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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, 2010

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 o NO o

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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This annual report on Form 10-K contains or incorporates by reference forward-looking statements. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as "believe," "may," "could," "would," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue", the negative of these words, other words and terms of similar meaning or the use of future dates. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the headings "Part I. Item I. Business — Forward-Looking Statement" and "Part I. Item 1A. Risk Factors." These factors may cause our actual results to differ materially from any forward-looking statement.

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

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

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PART I

Item 1. BUSINESS

Company Overview

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

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

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

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

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

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

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

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

BioSante's Primary Product Portfolio

Product	Indication	Early Human Clinical	Late Human Clinical	FDA Approval	Collaborations
Elestrin™	Menopausal	→	→	→	Azur

(estradiol gel)	symptoms		Pharma
LibiGel® (testosterone gel)	Female sexual dysfunction (FSD)		Non-partnered
Bio-T-Gel™ (testosterone gel)	Male Hypogonadism		Teva
The Pill Plus™ (birth control with androgen)	Contraception		Pantarhei for oral use Non-partnered for TD use
Cancer Vaccines	Various Cancers		Johns Hopkins

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

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

Overview. Our products for female sexual health, menopause, contraception and male hypogonadism include our gel formulations of estradiol or testosterone and combinations of estrogen, progestogen and androgen: LibiGel, Elestrin, Bio-T-Gel and Pill-Plus, our triple component contraceptive that uses various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

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

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

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

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

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

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

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

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

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

Both Phase III safety and efficacy trials are randomized, double-blind, placebo-controlled, multi-center trials of approximately 500 surgically menopausal women each, exposed to LibiGel or placebo for six months. We have completed enrollment in the first efficacy trial and plan to complete enrollment in the second efficacy trial in the near future The Phase III safety study currently is enrolling women and is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular and breast cancer safety study of between approximately 3,000 and 4,000 women exposed to LibiGel or placebo for a minimum average of 12 months. After data analysis and following NDA submission and potential FDA approval and product launch, we will continue to follow each woman in the safety study for 60 total months of exposure.

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

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

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

Although generally thought of as being limited to men, testosterone also is important to women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone therapy in women can boost sexual desire, sexual activity and pleasure, increase bone density, raise energy levels and improve mood. According to a study published in the *Journal of the American Medical Association*, 43 percent of American women between the ages of 18 to 59, or about 40 million women, experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex (low sexual desire). Furthermore, according to a study published in the *New England Journal of Medicine*, 43 percent of American women between the ages of 57 to 85 experience low sexual desire. Importantly, according to IMS data, two million testosterone prescriptions were written off-label for women by U.S. physicians in 2009 and according to independent primary market research, at least 2 million additional prescriptions of compounded testosterone were written off-label for women. Female sexual dysfunction is defined as a lack of sexual desire, arousal or pleasure. The majority of women with FSD are postmenopausal, experiencing symptoms due to hormonal changes that occur with aging or following surgical menopause.

Treatment with LibiGel in our Phase II clinical trial significantly increased satisfying sexual events in surgically menopausal women suffering from FSD. The Phase II trial results showed LibiGel significantly increased the number of satisfying sexual events by 238 percent versus baseline; this increase also was significant versus placebo. In this study, the effective dose of LibiGel produced testosterone blood levels within the normal range for pre-menopausal women and had a safety profile similar to that observed in the placebo group. In addition, no serious adverse events and no discontinuations due to adverse events occurred in any subject receiving LibiGel. The Phase II clinical trial was a double-blind, placebo-controlled trial, conducted in the United States, in surgically menopausal women distressed by their low sexual desire and activity.

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

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

Elestrin is indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. Elestrin is administered using a metered dose applicator. Two doses of Elestrin were approved by the FDA. The lower dose of Elestrin is one of the lowest daily doses of estradiol approved by the FDA for the treatment of hot flashes and is 67 percent lower than the lowest dose, FDA-approved estrogen patch for hot flashes on the market. The Elestrin FDA approval was a non-conditional and full approval.

