had warrants to purchase an aggregate of 22.8 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 7.1 million shares of our common stock outstanding that are exercisable at prices ranging from $0.684 per share to $36.82 per share. In addition, as of March 12, 2012, we had an aggregate of $11.8 million in principal amount of convertible senior notes that are convertible into an aggregate of 3.2 million 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

Table of Contents

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 either registered or otherwise available for immediate resale, and thus once issued, will be available for immediate resale in the public market. In addition, we have the ability to offer and sell common stock, preferred stock and warrants under currently effective universal shelf registration statements. Any issuance of additional equity securities 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.

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.

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

None.

ITEM 2. PROPERTIES

Our principal executive offices are located in a leased facility in Lincolnshire, Illinois, where we lease approximately 20,000 square feet of office space for approximately $20,000 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

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption *Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes* naming BioSante and our President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that

Table of Contents

certain of our disclosures relating to the efficacy of LibiGel and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of our securities resulting in violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act. A substantially similar complaint was filed in the same court on February 21, 2012. The plaintiffs seek to represent a class of persons who purchased our securities between February 8, 2010 and December 15, 2011, and seek unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. We believe the actions are without merit and intends to defend the actions vigorously. Additional lawsuits may be filed and, at this time, because the litigation is in its early stages, we are unable to predict the outcome of these lawsuits, the possible loss or range of loss, if any, associated with their resolution or any potential effect they may have on our company or our operations. Failure by us to obtain a favorable resolution of the lawsuits, however, could have a material effect on our business, operating results and financial condition.

We presently are not involved in any other 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. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and the offices held, as of March 13, 2012, are as follows:

Name	Age	Title
Stephen M. Simes	60	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	51	Senior Vice President of Finance, Chief Financial Officer and Secretary
Michael C. Snabes, M.D., Ph.D.	63	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 s career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.). Mr. Simes currently serves as our designee on the

Table of Contents

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 1998. Before joining our company, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of Abbott Laboratories) from 1995 to 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc. (currently Savient Pharmaceuticals, Inc.), Applied NeuroSolutions, Inc. (formerly Molecular Geriatrics Corporation) and Xtramedics, Inc.

Michael C. Snabes, M.D., Ph.D., has served as 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 2011 and 2010.

2011	High	Low
First Quarter	$ 2.54	$ 1.62
Second Quarter	$ 3.20	$ 1.93
Third Quarter	$ 4.02	$ 2.02
Fourth Quarter	$ 2.76	$ 0.38

2010	High	Low
First Quarter	$ 2.08	$ 1.43
Second Quarter	$ 2.50	$ 1.75
Third Quarter	$ 1.76	$ 1.29
Fourth Quarter	$ 2.17	$ 1.40

Number of Record Holders; Dividends

As of March 12, 2012, there were 767 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

During the fourth quarter ended December 31, 2011, we did not issue or sell any equity securities of ours without registration under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2011. 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

Stock Performance Graph

The following graph compares the annual cumulative total stockholder return on our common stock from December 31, 2006 until December 31, 2011, with the annual cumulative total return over the same period of The NASDAQ Stock Market (U.S.) Index and Russell 3000 Index.

The comparison assumes the investment of $100 in each of our common stock, The NASDAQ Stock Market (U.S.) Index and Russell 3000 Index on December 31, 2006, and the reinvestment of all dividends.

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

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial information has been derived from 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,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 435	$ 2,474	$ 1,258	$ 3,781	$ 493
Expenses					
Research and development	44,182	39,706	13,681	15,790	4,751
General and administration	6,982	5,940	5,374	5,125	4,331
Acquired in-process research and development			9,000		
Excess consideration paid over fair value			20,192		
Licensing expense	50	269	300	836	
Depreciation and amortization	148	168	137	43	90
Total expenses	51,362	46,083	48,684	21,794	9,172
Other (expense) income					
Convertible note fair value adjustment	(23)	(1,871)	33		
Other expense Investment impairment charge		(286)			
Other interest (expense) income	(673)	(675)	(135)	588	1,095
Other income	15	245			
Net loss	$ (51,608)	$ (46,196)	$ (47,528)	$ (17,425)	$ (7,584)
Basic and diluted net loss per common share	$ (0.52)	$ (0.70)	$ (1.40)	$ (0.64)	$ (0.30)
Weighted average number of common shares and common equivalent shares outstanding	98,386	65,912	33,952	27,307	25,486

	As of December 31,				
	2011	2010	2009	2008	2007
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 57,225	$ 38,155	$ 29,858	$ 14,787	$ 30,655
Total assets	62,380	44,767	36,437	17,679	31,241
Total current liabilities (includes short-term convertible senior notes in 2010)	7,228	8,183	3,930	3,853	1,516
Convertible senior notes, total long-term	17,337	17,436	16,676		
Stockholders equity	37,815	19,147	15,830	13,826	29,725

54

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 2011 Financial Results and Outlook for 2012**. This section provides a brief summary of our financial results and financial condition for 2011 and our outlook for 2012.

- **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.

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

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

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

- GVAX cancer vaccines a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers.

Table of Contents

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

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

Our corporate strategy always has included product development of high value medically-needed pharmaceutical products. In light of the recently announced top-line results from our two pivotal LibiGel Phase III efficacy trials as described below, we are assessing our corporate strategy. We are determining LibiGel s path forward and potential alternative strategies to utilize the continuing LibiGel Phase III cardiovascular events and breast cancer safety study. We also have expanded our efforts to explore new product development projects through in-licensing and mergers and acquisitions. In addition, a full review of our GVAX cancer vaccine portfolio is underway.

Our lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. We continue to analyze the data from the two pivotal LibiGel Phase III efficacy trials first reported on December 14, 2011. Initial analysis of the efficacy data from these trials shows that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD. However, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel s results were not shown to be statistically different from placebo. The LibiGel Phase III safety study, which completed enrollment in June 2011, continues and will continue during further analysis of the LibiGel efficacy data and until a final strategic decision has been made. It is our objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study. In the meantime, we have instituted certain cost savings measures to minimize the continuing cost of the safety study and our operating expenses overall, including the termination of several of our independent contractor arrangements and a reduction in our total employee headcount. In February 2012, we announced that based upon the eighth unblinded review of 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. At the time of such announcement, 3,656 subjects were enrolled in the safety study resulting in over 5,800 subject-years of exposure.

Our male testosterone gel is our second FDA approved product. This product was initially developed by BioSante, and then licensed by us to Teva for late stage clinical development. Teva submitted a new drug application (NDA) to the FDA in the beginning of 2011, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, a subsidiary of Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement. This litigation was settled in December 2011; however, the terms of the settlement agreement are confidential and have not been publicly disclosed. To the extent Teva has agreed with the subsidiary of Abbott Laboratories to delay the commercial launch of our male testosterone gel, the settlement agreement could delay our receipt of royalties based on sales of our male testosterone gel by Teva.

Our GVAX cancer vaccines, which are designed to stimulate a patient s immune system to fight effectively the patient s own cancer, are in development for the treatment of several different types of cancer including melanoma, leukemia, pancreatic, breast and prostate cancer. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. Currently, there are 17 Phase I and Phase II clinical studies

Table of Contents

involving our GVAX cancer vaccines ongoing, primarily being conducted at Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in Baltimore, Maryland. The studies are being funded by various sources, including certain foundations and our licensees. Our objective with respect to our GVAX cancer vaccines is to help facilitate further studies and commercialization in order to bring important cancer therapies to patients in need and to maximize the value of our GVAX cancer vaccine portfolio to our stockholders. This objective includes seeking additional licensees to fund and develop the cancer vaccines.

Elestrin is our first FDA approved product. Jazz Pharmaceuticals, Inc. (which recently acquired Azur Pharma International II Limited (Azur), our prior 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 sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Jazz Pharmaceuticals 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, but not our male testosterone gel, 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. Our male testosterone 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.

One of our strategic goals has been, and continues to be, 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. In particular, as mentioned above, in light of recently announced results from our two pivotal LibiGel Phase III efficacy trials, we have expanded our exploration of new product development projects through in-licensing and mergers and acquisitions. 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 the products and technologies of others or a merger or sale of our company.

Summary of 2011 Financial Results and Outlook for 2012

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. Our business operations to date have consisted primarily 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. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our 2009 merger with Cell Genesys, Inc. (Cell Genesys) to fund our ongoing business operations and short-term liquidity needs.