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

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

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

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

Bio-T-Gel is subject to a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA has agreed to develop and market Bio-T-Gel for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA, certain milestones and royalties on sales of the product, if and when approved and marketed, in exchange for rights to develop and market the product. Teva USA also is responsible under the terms of the agreement for continued

development, regulatory filings and all manufacturing and marketing associated with the product. It is anticipated that Teva USA will submit an application for approval to market Bio-T-Gel to the FDA during the first half of 2011.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone also may experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Approximately five million men in the United States, primarily over age 40, have lower than normal levels of testosterone. Testosterone therapy has been shown to restore levels of testosterone with minimal side effects.

There are currently several products on the market for the treatment of low testosterone levels in men. As opposed to estrogen therapy products, oral administration of testosterone is currently not possible as the hormone is, for the most part, rendered inactive in the liver making it difficult to achieve adequate levels of the compound in the bloodstream. Current methods of administration include testosterone injections, patches and gels. Testosterone injections require large needles, are often painful and not effective for maintaining adequate testosterone blood levels throughout the day. Delivery of testosterone through transdermal patches was developed primarily to promote the therapeutic effects of testosterone therapy without the often painful side effects associated with testosterone injections. Transdermal patches, however, similar to estrogen patches, have a physical presence, can fall off, and can result in skin irritation. Testosterone formulated gel products for men are designed to deliver testosterone without the pain of injections and the physical presence, skin irritation and discomfort associated with transdermal patches. We are aware of two gel testosterone products for men currently on the market in the United States and two others have been FDA approved but have not been commercially launched yet. According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 17 percent in 2010 to $1.1 billion from $968 million in 2009.

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

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

We have an exclusive license from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center for the three issued U.S. patents for triple component contraception. The financial terms of the license include an upfront payment, regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently is marketed.

The Pill-Plus is subject to a sublicense agreement with Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market the product. We may receive certain development and regulatory milestones for the first product developed under the license. In addition, we will receive royalty payments on any sales of the product in the U.S., if and when approved and marketed. If the product is sublicensed by Pantarhei to another company, we will receive a percentage of any and all payments received by Pantarhei for the sublicense from a third party. We have retained all rights under our licensed patents to the transdermal delivery of triple component contraceptives.

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

Other Products. Marketing rights to our gel products in Canada are subject to an agreement with Paladin Labs Inc. In exchange for the sublicense, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments are required to be in the form of a series of equity investments by Paladin in our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made.

Description of Our Cancer Vaccines and Other Technologies

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

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

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

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

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

Oncolytic Virus Technology. On November 15, 2010, we entered into an assignment and technology transfer agreement with Cold Genesys, Inc. pursuant to which we sold to Cold Genesys exclusive, worldwide rights to develop and commercialize our oncolytic virus technology. The oncolytic virus technology uses replication-competent adenoviruses derived from Adenovirus type 5, a common “cold” virus that replicate in and selectively kill tumor cells. The replication of the virus is controlled by replacing the promoter of a gene required for replication with a promoter that is preferentially expressed only in tumor cells. Furthermore, the virus may optionally include a gene encoding a cytokine, which enhances immune stimulation to the tumor, thereby providing a dual mechanism of action for killing targeted cancer cells by direct cell lysis as well as via cellular and humoral immune responses to the tumor. The oncolytic virus technology includes CG0070, a replication-competent adenovirus that has completed a Phase I clinical trial for treatment of superficial bladder cancer. In exchange for the technology, we received a 19.9 percent ownership position in Cold Genesys and a $95,000 upfront cash payment and are eligible to receive future milestone and royalty payments.

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

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

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

Sales and Marketing

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

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

Research and Product Development

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

Manufacturing

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

Patents, Licenses and Proprietary Rights

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

Gel Products. We licensed the technology underlying LibiGel, Elestrin and certain of our other gel products, other than Bio-T-Gel, from Antares Pharma, Inc. Under the agreement, Antares granted us an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories, including the U.S., Canada, New Zealand, South Africa, Israel, Mexico, China (including Hong Kong) and Indonesia. We are the exclusive licensee in certain territories for issued U.S. patents for these products and additional patent applications have been filed for this licensed technology in the U.S. and several foreign jurisdictions. Under the agreement, we are required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products we or our sub-licensees sell incorporating the in-licensed technology. The patents covering the formulations used in these gel products are expected to expire in 2022 unless patent-term extensions are granted. In addition, we have other patents pending, which, if issued, may expire later than 2022. Bio-T-Gel was developed and is fully-owned by us and not covered under the Antares license.

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

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

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

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

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

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

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

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

Trademarks and Trademark Applications/Registrations. We own trademark registrations in the U.S. and/or in certain foreign jurisdictions for several marks, including BIOSANTE®, LIBIGEL® and BIO-E-GEL®. In addition, we have filed trademark applications for several other marks including ELESTRIN™ (pursuant to our license of Elestrin to Azur in the U.S., we transferred the Elestrin trademark in the U.S. to Azur) and BIO-T-GEL™. In addition, we own common law rights to several trademarks, including BIOSANTE®, LIBIGEL®, ELESTRIN™, BIO-E-GEL®, BIO-T-GEL™, THE PILL-PLUS™, LIBIGEL-E/T™, and BIOLOOK™. For those trademarks for which registration has been sought, registrations have issued for some of those trademarks in certain jurisdictions and others currently are in the application/prosecution phase.

Confidentiality and Assignment of Inventions Agreements. We require our employees, consultants and advisors having access to our confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with us. These agreements generally provide that all confidential information we develop or make known to the individual during the course of the individual's employment or consulting relationship with us must be kept confidential by the individual and not disclosed to any third parties. We also require all of our employees and consultants who perform research and development for us to execute

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

Competition

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

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

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

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

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

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

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

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

- Another form of an NDA is the "505(b)(2) NDA," which typically is used to seek FDA approval of products that share characteristics (often, the active ingredient(s)) with a previously approved product of another company, but contain modifications to, or differences from, the approved product that preclude submission of an abbreviated new drug application. A 505(b)(2) NDA is in order where at least some of the information required for approval does not come from studies conducted by or for the applicant or for which the applicant has obtained a right of reference. Usually, this means the application relies on the FDA's previous approval of a similar product or reference listed drug, or published data in scientific literature that are not the applicant's.

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

- laboratory and preclinical tests;

- submission of an Investigational New Drug (IND) application, which must become effective before clinical studies may begin;

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- adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed product for its intended use;

- submission of a full NDA or 505(b)(2) NDA containing, to the extent required, the results of the preclinical tests and clinical studies establishing the safety and efficacy of the proposed product for its intended use, as well as extensive data addressing matters such as manufacturing and quality assurance;

- scale-up to commercial manufacturing;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and

- FDA approval of the application.

To the extent that a 505(b)(2) NDA applicant can rely on the referenced application, it may not be required to conduct some of these steps.

Pre-Clinical Studies and Clinical Trials. Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a product's uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information.

Our submission of an IND, or those of our collaboration partners, may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND also must be made for each successive clinical trial conducted during product development. Depending on its significance, the FDA also must approve changes to an existing IND. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center and it must monitor the study until completed. Alternatively, a central IRB may be used instead of individual IRBs. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice requirements and regulations for informed consent.

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

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

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product

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and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials are usually conducted with several hundred to several thousand subjects.

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

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

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

The FDA reviews each submitted application before accepting it for filing, and may refuse to file the application if it does not appear to meet the minimal standards for filing. If the FDA refuses to file an application and requests additional information, the application must be resubmitted with the requested information. Once the submission is accepted for filing, the FDA begins an in-depth review of the application to determine, among other things, whether a product is safe and effective for its intended use. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. The FDA typically takes from 10 to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy, and there is no assurance that the FDA will ultimately approve an NDA.

Acceptance for filing of an application does not assure FDA approval for marketing. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the submitted data, which could delay, limit, or prevent regulatory approval. If it concludes that the application does not satisfy the regulatory criteria for approval, the FDA typically issues a "Complete Response" letter communicating the agency's decision not to approve the application and outlining the deficiencies in the submission. The Complete Response letter may request additional information, including additional preclinical testing or clinical trials. Even if such information and data are submitted, the FDA may ultimately decide that the NDA or 505(b)(2) NDA does not satisfy the criteria for approval.