Table of Contents

As of December 31, 2011, we had $57.2 million of cash and cash equivalents. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III cardiovascular and breast cancer safety study if we decide to continue such study. As of March 12, 2012, we had $11.8 million in principal amount of convertible senior notes outstanding that mature on May 1, 2013. In February 2012, we issued an aggregate of approximately 11.2 million shares of our common stock to one of the holders of our convertible senior notes in exchange for cancellation of an aggregate of $9.0 million principal amount of such notes, including accrued and unpaid interest. Assuming we continue our LibiGel Phase III cardiovascular and breast cancer safety study, we expect our cash and cash equivalents as of December 31, 2011 to meet our liquidity requirements through mid 2013. If we terminate our LibiGel Phase III cardiovascular and breast cancer safety study and assuming we do so during the second quarter of 2012 and assuming no other corporate product development and activities, we expect our cash and cash equivalents to meet our liquidity requirements through late 2014. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

We incurred expenses of $44.2 million on research and development activities during 2011, which is an 11.3 percent increase compared to 2010, primarily as a result of the conduct of the three LibiGel Phase III clinical studies. Our research and development expenses for 2012 will depend significantly upon whether we continue our LibiGel Phase III safety study and if we in-license additional products and technologies requiring additional development. If we continue our LibiGel Phase III safety study and assuming we do not in-license additional products and technologies requiring additional development, we expect to spend approximately $1.8 million per month on research and development activities during 2012. If we discontinue our LibiGel Phase III safety study and assuming we do not in-license additional products and technologies requiring additional development, we expect to spend a minimal amount on research and development activities thereafter during the remainder of 2012.

Our general and administrative expenses for 2011 increased 17.5 percent compared to 2010 due primarily to an increase in personnel-related costs, professional fees and other administrative expenses. Our general and administrative expenses for 2012 will depend upon whether we continue our LibiGel Phase III safety study and if we in-license additional products and technologies requiring additional development. Our general and administrative expenses may fluctuate depending upon the amount of non-cash, stock-based compensation expense and the amount of legal, public and investor relations, accounting, corporate governance and other general and administrative fees and expenses incurred.

We recognized a net loss for 2011 of $51.6 million compared to a net loss of $46.2 million for 2010. This increase was due primarily to the increased LibiGel clinical development expenses discussed above. We recognized a net loss per share for 2011 of $0.52 compared to a net loss per share of $0.70 for 2010. The decrease in net loss per share was the result of the significantly higher weighted average number of shares outstanding, partially offset by the higher net loss described above, in each case in 2011 as compared to 2010. We expect to continue to incur substantial and continuing losses for the foreseeable future.

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

58

Table of Contents

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

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 at that time 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.

We assumed $22.0 million in aggregate principal amount of convertible senior notes in connection with the Cell Genesys acquisition, including $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011, which were repaid prior to the November 1, 2011 maturity date, and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013, which were outstanding as of December 31, 2011. As of March 12, 2012, $11.8 million in aggregate principal amount of convertible notes remained outstanding following the exchange transactions previously discussed.

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 senior notes recognized in our statements of operations immediately. As a result of this election, we periodically must estimate the fair value of our convertible senior 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 senior notes. The most sensitive of these assumptions is the discount rate used in the fair value estimate, which was 18.5% at December 31, 2011, and is based on the median yield to maturity of Ca and Caa3 rated debt instruments as of December 31, 2011. A one percentage point increase or decrease in the discount rate would cause the recorded value of the convertible senior notes to decrease or increase by approximately $191,000 and $194,000, respectively.

Table of Contents

Results of Operations

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

	Year Ended December 31,		
	2011	2010	2009
Revenue	$ 435,160	$ 2,474,237	$ 1,258,054
Expenses			
Research and development	44,182,260	39,705,502	13,680,573
General and administrative	6,981,490	5,940,360	5,373,945
Acquired in-process research and development			9,000,000
Excess consideration paid over fair value			20,192,194
Licensing expense	50,000	268,750	299,616
Total expenses	51,361,990	46,082,598	48,683,608
Other (expense) income Convertible note fair value adjustment	(23,427)	(1,870,916)	33,163
Other expense Investment impairment charge		(286,000)	
Other expense Interest expense	(681,573)	(688,083)	147,025
Other income	15,000	244,479	
Other income Interest income	8,326	12,665	11,648
Net loss	$ (51,608,504)	$ (46,196,216)	$ (47,527,768)
Net loss per common share (basic and diluted)	$ (0.52)	$ (0.70)	$ (1.40)
Weighted average number of common shares and common equivalent shares outstanding	98,385,709	65,911,750	33,951,652

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

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

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

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

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

Interest expense for 2011 was $681,573 compared to $688,083 for 2010. We expect interest expense to decrease in 2012 compared to 2011 as a result of the repayment of $1.2 million in aggregate principal amount of our 3.125% convertible senior notes due November 1, 2011 and the cancellation of

Table of Contents

$9.0 million in aggregate principal amount of our 3.125% convertible senior notes previously due May 1, 2013, which were exchanged for shares of common stock as previously discussed.

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

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 Jazz Pharmaceuticals 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 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 Jazz Pharmaceuticals 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.

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 Jazz Pharmaceuticals license amendment compared to licensing expense of $299,616 in 2009 as a result of expenses associated with the Jazz Pharmaceuticals 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 third-party investment in Ceregene in 2010. 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.

Table of Contents

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.

Liquidity and Capital Resources

The following table highlights several items from our balance sheets:

Balance Sheet Data	December 31, 2011	December 31, 2010
Cash and cash equivalents	$ 57,225,234	$ 38,155,251
Total current assets	58,026,381	40,625,130
Investments	3,405,807	3,405,807
Total assets	62,379,755	44,766,650
Total current liabilities	7,227,703	8,183,327
Convertible senior notes due November 1, 2011	0	1,111,132
Convertible senior notes due May 1, 2013	17,336,760	17,436,201
Total liabilities	24,564,463	25,619,528
Total stockholders equity	37,815,292	19,147,122

Liquidity

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. Our business operations to date have consisted primarily 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.

Since our inception, we have incurred significant operating losses resulting in an accumulated deficit of $217.2 million as of December 31, 2011. To date, we have used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from our 2009 merger with Cell Genesys to fund our ongoing business operations and short-term liquidity needs.

During 2011, we raised approximately $68.9 million in net proceeds, after deducting placement agent fees, underwriters discounts, commissions and other offering expenses, through the sale of our common stock in an underwritten public offering and our common stock and warrants to purchase our common stock in a registered direct offering. In August 2011, we completed an underwritten public offering issuing 16.0 million shares of our common stock, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses. In March 2011, we completed an offering of an aggregate of approximately 12.2 million shares of our common stock and warrants to purchase an aggregate of approximately 4.3 million shares of our common stock, resulting in net proceeds of $23.9 million, after deducting placement agent fees and other offering expenses. We expect to use the net proceeds from these offerings for general corporate purposes and for working capital.

As of December 31, 2011, we had $57.2 million of cash and cash equivalents. Absent the receipt of any additional licensing income or financing, we expect our cash and cash equivalents balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel Phase III safety study if we decide to continue such study. As of March 12, 2012, we had outstanding $11.8 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013. In February 2012, we issued an aggregate of approximately 11.2 million shares of our common stock to one

Table of Contents

of the holders of our convertible senior notes in exchange for cancellation of $9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest. Assuming we continue our LibiGel Phase III safety study, we expect our cash and cash equivalents as of December 31, 2011 to meet our liquidity requirements through mid 2013. If we terminate our LibiGel Phase III safety study and assuming we do so during the second quarter of 2012 and assuming no other corporate product development and activities, we expect our cash and cash equivalents to meet our liquidity requirements through late 2014. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

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 if we decide to continue our LibiGel Phase III safety study;

- whether we in-license additional new products that require further development;

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

- our ability to obtain value from our current products and technologies and our ability to out-license our products and technologies to third parties for development and commercialization and the terms of such out-licensings;

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

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

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

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

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

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

- our operating expenses;

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

- the resolution of our pending purported class action litigation.