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

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

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

The Hatch-Waxman Act. The Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act ("Hatch-Waxman"), established an abbreviated process for obtaining FDA approval for generic versions of approved branded drug products. In addition to establishing a shorter, less expensive pathway for approval of generic drugs, Hatch-Waxman provides incentives for the development of new branded products and innovations to approved products by means of marketing exclusivities and extension of patent rights. Under the Hatch-Waxman Act, newly-approved drugs and new conditions of use may benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides three years of marketing exclusivity for the approval of new and supplemental NDAs for, among other things, new indications, dosages or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. This three-year marketing exclusivity period protects against the approval of abbreviated new drug application and 505(b)(2) NDAs for the innovation that required clinical data; it does not prohibit the FDA from accepting or approving abbreviated new drug application or 505(b)(2) applications for other products containing the same active ingredient. The five- and three-year marketing exclusivity periods apply equally to patented and non-patented drug products. It is under this provision that we received three years marketing exclusivity for Elestrin and expect to receive three years of marketing exclusivity for LibiGel.

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

Other Regulatory Requirements. Regulations continue to apply to pharmaceutical products after FDA approval occurs. Post-marketing safety surveillance is required in order to continue to market an approved product. The

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FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with "current good manufacturing practice" regulations, commonly referred to as "cGMP" regulations, which govern the production of pharmaceutical products. We currently do not have any manufacturing capability. In the event we undertake any manufacturing activities or contract with a third-party manufacturer to perform our manufacturing activities, we intend to establish a quality control and quality assurance program to ensure that our products are manufactured in accordance with the cGMP regulations and any other applicable regulations.

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

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

Employees

We had 45 employees as of December 31, 2010, including 38 in product development and seven in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We also engage independent contractors from time to time on an as needed basis.

Forward-Looking Statements

This annual report on Form 10-K contains or incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in news releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, 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" or "continue", the negative of these words, other words and terms of similar meaning or the use of future dates. These forward-looking statements may be contained in the notes to our financial statements and elsewhere in this report, including under the heading "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations." Our forward-looking statements generally relate to:

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- the timing of the commencement, enrollment and successful completion of our clinical studies, the submission of new drug applications and other regulatory status of our products in development;
- approval by the FDA of our products that are currently in clinical development and other regulatory decisions and actions;
- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes and licensure or acquisition of new products;
- our spending on general and administrative expenses;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;

- the future market size and market acceptance of our products;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading "Part I. Item 1A. Risk Factors" below. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading "Part I. Item 1A. Risk Factors" below, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading "Part I. Item 1A. Risk Factors." The risks and uncertainties described under the heading "Item 1A. Risk Factors" below are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

Available Information

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

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

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

Item 1A. RISK FACTORS

The following are significant risk factors known to us that could have a material adverse effect on our business, financial condition or operating results.

Risks Related to Our Financial Condition and Future Capital Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on the products, suppliers or manufacturing processes;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- demonstration of efficacy and safety in clinical trials;
- the existence, prevalence and severity of any side effects;
- the availability of alternative treatments and potential or perceived advantages or disadvantages compared to alternative treatments;
- perceptions about the relationship or similarity between our products and the parent drug compound upon which the product is based;
- the timing of market entry relative to competitive treatments;

- the ability to offer our products for sale at competitive prices;
- relative convenience, product dependability and ease of administration;
- the strength of marketing and distribution support;
- the sufficiency of coverage and reimbursement of our products by third-party payors and governmental and other payors; and
- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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

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

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

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

- private health insurers;
- health maintenance organizations;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Industry

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

these third parties also may compete with us with respect to some of our products.