Table of Contents

We do not have any existing credit facilities under which we could borrow funds. In the event that we would require additional working capital to fund future operations, we could seek to acquire such funds through additional equity or debt financing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to us, or at all. As an alternative to raising additional financing, we may choose to license one or more of our products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company. In addition, from time to time, we may purchase, exchange or restructure our outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of our company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, our available cash and cash equivalents, our liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of our stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of our existing stockholders and/or decrease our cash balance. A significant decrease in our cash balance may impair our ability to execute strategic alternatives or leave us without sufficient cash remaining for operations.

The announcement of the results of our LibiGel Phase III efficacy trials has significantly depressed the trading price of our common stock and if we terminate our LibiGel Phase III safety study, the trading price of our common stock could be depressed further and affect adversely our ability to raise additional capital. The decrease in the trading price of our common stock has resulted in the bid price for our common stock failing to meet the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market. We have until July 30, 2012 to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. If we do not regain compliance by July 30, 2012, we may transfer our common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if we meet the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, we also would need to provide NASDAQ written notice of our intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we do not indicate our intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for us to cure the deficiency, we will not be eligible for the second 180-day grace period and our common stock will be subject to delisting, which delisting determination we may appeal to a hearings panel at that time. A delisting of our common stock from NASDAQ or even the transfer of our common stock listing to The NASDAQ Capital Market could result in further decreases in the trading price of our common stock and, among other things, could harm our ability to raise additional financing.

In addition, the announcement of the results of our LibiGel Phase III efficacy trials has resulted in pending purported class action litigation of which we, along with our President and Chief Executive Officer, are defendants, which litigation is described in more detail under Part I. Item 3. Legal Proceedings of this report. While we believe the actions are without merit and intend to defend the actions vigorously, such litigation could divert management s attention, harm our business and/or reputation and result in significant liabilities, as well as harm our ability to raise additional financing.

Table of Contents

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 investors are not confident in the future value of our company, we lose the NASDAQ listing of our common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when we need them, we may need to cut our operating costs further or we may be forced to explore other strategic alternatives, such as selling or merging our company or winding down our operations and liquidating our company. In such case, our stockholders could lose some or all of their investment.

3.125% Convertible Senior Notes Due May 1, 2013

As a result of our merger with Cell Genesys in 2009, we assumed $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 (the 2011 Notes) and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes and together with the 2011 Notes, the Notes) issued by Cell Genesys. Prior to the November 1, 2011 maturity date, we repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued and unpaid interest thereon through such date. In February 2012, we issued an aggregate of approximately 11.2 million shares of our common stock to one of the holders of the 2013 Notes in exchange for cancellation of $9.0 million in aggregate principal amount of the 2013 Notes, including accrued and unpaid interest.

Contractual interest payments on the 2013 Notes are due on May 1 and November 1 of each year through maturity. Annual interest on the Notes was approximately $0.7 million during 2011, which annual interest will decrease in 2012 as a result of the repayment of the 2011 Notes and the cancellation of $9.0 million in aggregate principal amount of the 2013 Notes in February 2012.

The remaining outstanding 2013 Notes are convertible into an aggregate of approximately 3.2 million shares of our common stock at a conversion price of $3.72 per share, subject to adjustments for stock dividends, stock splits and other similar events. The 2013 Notes are our general, unsecured obligations, ranking equally with all of our existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of our subsidiaries. The 2013 Notes are subject to repurchase by us at each holder s option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by us, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of our common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of December 31, 2011, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indenture.

In addition, from time to time, we may purchase, exchange or restructure our outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of our company, in open market purchases, privately negotiated transactions and/or a tender offer. The amounts involved may be material. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market

Table of Contents

conditions, our available cash and cash equivalents, our liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of our stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of our existing stockholders and/or decrease our cash balance. A significant decrease in our cash balance may impair our ability to execute strategic alternatives or leave us without sufficient cash remaining for operations.

We have elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which otherwise would require specialized valuation, bifurcation and recognition. Accordingly, we have adjusted the carrying value of the Notes to their fair value as of December 31, 2011, with changes in the fair value of the Notes occurring since December 31, 2010 reflected in convertible note fair value adjustment in our 2011 statement of operations. The fair value of the Notes are based on Level 2 inputs. The aggregate recorded fair value of the Notes of $17.3 million as of December 31, 2011 differs from their total stated principal amount of $20.8 million as of such date by $3.5 million. The aggregate recorded fair value of the Notes of $18.6 million as of December 31, 2010 differs from their total stated principal amount of $22.0 million as of such date by $3.4 million.

Uses of Cash and Cash Flow

Net cash used in operating activities was $47.9 million for the year ended December 31, 2011 compared to net cash used in operating activities of $40.1 million for the year ended December 31, 2010 and net cash used in operating activities of $18.4 million for the year ended December 31, 2009. Net cash used in operating activities for 2011 was primarily the result of the net loss for that period which was higher compared to 2010 due to higher LibiGel Phase III clinical study related expenses, partially offset by a decrease in prepaid expenses and other assets and an increase in accounts payable and accrued liabilities and the non-cash mark-to-market expense for our convertible senior notes. Net cash used in operating activities for 2010 was primarily the result of the net loss for that period, which was slightly higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets. Net cash used in 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 2009 but did not result in an operating cash payment by us as we issued shares of our common stock 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 investing activities was $719,925 for the year ended December 31, 2011 compared to net cash provided by investing activities of $60,366 for the year ended December 31, 2010 and net cash provided by investing activities of $2.9 million for the year ended December 31, 2009. The increase in net cash used in investing activities for 2011 compared to 2010 was due to a significant increase in the purchase of fixed assets, including in particular machinery, computers and furniture. The machinery purchased during 2011 relates to new BioSante-owned machinery for LibiGel product manufacturing at our contract manufacturer and the increased amounts spent on computers and furniture during 2011 was due primarily to our increased number of personnel compared to 2010. Net cash used in investing activities for 2011 and 2010 was primarily for the purchase of capital assets.

Net cash provided by financing activities was $67.7 million for the year ended December 31, 2011 compared to $48.5 million for the year ended December 31, 2010 and $33.7 million for the year ended December 31, 2009. Net cash provided by financing activities in 2011 resulted from the net proceeds to us, after deducting placement agent fees, underwriters discounts, commissions and other

Table of Contents

offering expenses, from the completion of our March 2011 registered direct offering and August 2011 underwritten public offering, partially offset by the repayment of the 2011 Notes of $1.2 million. 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.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2011, other than a purchase obligation relating to a gel filling machine of approximately $500,000. As of December 31, 2011, we, however, had several financial commitments, including $20.8 million in aggregate principal amount of our 3.125% convertible senior notes due May 1, 2013, 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. As discussed above, in February 2012, we issued an aggregate of approximately 11.2 million shares of our common stock to one of the holders of our convertible senior notes in exchange for cancellation of $9.0 million in aggregate principal amount of the convertible senior notes, including accrued and unpaid interest.

The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2011:

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible senior notes	$ 20,782,000	$ 0	$ 20,782,000	0	0
Interest payment obligations related to convertible senior notes	673,806	509,410	164,396	0	0
Operating lease	527,115	236,765	290,350	0	0
Purchase obligations gel filling machine	505,644	505,644	0	0	0
Commitments under license agreements with Johns Hopkins University	400,000	105,000	135,000	90,000	70,000
Commitments under license agreement with Massachusetts Institute of Technology	150,000	50,000	100,000	0	0
Commitments under license agreement with University of California	320,000	20,000	60,000	40,000	200,000
Commitments under license agreement with Wake Forest	440,000	80,000	240,000	80,000	40,000
Total contractual cash obligations	$ 23,798,565	$ 1,506,819	$ 21,771,746	$ 210,000	$ 310,000

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.

Table of Contents

Recent Accounting Pronouncements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

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

Interest Rate Sensitivity

Principal Amount by Expected Maturity and Average Interest Rate

As of December 31, 2011	2012	2013	2014	Total	Fair Value December 31, 2011
Money market fund	$ 55,465,507				$ 55,465,507
Average interest rate	0.02%				
Fixed interest rate 2013 convertible senior notes		$ 20,782,000		$ 20,782,000	
Average interest rate	3.125%	3.125%	3.125%	3.125%	

As of December 31, 2010	2011	2012	2013	Total	Fair Value December 31, 2010
Money market fund	$ 21,729,230				$ 21,729,230
Average interest rate	0.04%				

Fixed interest rate 2011 convertible senior notes	$ 1,234,000			$ 1,234,000	$	1,111,132
Average interest rate	3.125%	3.125%	3.125%	3.125%		
Fixed interest rate 2013 convertible senior notes			$ 20,782,000	$ 20,782,000	$	17,436,201
Average interest rate	3.125%	3.125%	3.125%	3.125%		

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Description	Page
Management s Report on Internal Control Over Financial Reporting	70
Report of Independent Registered Public Accounting Firm	71
Report of Independent Registered Public Accounting Firm	72
Balance Sheets as of December 31, 2011 and 2010	73
Statements of Operations for the years ended December 31, 2011, 2010 and 2009	74
Statements of Stockholders Equity for the years ended December 31, 2011, 2010 and 2009	75
Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009	76
Notes to the Financial Statements for the years ended December 31, 2011, 2010 and 2009	77-100

Table of Contents

MANAGEMENT S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

With our participation, management evaluated the effectiveness of BioSante s internal control over financial reporting as of December 31, 2011. 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, 2011.

/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 13, 2012

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, 2011, 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, 2011, 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, 2011 of the Company and our report dated March 13, 2012 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 13, 2012

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, 2011 and 2010, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 13, 2012 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 13, 2012

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Balance Sheets

December 31, 2011 and 2010

	December 31, 2011	December 31, 2010
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 57,225,234	$ 38,155,251
Prepaid expenses and other assets	801,147	2,469,879
	58,026,381	40,625,130
PROPERTY AND EQUIPMENT, NET	861,364	635,776
OTHER ASSETS		
Investments	3,405,807	3,405,807
Deposits	86,203	99,937
	$ 62,379,755	$ 44,766,650
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,150,677	$ 4,864,217
Accrued compensation	1,597,329	526,022
Other accrued expenses	2,479,697	1,681,956
Current portion of Convertible Senior Notes		1,111,132
	7,227,703	8,183,327
Long-term Convertible Senior Notes	17,336,760	17,436,201
TOTAL LIABILITIES	24,564,463	25,619,528
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2011 - 391,286; 2010 - 391,286 Class C special stock	391	391
2011 - 109,618,529; 2010 - 81,391,130 Common stock	255,054,049	184,777,375
	255,054,440	184,777,766
Accumulated deficit	(217,239,148)	(165,630,644)
	37,815,292	19,147,122
	$ 62,379,755	$ 44,766,650

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Operations

Years ended December 31, 2011, 2010 and 2009

	Year Ended December 31,		
	2011	2010	2009
REVENUE			
Licensing revenue	$ 100,000	$ 115,807	$
Grant revenue		51,870	116,389
Royalty revenue	335,160	2,306,560	1,141,665
	435,160	2,474,237	1,258,054
EXPENSES			
Research and development	44,182,260	39,705,502	13,680,573
General and administration	6,981,490	5,940,360	5,373,945
Acquired in-process research and development			9,000,000
Excess consideration paid over fair value			20,192,194
Licensing expense	50,000	268,750	299,616
Depreciation and amortization	148,240	167,986	137,280
	51,361,990	46,082,598	48,683,608
OTHER			
Convertible note fair value adjustment	(23,427)	(1,870,916)	33,163
Investment impairment charge		(286,000)	
Interest expense	(681,573)	(688,083)	(147,025)
Other income	15,000	244,479	
Interest income	8,326	12,665	11,648
NET LOSS	$ (51,608,504)	$ (46,196,216)	$ (47,527,768)
Loss per common share:			
Basic	$ (0.52)	$ (0.70)	$ (1.40)
Diluted	$ (0.52)	$ (0.70)	$ (1.40)
Weighted average number of common and common equivalent shares outstanding:			
Basic	98,385,709	65,911,750	33,951,652
Diluted	98,385,709	65,911,750	33,951,652

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Stockholders Equity

Years ended December 31, 2011, 2010 and 2009

	Class C Special Shares		Common Stock		Accumulated	
	Shares	Amount	Shares	Amount	Deficit	Total
Balance, January 1, 2009	**391,286**	**$ 391**	**27,042,764**	**$ 85,732,688**	**$ (71,906,660)**	**$ 13,826,419**
Issuance of common shares						
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)
Balance, December 31, 2009	**391,286**	**$ 391**	**53,262,568**	**$ 135,264,431**	**$ (119,434,428)**	**$ 15,830,394**
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)
Balance, December 31, 2010	**391,286**	**$ 391**	**81,391,130**	**$ 184,777,375**	**$ (165,630,644)**	**$ 19,147,122**
Issuance of common shares						
Stock option exercise			**19,167**	**32,442**		**32,442**
Warrant exercises - various			**8,750**	**24,062**		**24,062**
Stock option expense				**1,177,683**		**1,177,683**
Stock warrant expense				**204,980**		**204,980**
Underwritten offering of common shares, net			**16,000,000**	**44,961,137**		**44,961,137**
Registered direct offering of common shares and warrants, net			**12,199,482**	**23,876,370**		**23,876,370**
Net loss					**(51,608,504)**	**(51,608,504)**
Balance, December 31, 2011	**391,286**	**$ 391**	**109,618,529**	**$ 255,054,049**	**$ (217,239,148)**	**$ 37,815,292**

See accompanying notes to the financial statements.

75

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Statements of Cash Flows

Years ended December 31, 2011, 2010 and 2009

	Year Ended December 31,		
	2011	2010	2009
CASH FLOWS (USED IN) OPERATING ACTIVITIES			
Net loss	$ (51,608,504)	$ (46,196,216)	$ (47,527,768)
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	148,240	167,986	137,280
Employee and director stock-based compensation	1,177,683	992,757	1,254,503
Stock warrant expense - noncash	204,980	65,529	64,103
Loss on disposal of equipment	367,502	4,583	
Investment impairment charge		286,000	
Other non-cash items		(65,807)	60,739
Convertible note fair value adjustment	23,427	1,870,916	(33,163)
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	1,682,466	(365,332)	(30,263)
Accounts payable and accrued liabilities	134,103	3,142,078	(1,548,535)
Net cash used in operating activities	(47,870,103)	(40,097,506)	(18,430,910)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES			
Redemption of short term investments			3,026,334
Proceeds from sale of fixed assets		3,075	
Purchase of fixed assets	(719,925)	(63,441)	(165,724)
Net cash (used in) provided by investing activities	(719,925)	(60,366)	2,860,610
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Cash paid for transaction related costs			(2,431,252)
Cash received in transaction			24,746,346
Cash paid for convertible note repayment	(1,234,000)		
Proceeds from common stock option exercises	32,442	2,014	
Proceeds from common stock warrant exercises	24,062		
Proceeds from issuance of common stock by underwritten offering	44,961,137		
Proceeds from issuance of common stock by registered direct offering	23,876,370	48,452,644	11,352,751
Net cash provided by financing activities	67,660,011	48,454,658	33,667,845
NET INCREASE IN CASH AND CASH EQUIVALENTS	19,069,983	8,296,786	18,097,545
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	38,155,251	29,858,465	11,760,920
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 57,225,234	$ 38,155,251	$ 29,858,465
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			

Interest paid, including acquired accrued interest	**$ 688,000**	**$ 688,000**	**$ 248,388**
Noncash Investing and Financing Activities:			
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	**$ 21,405**	**$**	**$**

See accompanying notes to the financial statements.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements

December 31, 2011

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 products, either approved or in human clinical development, include: (1) LibiGel, once daily transdermal testosterone gel in Phase III clinical development for the treatment of female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD); (2) a once daily transdermal testosterone gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of hypogonadism, or testosterone deficiency in men, and licensed to Teva Pharmaceuticals USA, Inc. (Teva); (3) GVAX cancer vaccines, a portfolio of cancer vaccines, four of which have been granted FDA orphan drug designation, and are currently in 17 Phase I and Phase II clinical trials for the treatment of various cancers; (4) The Pill-Plus (triple component contraceptive), once daily use of various combinations of estrogens, progestogens and androgens in Phase II development; and (5) Elestrin, once daily transdermal estradiol (estrogen) gel approved by the FDA indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S. by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals), our licensee.