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

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

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

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

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

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

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

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

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

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

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

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

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the U.S. patents covering the formulations used in Elestrin and

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

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

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:

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

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

Risks Related to Our Common Stock

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

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

- general stock, market and general economic conditions in the United States and abroad, not directly related to our company or our business.
- our ability to obtain needed financing;
- equity sales by us to fund our operations;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products in development or our competitors' products;
- actual or anticipated results of our clinical studies or those of our competitors;
- changes in laws or regulations applicable to our products;
- changes in the anticipated or actual timing of our development programs, including delays or cancellations of clinical studies for our products;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors or licensees of our technology;
- entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;

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- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- developments or disputes concerning patents or other proprietary rights;
- period-to-period fluctuations in our financial results, including our cash and cash equivalents, operating expenses, cash burn rate or revenues;

- loss of key management;
- common stock sales and purchases in the public market by one or more of our larger stockholders, officers or directors;
- reports issued by securities analysts regarding our common stock and articles published regarding our business and/or products;
- changes in the market valuations of other life science or biotechnology companies; and
- other financial announcements, including delisting of our common stock from the NASDAQ Global Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in our filings with the SEC or our failure to maintain effective internal control over financial reporting.

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

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

We currently have the ability to offer and sell common stock, preferred stock and warrants under currently effective universal shelf registration statements. We typically sell shares of our common stock and warrants to purchase shares of our common stock to raise additional financing and fund our operations. We may issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances would dilute your share ownership. In addition, these sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

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

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

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

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

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

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

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Stock Market rules are creating uncertainty for public companies. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of these costs. For example, the SEC has adopted regulations that will require us to file corporate financial statement information in a new interactive data format known as XBRL

beginning with our quarterly report on Form 10-Q for our second quarter of 2011. We will incur significant costs and need to invest considerable resources to implement and to remain in compliance with these new requirements.

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

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

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

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

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

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

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

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

Item 2. PROPERTIES

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

Item 3. LEGAL PROCEEDINGS

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

Item 4. [REMOVED AND RESERVED]

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Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

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

Name	Age	Title
Stephen M. Simes	59	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	50	Senior Vice President of Finance, Chief Financial Officer and Secretary

Michael C. Snabes, M.D., Ph.D.	62	Senior Vice President, Medical Affairs

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

Stephen M. Simes has served as our Vice Chairman, President and Chief Executive Officer and a director of our company since 1998. From 1994 to 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., (currently a wholly owned subsidiary of Abbott Laboratories) a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes'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 board of directors of Ceregene, Inc., a privately-held biotechnology company focused on the treatment of major neurodegenerative disorders.

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

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

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PART II

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

Market Price

Our common stock is listed for trading on the NASDAQ Global Market, under the symbol "BPAX." The following table sets forth the high and low daily sale prices for our common stock, as reported by the NASDAQ Global Market, for each calendar quarter during 2010 and 2009.

2010	High	Low
First Quarter	$ 2.081	$ 1.43
Second Quarter	$ 2.50	$ 1.75
Third Quarter	$ 1.76	$ 1.29
Fourth Quarter	$ 2.1685	$ 1.40

2009	High	Low
First Quarter	$ 2.33	$ 1.03
Second Quarter	$ 2.67	$ 1.30
Third Quarter	$ 2.70	$ 1.45
Fourth Quarter	$ 2.15	$ 1.33

Number of Record Holders; Dividends

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

Recent Sales of Unregistered Equity Securities

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

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

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

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

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

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2010. Our Board of Directors has not authorized any repurchase plan or program for the purchase of our shares of common stock or other securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

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Item 6. SELECTED FINANCIAL DATA