The Company s lead product in development has been LibiGel for the treatment of FSD, specifically HSDD, in postmenopausal women, for which there is no FDA-approved pharmaceutical product. The Company continues to analyze the data from the two pivotal LibiGel Phase III efficacy trials first reported on December 14, 2011. Initial analysis of the efficacy data from these trials shows that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences from placebo, results indicated that LibiGel performed as predicted based on previous experience with testosterone products for FSD. However, the placebo response in the two efficacy trials was overwhelming and unpredictable; and therefore, LibiGel s results were not shown to be statistically different from placebo. The LibiGel Phase III safety study, which completed enrollment in June 2011, continues and will continue during further analysis of the LibiGel efficacy data and until a final strategic decision has been made. It is the Company s objective to meet with the FDA to determine the best path forward, and to make a decision during the second quarter of 2012 whether to continue the LibiGel Phase III safety study.

The Company s corporate strategy always has included product development of high value medically-needed pharmaceutical products. In light of recently announced top-line results from the Company s two pivotal LibiGel Phase III efficacy trials, the Company is assessing its corporate strategy. The Company is determining LibiGel s path forward and potential alternative strategies to utilize the continuing LibiGel Phase III cardiovascular events and breast cancer safety study. The Company also has expanded its efforts to explore new product development projects through in-licensing and mergers and acquisitions. In addition, a full review of the Company s GVAX cancer vaccine portfolio is underway.

On January 31, 2012, the Company received a notice from the Listing Qualifications Department of The NASDAQ Stock Market indicating that, for the last 30 consecutive business days, the bid price for the Company s common stock had closed below the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market under NASDAQ Listing Rule 5450(a)(1). The notification letter stated that pursuant to NASDAQ Listing Rule 5810(c)(3)(A), the Company will be afforded 180 calendar days, or until July 30, 2012, to regain compliance

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

1. DESCRIPTION OF BUSINESS (continued)

with the minimum bid price requirement. In order to regain compliance, shares of the Company s common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. If the Company does not regain compliance by July 30, 2012, the Company may transfer its common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if the Company meets the market value of publicly held shares requirement for continued listing and all other initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, the Company also would need to provide NASDAQ written notice of its intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not indicate its intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for the Company to cure the deficiency, the Company will not be eligible for the second 180-day grace period and its common stock will be subject to delisting, which delisting determination the Company may appeal to a hearings panel at that time.

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.

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.

78

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Reclassifications

Certain amounts in the 2010 and 2009 financial statements have been reclassified to conform to their presentation in the 2011 financial statements. Specifically, in the statement of cash flows, the changes related to Accounts receivable in the amounts of $64,645 and $285,838 for the years ended December 31, 2010 and 2009, respectively, have been combined into the Prepaid expenses and other assets line item within the net cash used in operating activities section.

Cash and Cash Equivalents

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

As of December 31, 2011, all of the Company s cash and cash equivalents resided in a 100 percent FDIC-insured non-interest bearing checking account, a U.S. Treasury money market fund or a certificate of deposit. As of December 31, 2010, 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.

Fair Value of Financial Instruments

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

Property and Equipment

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

for software and computer equipment and 10 years for non-computer equipment.

Long-Lived Assets

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

Convertible Senior Notes

The Company assumed two series of 3.125% 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 made an irrevocable election to account for these convertible senior notes at fair value

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

commencing from the date of the merger, resulting in recognition of a single liability for the convertible senior notes which are reported at fair value at each reporting date. Subsequent changes in the carrying value of the convertible senior notes are reflected in fair value adjustment in the accompanying statements of operations.

Research and Development

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

Legal Costs

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

Basic and Diluted Net Loss Per Share

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

Stock-Based Compensation

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

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

Revenue Recognition

The Company has entered into various licensing agreements that have generated license revenue or other upfront fees and which also may involve subsequent milestone payments earned upon completion of development milestones by the Company or upon the occurrence of certain regulatory actions, such as the filing of a regulatory application or the receipt of a regulatory

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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, 2011 and 2010.

Investments

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

was based on a third-party investment in Ceregene in 2010.

The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest the investment may not be recoverable. The fair value of the cost method investments are not

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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

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.

During 2011, the Company raised approximately $68.9 million in net proceeds, after deducting placement agent fees, underwriters discounts, commissions and other offering expenses, through the sale of common stock in an underwritten public offering and common stock and warrants in a registered direct offering, as more fully described in Note 9, Stockholders Equity.

As of December 31, 2011, the Company had $57.2 million of cash and cash equivalents. Absent the receipt of any additional 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 safety study if the Company decides to continue such study. As of March 12, 2012, the Company has $11.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 outstanding. In February 2012,

the Company issued an aggregate of approximately 11.2 million shares of its common stock to one of the holders of the Company s 3.125% convertible senior notes due May 1, 2013 in exchange for cancellation of $9.0 million in aggregate principal amount of such notes, including accrued and unpaid interest. Assuming the Company continues its LibiGel Phase III safety study, the

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

3. LIQUIDITY AND CAPITAL RESOURCES (continued)

Company expects its cash and cash equivalents as of December 31, 2011 to meet its liquidity requirements through June 2013. If the Company terminates its LibiGel Phase III safety study and assuming that the Company does so during the second quarter of 2012 and assuming no other corporate product development and activities, the Company expects its cash and cash equivalents to meet its liquidity requirements through December 2014. These estimates may prove incorrect or the Company, nonetheless, may choose to raise additional financing earlier.

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

- the progress, timing, cost and results of the Company s preclinical and clinical development programs, including in particular if the Company decides to continue its LibiGel Phase III safety study;

- whether the Company in-licenses additional new products that require further development;

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

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

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

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

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

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

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

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

- the Company s operating expenses;

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

3. LIQUIDITY AND CAPITAL RESOURCES (continued)

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

- the resolution of the Company s pending purported class action litigation.

The Company does not have any existing credit facilities under which the Company could borrow funds. In the event that the Company would require additional working capital to fund future operations, the Company could seek to acquire such funds through additional equity or debt financing arrangements. If the Company raises additional funds by issuing equity securities, the Company s stockholders may experience dilution. Debt financing, if available, may involve covenants restricting the Company s operations or the Company s ability to incur additional debt. There is no assurance that any financing transaction will be available on terms acceptable to the Company, or at all. As an alternative to raising additional financing, the Company may choose to license one or more of its products or technologies to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under the Company s existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. In addition, from time to time, the Company may purchase, exchange or restructure its outstanding convertible senior notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company s available cash and cash equivalents, the Company s liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company s stockholders, result in the issuance of securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company s existing stockholders and/or decrease the Company s cash balance. A significant decrease in the Company s cash balance may impair the Company s ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

The announcement of the results of the Company s LibiGel Phase III efficacy trials has significantly depressed the trading price of the Company s common stock and if the Company terminates its LibiGel Phase III safety study, the trading price of the Company s common stock could be depressed further and affect adversely the Company s ability to raise additional capital. The decrease in the trading price of the Company s common stock has resulted in the bid price for the Company s common stock failing to meet the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market. The Company has until July 30, 2012 to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company s common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. If the Company does not regain compliance by July 30, 2012, the Company may transfer its common stock listing to The NASDAQ Capital Market and be eligible for an additional 180-day grace period if the Company meets the market value of publicly held shares requirement for continued listing and all other

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

3. LIQUIDITY AND CAPITAL RESOURCES (continued)

initial inclusion requirements for listing on The NASDAQ Capital Market, other than the minimum bid price requirement. In order to be afforded the additional 180-day compliance period, the Company also would need to provide NASDAQ written notice of the Company s intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. If the Company does not indicate its intent to cure the deficiency or if it does not appear to NASDAQ that it is possible for the Company to cure the deficiency, the Company will not be eligible for the second 180-day grace period and its common stock will be subject to delisting, which delisting determination the Company may appeal to a hearings panel at that time. A delisting of the Company s common stock from NASDAQ or even the transfer of the Company s common stock listing to The NASDAQ Capital Market could result in further decreases in the trading price of the Company s common stock and, among other things, could harm the Company s ability to raise financing.

In addition, the announcement of the results of the Company s LibiGel Phase III efficacy trials has resulted in pending purported class action litigation of which the Company, along with its President and Chief Executive Officer, are defendants, which litigation is described in more detail in Note 13, Commitments and Contingencies . While the Company believes the actions are without merit and intends to defend the actions vigorously, such litigation could divert management s attention, harm the Company s business and/or reputation and result in significant liabilities, as well as harm the Company s ability to raise financing.

The Company can provide no assurance that additional financing, if needed, will be available on terms favorable to the Company, or at all. This is particularly true if investors are not confident in the future value of the Company, the Company loses the NASDAQ listing of its common stock and/or economic and market conditions deteriorate. If adequate funds are not available or are not available on acceptable terms when the Company needs them, the Company may need to cut its operating costs further or the Company may be forced to explore other strategic alternatives, such as selling or merging the Company or winding down its operations and liquidating the Company. In such case, the Company s stockholders could lose some or all of their investment.

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

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

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

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

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 also was expensed as of the date of the acquisition.

In addition, as a result of the merger, the Company assumed $1.2 million in aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 and $20.8 million in aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 issued by Cell Genesys. As a result of the merger and in accordance with the terms of the indentures governing the 3.125% convertible senior notes due May 1, 2013 as supplemented by supplemental indentures entered into between the Company and the trustees thereunder, such 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 and Elestrin, but not its male testosterone gel, from Antares Pharma, Inc. (Antares). Under the agreement, Antares granted the Company an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories. Under the agreement, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology. The patents covering the formulations used in these gel products are expected to

expire in 2022 and 2028. The Company s male testosterone gel was developed and is fully-owned by the Company and is not covered under the Antares license.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

5. LICENSE AGREEMENTS (continued)

GVAX Cancer Vaccine Technology

The Company owns development and commercialization rights to its GVAX 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.

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.

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, 2011 and 2010 consists of the following:

	2011	2010
Computer equipment	**$ 520,647**	$ 417,840
Office equipment	**388,659**	163,653
Equipment	**378,147**	500,130
	1,287,453	1,081,623
Accumulated depreciation and amortization	**(426,089)**	(445,847)
	$ 861,364	$ 635,776

There was no construction in progress as of December 31, 2011 or December 31, 2010.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

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 - $1,234,000 aggregate principal amount of 3.125% convertible senior notes due November 1, 2011 (the 2011 Notes) and $20,782,000 aggregate principal amount of 3.125% convertible senior notes due May 1, 2013 (the 2013 Notes and collectively with the 2011 Notes, the Notes). The conversion features of the Notes were adjusted for the exchange ratio used in the merger, as described in Note 9, Stockholders Equity.

Immediately prior to November 1, 2011, the Company repaid in its entirety the outstanding aggregate principal amount of the 2011 Notes and all accrued interest thereon through such date. As of December 31, 2011, the 2013 Notes remained outstanding. In February 2012, the Company issued 11.2 million shares of its common stock to one of the holders of the 2013 Notes in exchange for cancellation of an aggregate of $9.0 million principal amount of such notes, including accrued and unpaid interest. The $11.8 million principal amount of the remaining 2013 Notes are exchangeable at the option of the holder or upon certain specified events into an aggregate of approximately 3.2 million shares of the Company s common stock at a conversion price of $3.72 per share. The 2013 Notes are our general, unsecured obligations, ranking equally with all of the Company s existing and future unsubordinated, unsecured indebtedness and senior in right of payment to any subordinated indebtedness, but are effectively subordinated to all of the Company s existing and future secured indebtedness to the extent of the value of the related security, and structurally subordinated to all existing and future liabilities and other indebtedness of the Company s subsidiaries. The 2013 Notes are subject to repurchase by the Company at each holder s option, if a fundamental change (as defined in the indenture) occurs, at a repurchase price equal to 100 percent of the principal amount of the 2013 Notes, plus accrued and unpaid interest on the repurchase date and are subject to redemption for cash by the Company, in whole or in part, at a redemption price equal to 100 percent of the principal amount of such notes plus accrued and unpaid interest to the redemption date, if the closing price of the Company s common stock has exceeded 150 percent of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. As of December 31, 2011, the 2013 Notes were not eligible for redemption. The indenture governing the 2013 Notes, as supplemented by the supplemental indenture, does not contain any financial covenants and does not restrict the Company from paying dividends, incurring additional debt or issuing or repurchasing the Company s other securities. In addition, the indenture, as supplemented by the supplemental indenture, does not protect the holders of the 2013 Notes in the event of a highly leveraged transaction or a fundamental change of the Company except in certain circumstances specified in the indenture.

From time to time, the Company may purchase, exchange or restructure its outstanding 2013 Notes through cash purchases and/or exchanges for other equity securities of the Company, in open market purchases, privately negotiated transactions and/or a tender offer. Such additional purchases, exchanges or restructurings, if any, will depend on prevailing market conditions, the Company s available cash and cash equivalents, the Company s liquidity requirements, contractual restrictions and other factors. Such future purchases, exchanges or restructurings could dilute the percentage ownership of the Company s stockholders, result in the issuance of

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2011

7. CONVERTIBLE SENIOR NOTES (continued)

securities at a discount to market price or that may have rights, preferences or privileges senior to those of the Company s existing stockholders and/or decrease the Company s cash balance. A significant decrease in the Company s cash balance may impair the Company s ability to execute strategic alternatives or leave the Company without sufficient cash remaining for operations.

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, 2011, with changes in the fair value of the Notes occurring since December 31, 2010, 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 $17,336,760 as of December 31, 2011 differs from their total stated principal amount of $20,782,000 by $3,445,240. The recorded value of the 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 Company recorded fair value adjustments of $(23,427) and $(1,870,916) related to the Notes for the years ended December 31, 2011 and 2010, respectively, to increase its recorded liability and corresponding expense in 2011 and 2010.

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 years ended December 31, 2011 or 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, 2011 were:

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

89

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

7. CONVERTIBLE SENIOR NOTES (continued)

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

The following table represents the scheduled maturities of required principal payments by year related to the convertible senior notes at December 31, 2011:

2012	$	
2013		20,782,000
Total	$	20,782,000

8. INCOME TAXES

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company s U.S. and state tax returns remain subject to examination for the year ended 1998 and all subsequent periods due to the availability of tax loss and credit carryforwards. The Company determined there are no uncertain tax positions existing as of December 31, 2011 or 2010.

The components of the Company s net deferred tax asset at December 31, 2011 and 2010 were as follows:

	2011	2010
Net operating loss carryforwards	**$ 63,969,813**	$ 46,071,206
Tax basis in intangible assets	**4,095,269**	4,452,360
Deferred financing costs for tax	**7,010,462**	7,001,619
Research & development credits	**8,266,610**	5,796,148
Stock option expense	**2,754,981**	2,310,405
Other	**448,140**	25,955
	86,545,275	65,657,693
Valuation allowance	**(86,545,275)**	(65,657,693)
	$	$

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

8. INCOME TAXES (continued)

The Company has no current tax provision due to its current and accumulated losses, which result in net operating loss carryforwards. At December 31, 2011, the Company had approximately $169,456,000 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 2018-2031 and their utilization in future years may be limited as prescribed by Section 382 of the United States Internal Revenue Code. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, and other items have generated deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, which is the amount management believes is more likely than not to be realized . Additionally, the Company has provided a full valuation allowance against $8,266,610 of research and development credits, which are available to reduce future income taxes, if any in the future. The research and development credits expire in the years 2018-2031.

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:

	2011	2010	2009
Tax at U.S. federal statutory rate	**$ (17,804,934)**	$ (15,937,695)	$ (16,397,080)
State taxes, net of federal benefit	**(1,677,276)**	(1,501,377)	(1,544,652)
Research and development credits	**(1,537,863)**	(966,941)	(515,235)
Other, net	**132,491**	133,932	17,718
Change in valuation allowance	**20,887,582**	18,272,081	18,439,249
	$	$	$

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, 2011 or 2010.

There were 391,286 shares of class C special stock issued and outstanding as of December 31, 2011 and 2010. 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 109,618,529 and 81,391,130 shares of common stock issued and outstanding as of December 31, 2011 and 2010, respectively. The Company has presented the par values of its common stock and the related additional paid in capital on a combined basis for all periods presented.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

9. STOCKHOLDERS EQUITY

Underwritten Public Offering

On August 2, 2011, the Company completed an underwritten public offering of an aggregate of 16.0 million shares of its common stock at a purchase price of $3.00 per share, resulting in net proceeds of approximately $45.0 million, after underwriters discounts, commissions and offering expenses.