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

	Year Ended December 31,				
	2010	2009	2008	2007	2006
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue					
Licensing revenue	$ 116	$ —	$ 3,384	$ 199	$ 14,136
Grant revenue	52	116	65	59	247
Royalty revenue	2,306	1,142	34	69	—
Other revenue	—	—	298	166	55
Total revenue	2,474	1,258	3,781	493	14,438
Expenses					
Research and development	39,706	13,681	15,790	4,751	3,908
General and administration	5,940	5,374	5,125	4,331	4,550
Acquired in-process research and development	—	9,000	—	—	—
Excess consideration paid over fair value	—	20,192	—	—	—
Licensing expense	269	300	836	—	3,500
Depreciation and amortization	168	137	43	90	118
Total expenses	46,083	48,684	21,794	9,172	12,076
Other (expense) income — Convertible note fair value adjustment	(1,871)	33	—	—	—
Other expense — Investment impairment charge	(286)	—	—	—	—
Other expense — Interest expense	(688)	(147)	—	—	—
Other income	245	—	—	—	—
Other income — Interest income	13	12	588	1,095	429
Net (loss) income	$ (46,196)	$ (47,528)	$ (17,425)	$ (7,584)	$ 2,791
Basic and diluted net (loss) income per common share	$ (0.70)	$ (1.40)	$ (0.64)	$ (0.30)	$ 0.13
Weighted average number of common shares and common equivalent shares outstanding	65,912	33,952	27,307	25,486	21,484

	As of December 31,				
	2010	2009	2008	2007	2006
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 38,155	$ 29,858	$ 14,787	$ 30,655	$ 11,450

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

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Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings "Part I. Item 1. Business—Forward-Looking Statements" and "Part I. Item 1A. Risk Factors" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this report. This Management's Discussion and Analysis is organized in the following major sections:

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

Business Overview

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

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

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

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

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

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

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

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

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Summary of 2010 Financial Results and Outlook for 2011

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

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

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

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

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

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

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

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 2 to our financial statements included under the heading “Part II. Item 8. Financial Statements and Supplementary Data” of this report. The discussion and analysis of our financial statements and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amount of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. The Securities and Exchange Commission has defined a company’s most critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which requires the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified the critical accounting policies described below. Although we believe that our estimates and assumptions are reasonable, they are based upon information available when they are made. Actual results may differ significantly from these estimates under different assumptions or conditions.

Accounting Treatment Related to Acquisition of Assets and Liabilities of Cell Genesys

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

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

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

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

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

Results of Operations

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

	Year Ended December 31,		
	2010	2009	2008
Revenue	$ 2,474,237	$ 1,258,054	$ 3,780,829
Expenses	46,082,598	48,683,608	21,794,471
Research and development	39,705,502	13,680,573	15,789,980
General and administrative	5,940,360	5,373,945	5,124,934
Acquired in-process research and development	—	9,000,000	—
Excess consideration paid over fair value	—	20,192,194	—
Licensing expense	268,750	299,616	836,420
Other (expense) income — Convertible note fair value adjustment	(1,870,916)	33,163	—

Other expense — Investment impairment charge	(286,000)	—	—
Other expense — Interest expense	(688,083)	147,025	—
Other income	244,479	—	—
Other income — Interest income	12,665	11,648	588,464
Net loss	$ (46,196,216)	$ (47,527,768)	$ (17,425,178)
Net loss per common share (basic and diluted)	$ (0.70)	$ (1.40)	$ (0.64)
Weighted average number of common shares and common equivalent shares outstanding	65,911,750	33,951,652	27,307,494

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

Revenue increased $1.2 million in 2010 compared to 2009 primarily as a result of an increase in royalty and licensing revenue during 2010 compared to 2009. Of the $2.3 million in royalty revenue during 2010, $2.2 million resulted from our receipt of non-refundable upfront payments from Azur as a result of the December 2009 amendment to our license agreement. Pursuant to a separate agreement with Antares and related to the December 2009 amendment, we paid Antares an aggregate of $268,750 in February 2010. In addition, during 2010, we recorded royalty revenue of $152,228 and a corresponding amount of royalty expense, which is recorded within general and administrative expenses in our statements of operations, to reflect the Antares portion of the Elestrin royalty revenues, which revenues were not eliminated as a result of the December 2009 Azur license amendment. In October 2010, we received $244,479, the maximum per project, after LibiGel qualified for a grant under the Qualifying Therapeutic Discovery Project Program which was created in March 2010 as part of the Patient Protection and Affordability Care Act.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Liquidity and Capital Resources

The following table highlights several items from our balance sheets:

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

Liquidity

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

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

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

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

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

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

We expect our current cash and cash equivalent to meet our liquidity requirements through at least the next 15 to 18 months. These estimates may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. Exactly how long our current cash resources will last will depend upon several

factors, including the pace and timing of enrollment in the LibiGel safety study and perhaps more importantly, the number of women we will enroll in the safety study, which number cannot be determined at this time.