Registered Direct Offerings

On March 8, 2011, the Company completed a registered direct offering of 12,199,482 shares of its common stock and warrants to purchase an aggregate of 4,269,817 shares of its common stock at a purchase price of $2.0613 per share to institutional investors for gross proceeds of $25.1 million. The offering resulted in net proceeds to the Company of $23.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately and continuing for a period of three years, at an exercise price of $2.25 per share. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 243,990 shares of the Company s common stock at an exercise price of $2.58 per share, which warrants are exercisable immediately and will expire on June 9, 2014.

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

On June 23, 2010, the Company completed a registered direct offering of 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.

92

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

9. STOCKHOLDERS EQUITY (continued)

On December 31, 2010, the Company completed a registered direct 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 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 Note 7, Convertible Senior Notes for information regarding the convertible senior notes assumed in the Cell Genesys merger.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

9. STOCKHOLDERS EQUITY (continued)

Warrants

As of December 31, 2011, warrants to purchase an aggregate of 22,768,448 shares of the Company s common stock were outstanding and exercisable as of December 31, 2011:

Issue Date	Number of Underlying Shares Of Common Stock		Per Share Exercise Price	Expiration Date
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
March 8, 2011	4,025,827	$	2.25	March 8, 2014
March 8, 2011	243,990	$	2.58	June 9, 2014

During 2011, the Company issued warrants to purchase an aggregate of 4,269,817 shares of the Company s common stock in connection with the March 2011 registered direct offering as described above. During 2011, warrants to purchase an aggregate of 8,750 shares of common stock were exercised and warrants to purchase an aggregate of 911,209 shares of the Company s common stock expired unexercised.

During 2010, the Company issued warrants to purchase an aggregate of 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 an aggregate of 763,750 shares of the Company s common stock expired unexercised.

During 2009, the Company issued warrants to purchase an aggregate of 2,640,000 shares of the Company s common stock in connection with a registered direct offering, warrants to purchase an aggregate of 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 an aggregate of 534,996 shares of the Company s common stock expired unexercised.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

9. STOCKHOLDERS EQUITY (continued)

In 2011, 2010 and 2009, the Company issued warrants to purchase 0, 180,000 and 180,000 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 from the date of grant. The Company uses the Black-Scholes pricing model to value these types of warrants and remeasures the awards each quarter until the measurement date is established. For the years ended December 31, 2011, 2010 and 2009, the Company recorded $204,980, $65,529 and $64,103, respectively, in non-cash general and administrative expense pertaining to consultant warrants.

10. STOCK-BASED COMPENSATION

The Company has two stockholder-approved equity-based compensation plans under which stock options have been granted the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. Second 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, 2011, 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 6,000,000 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, 20,501 shares had been issued and 3,525,999 shares were subject to outstanding stock options as of December 31, 2011.

Outstanding employee stock options generally vest over a period of three or four years and have 10-year contractual terms. Upon exercise of an option, the Company issues new shares of its common stock. From time to time, the Company grants employee stock options that have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. None of these options were outstanding as of December 31, 2011. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan and the 2008 Plan was $1,177,683, $992,757 and $1,254,503 for the years ended December 31, 2011, 2010 and 2009, respectively. No income tax benefit was recognized in the Company s statements of operations for stock-based compensation arrangements due to the Company s net loss position.

The weighted average fair value of the options at the date of grant for options granted during 2011, 2010 and 2009 was $1.22, $1.11 and $1.04 per share, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2011	2010	2009
Expected option life (years)	**5.5 6.25**	6.00	6.00
Risk-free interest rate	**1.175% - 2.57%**	2.42%	2.74%
Expected stock price volatility	**69.07% - 72.16%**	76.05%	76.75%

Dividend yield

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

10. STOCK-BASED COMPENSATION (continued)

The Company uses the simplified method to estimate the life of options. The risk-free interest rate used is the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company calculated a volatility rate based on the closing price for its common stock at the end of each calendar month as reported by the NASDAQ Global Market. The Company has not in the past issued a cash dividend nor does it have any current plans to do so in the future; and therefore, an expected dividend yield of zero was used.

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:

	2011	2010	2009
Research and development	**$ 423,925**	$ 325,208	$ 361,773
General and administrative	**753,758**	667,549	892,730
Total stock-based compensation expense	**$ 1,177,683**	$ 992,757	$ 1,254,503

A summary of activity under the Plans during the year ended December 31, 2011 is presented below:

Options	Option Shares	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value
Outstanding December 31, 2010	3,717,436	$ 3.69	6.74	$ 162,892
Granted	2,079,250	$ 1.90		
Exercised	19,167	$ 1.69		
Forfeited or expired	336,354	$ 2.95		
Outstanding December 31, 2011	5,441,165	$ 3.06	6.97	$ 0
Exercisable at December 31, 2011	2,848,027	$ 4.19	5.40	$ 0
Vested or expected to vest at December 31, 2011	5,278,665	$ 3.06	6.95	$ 0

There is no aggregate intrinsic value of the Company s outstanding and exercisable options as of December 31, 2011.

As of December 31, 2011, there was $2,089,729 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 2.76 years.

The intrinsic value of options exercised during the year ended December 31, 2011 and 2010 was $22,106 and $974, respectively. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position. The total fair value of shares vested during the years ended December 31, 2011, 2010 and 2009 was $667,171, $764,921 and $788,461, respectively.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

11. RETIREMENT PLAN

The Company offers a discretionary 401(k) Plan to all of its employees. Under the 401(k) Plan, employees may defer income on a tax-exempt basis, subject to limitations under the Internal Revenue Code of 1986, as amended. Under the 401(k) Plan, the Company may make discretionary matching contributions. Company contributions expensed in 2011, 2010 and 2009 totaled $211,494, $179,349 and $117,969, 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 2012, 2013 and 2014 are $236,747, $248,632 and $41,718, respectively.

Rent expense amounted to $424,294, $338,588 and $325,093 for the years ended December 31, 2011, 2010 and 2009, respectively.

13. COMMITMENTS AND CONTINGENCIES

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. In 2011, 2010 and 2009, the Company paid or accrued $335,160, $152,228 and $63,749, 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 license amendment with Azur Pharma International II Limited (now known as Jazz Pharmaceuticals, in light of Jazz Pharmaceuticals acquisition of Azur), the Company paid Antares an aggregate of $268,750 in February 2010, which is recorded in licensing expense.

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.

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

13. COMMITMENTS AND CONTINGENCIES (continued)

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

Year	Minimum Amount Due
2012	$ 80,000
2013	80,000
2014	80,000
2015	80,000
2016	40,000
Thereafter	80,000

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.

Aptar Pharma Gel Filling Machine

The Company currently has a commitment with Aptar Pharma to purchase a gel filling machine for $842,740. As of December 31, 2011, the Company has paid $337,096 resulting in a remaining obligation of $505,644.

Pending Litigation

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

Securities Exchange Act of 1934, as amended (Exchange Act), Rule 10b-5 and Section 20(a) of the Exchange Act. A substantially similar complaint was filed in the same court on February 21, 2012. The plaintiffs seek to represent a class of persons who purchased the Company s securities between February 8, 2010 and December 15, 2011, and seek unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys fees on behalf of such purchasers. BioSante believes the actions are without merit and intends to defend the actions vigorously. Additional lawsuits may be filed and, at this time, because the litigation is in its early stages, the Company is unable to predict the outcome of these lawsuits, the possible loss or range of loss, if

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

13. COMMITMENTS AND CONTINGENCIES (continued)

any, associated with their resolution or any potential effect they may have on BioSante s operations. Failure by the Company to obtain a favorable resolution of the lawsuits, however, could have a material effect on the Company s financial condition, results of operations, cash flows or its operations.

14. FAIR VALUE MEASUREMENTS

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

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

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

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, 2011 and 2010 are classified in the table below in one of the three categories described above:

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

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2011

14. FAIR VALUE MEASUREMENTS (continued)

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

The Company made an election to record the values of the 2011 Notes and 2013 Notes at fair value with gains and losses related to fluctuations in the value of these financial liabilities recorded in earning immediately pursuant to ASC 825. The fair values of the 2011 Notes and 2013 Notes are estimated based on the risk-free borrowing rate, the volatility of the Company s stock, and the current borrowing rates for similar companies. See Note 7, Convertible Senior Notes for more information and disclosures regarding key assumptions used in this fair value determination.

15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2011 and 2010 is as follows:

	2011			
	First	Second	Third	Fourth
Revenue	$ 57,000	$ 81,003	$ 182,784	$ 114,373
Research and development expenses	14,864,420	11,116,323	11,500,053	6,701,465
General and administrative expenses	1,593,557	1,989,103	1,675,268	1,723,562
Licensing expense	0	0	50,000	0
Operating loss	(16,442,921)	(13,064,942)	(13,028,207)	(8,340,710)
Net loss	(17,250,676)	(14,975,231)	(12,733,691)	(6,648,906)
Loss per share:				
Basic and diluted	$ (0.20)	$ (0.16)	$ (0.12)	$ (0.06)

	2010			
	First	Second	Third	Fourth
Revenue	$ 2,279,874	$ 0	$ 51,331	$ 143,032

Research and development expenses	9,426,870	8,657,606	9,716,091	11,904,935
General and administrative expenses	1,498,252	1,540,200	1,534,417	1,367,491
Licensing expense	268,750	0	0	0
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)

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 Part II. Item 8, under the heading Report of Independent Registered Public Accounting Firm.

Change in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2011 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 and the NASDAQ Global Market 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.biosantepharma.com.

Changes to Nomination Procedures

During the fourth quarter of 2011, 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, 2011. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. Second 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	5,206,736(1)(2)	$ 2.31	2,453,500(3)
Equity compensation plans not approved by security holders	234,429	$ 19.73	0

Total	5,441,165	$	3.06	2,453,500

(1) Amount includes shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2011 under the BioSante Pharmaceuticals, Inc. Second 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, 2011, 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 4.4 years. All of the options assumed and outstanding in connection with our merger with Cell Genesys were exercisable as of December 31, 2011. 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, 2011, 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 May 26, 2011 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. (incorporated by reference to Exhibit 10.3 contained in BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)).

D. Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes (incorporated by reference to Exhibit 10.4 contained in BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)).

E. BioSante Pharmaceuticals, Inc. Officer Severance Policy (incorporated by reference to Exhibit 10.5 contained in BioSante s quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2011 (File No. 001-31812)).

F. BioSante Pharmaceuticals, Inc. Performance Incentive Plan (incorporated by reference to Exhibit 10.4 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)).

G. BioSante Pharmaceuticals, Inc. Second 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 May 27, 2011 (File No. 001-31812)).

H. Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)).

Table of Contents

I. Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)).

J. Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)).

K. BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.1 contained in BioSante s current report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)).

L. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.5 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 000-28637)).

M. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.30 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)).

N. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.31 to BioSante s annual report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)).

O. Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors and Executive Officers (incorporated by reference to Exhibit 10.30 to BioSante s annual report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)).

P. Description of Non-Employee Director Compensation Arrangements (filed herewith).

Q. Cell Genesys, Inc. 2005 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 contained in Cell Genesys s quarterly report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-19986)).

R. Cell Genesys, Inc. Amended and Restated 1998 Incentive Stock Plan (incorporated by reference to Exhibit 10.2 contained in Cell Genesys s quarterly report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-19986)).

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 13, 2012

BIOSANTE PHARMACEUTICALS, INC.

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

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
/S/ STEPHEN M. SIMES Stephen M. Simes	Vice Chairman, President and Chief Executive Officer	March 13, 2012
/S/ LOUIS W. SULLIVAN, M.D. Louis W. Sullivan, M.D.	Chairman of the Board	March 13, 2012
/S/ FRED HOLUBOW Fred Holubow	Director	March 13, 2012
/S/ ROSS MANGANO Ross Mangano	Director	March 13, 2012
/S/ JOHN T. POTTS, JR., M.D. John T. Potts, Jr., M.D.	Director	March 13, 2012
/S/ EDWARD C. ROSENOW, III, M.D. Edward C. Rosenow, III, M.D.	Director	March 13, 2012
/S/ STEPHEN A. SHERWIN, M.D. Stephen A. Sherwin, M.D.	Director	March 13, 2012

Table of Contents

BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

Exhibit No.	Exhibit	Method of Filing
1.1	Placement Agent Agreement dated as of August 13, 2009 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
1.2	Placement Agent Agreement dated as of March 4, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
1.3	Placement Agent Agreement dated as of June 20, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
1.4	Placement Agent Agreement dated as of December 27, 2010 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
1.5	Placement Agent Agreement dated March 3, 2011 between BioSante Pharmaceuticals, Inc. and Rodman & Renshaw, LLC	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
1.6	Underwriting Agreement, dated July 28, 2011 by and between BioSante Pharmaceuticals, Inc. and Jefferies & Company, Inc., as Representative of the Several Underwriters Named in Schedule A Thereto	Incorporated by reference to Exhibit 1.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 28, 2011 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
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 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 June 24, 2009, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to Cell Genesys s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-19986)
4.2	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of June 24, 2009, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2013	Incorporated by reference to Exhibit 4.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
4.3	Warrant dated December 15, 2008 issued by BioSante Pharmaceuticals, Inc. to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
4.4	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the August 2009 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
4.5	Form of Replacement Warrant issued to Investors in Cell Genesys, Inc. s April 2007 Registered Direct Offering	Incorporated by reference to Exhibit 4.9 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
4.6	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the March 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
4.7	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the June 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
4.8	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the December 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
4.9	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placement Agent in the March 2011 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.3	Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.3 contained in BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.4	Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes	Incorporated by reference to Exhibit 10.4 contained in BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.5	BioSante Pharmaceuticals, Inc. Officer Severance Policy	Incorporated by reference to Exhibit 10.5 contained in BioSante s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2011 (File No. 001-31812)
10.6	BioSante Pharmaceuticals, Inc. Performance Incentive Plan	Incorporated (by reference to Exhibit 10.4 contained in BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)
10.7	BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)
10.8	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)
10.9	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 27, 2011 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.10	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.4 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)
10.11	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.12	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.5 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.13	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.14	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Directors Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.31 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.15	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its Directors and Executive Officers	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
10.16	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.17	Cell Genesys, Inc. 2005 Equity Incentive Plan, as amended	Incorporated by reference to Exhibit 10.3 to Cell Genesys s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-19986)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.18	Cell Genesys, Inc. Amended and Restated 1998 Incentive Stock Plan	Incorporated by reference to Exhibit 10.2 to Cell Genesys s Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 (File No. 000-19986)
10.19	Office Lease, dated December 19, 2003, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.29 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.20	First Amendment to Lease, dated February 26, 2004, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Quarterly Report on Form 10-QSB for the fiscal quarter ended March 31, 2004 (File No. 001-31812)
10.21	Second Amendment to Lease dated as of January 4, 2005, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 6, 2005 (File No. 001-31812)
10.22	Third Amendment to Lease dated as of January 27, 2006 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 1, 2006 (File No. 001-31812)
10.23	Fourth Amendment to Lease dated as of March 7, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2007 (File No. 001-31812)
10.24	Fifth Amendment to Lease dated as of November 2, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago.	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 6, 2007 (File No. 001-31812)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.25	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 21, 2008 (File No. 001-31812)
10.26	Seventh Amendment to Lease dated as of November 17, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.22 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.27	Eighth Amendment to Lease dated as of September 8, 2009 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.23 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.28	Ninth Amendment to Lease dated as of January 19, 2011 by and between 111 Barclay Associates, the sole beneficiary under Chicago Title Land Trust Company, as successor trustee to LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 27, 2011 (File No. 001-31812)
10.29	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.27 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.30	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.28 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.31	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.32	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.30 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.33	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.31 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.34	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.32 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.35	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.33 to BioSante s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.36	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (2)	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.37	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (2)	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.38	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)

Table of Contents

Exhibit No.	Exhibit	Method of Filing
10.39	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)
10.40	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)
10.41	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)
10.42	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)
10.43	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)
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

Table of Contents

Exhibit No.	Exhibit	Method of Filing
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
101	The following materials from BioSante Pharmaceuticals, Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the audited Balance Sheets, (ii) the audited Statements of Operations, (iii) the audited Statements of Stockholders Equity; (iv) the audited Statements of Cash Flows, and (v) Notes to Financial Statements.*	Furnished herewith

(1) All exhibits and schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. BioSante will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Securities and Exchange Commission.

(2) Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.

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