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

Committed Equity Financing Facility with Kingsbridge Capital Limited

In December 2010, we extended the term of our committed equity financing facility with Kingsbridge Capital Limited by one additional year. Under the facility, Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of our common stock through the end of December 2011. We are not obligated to utilize any of the $25.0 million available under the facility and there are no minimum commitments or minimum use penalties. We have access, at our discretion, to the funds through the sale of newly-issued shares of our common stock. The funds that can be raised under the facility will depend on the then-current price for our common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. We may access capital under the facility by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the facility unless certain conditions are met, which include a minimum price for our common stock of $1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of common stock issued or issuable to Kingsbridge; and the continued listing of our common stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the facility if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. Other than the issuance of a warrant to purchase 300,000 shares of our common stock at an exercise price of $4.00 per share in December 2008, attorneys' fees and other direct costs related to the registration of these shares, we did not make any other payments to secure or extend the term of the facility. The facility does not impose any material

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

Convertible Senior Notes Due November 2011 and May 2013

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

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

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

Uses of Cash and Cash Flow

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

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activities of $15.5 million for the year ended December 31, 2008. Net cash used in operating activities for 2010 was primarily the result of the net loss for that period, which was slightly higher compared to the prior year period due primarily to higher LibiGel Phase III clinical study related expenses, partially offset by an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses and other assets. Net cash used in operating activities for 2009 was primarily the result of the net loss for that period. Technology and transaction related expenses and charges of $29.2 million were incurred as a result of our merger with Cell Genesys in October 2009 but did not result in an operating cash payment by us as we issued shares as consideration for the transaction and cash payments for transaction costs were classified as a financing activity based on the nature of the transaction. Net cash used in operating activities for 2008 was primarily the result of the net loss for that period, and to a lesser extent, an increase in prepaid expenses and other assets related to an increase in our prepaid clinical study related costs, partially offset by an increase in accounts payable and accrued liabilities.

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

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

Commitments and Contractual Obligations

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

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

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Convertible Senior Notes	$ 22,016,000	$ 1,234,000	$ 20,782,000	$ 0	$ 0
Interest Payment Obligations Related to Convertible Senior Notes	1,547,490	681,573	865,917	0	0
Operating Lease	1,306,492	353,880	952,612	0	0
Commitments Under License Agreements with Johns Hopkins University	455,000	95,000	185,000	70,000	105,000
Commitments Under License Agreement with Massachusetts Institute of Technology	200,000	50,000	150,000	0	0
Commitments Under License Agreement with University of California	340,000	20,000	60,000	40,000	220,000
Commitments Under License Agreement with Wake Forest	720,000	280,000	240,000	120,000	80,000
Total Contractual Cash Obligations	$ 26,584,982	$ 2,714,453	$ 23,235,529	$ 230,000	$ 405,000

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Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

2010, and will be adopted by us in the fiscal year beginning January 1, 2011. The impact of ASU 2010-17 on our financial position, results of operations and cash flows is dependent on the nature and structure of our future arrangements.

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

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

With our participation, management evaluated the effectiveness of BioSante's internal control over financial reporting as of December 31, 2010. In making this evaluation, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework. Based on this assessment, management concluded that BioSante's internal control over financial reporting was effective as of December 31, 2010.

/s/ Stephen M. Simes	/s/ Phillip B. Donenberg
Stephen M. Simes	Phillip B. Donenberg
Vice Chairman, President and Chief Executive Officer	Senior Vice President of Finance, Chief Financial Officer and Secretary

March 16, 2011

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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
BioSante Pharmaceuticals, Inc.
Lincolnshire, Illinois

We have audited the internal control over financial reporting of BioSante Pharmaceuticals, Inc. (the "Company") as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2010 of the Company and our report dated March 16, 2011 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 16, 2011

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
BioSante Pharmaceuticals, Inc.
Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (the "Company") as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such financial statements present fairly, in all material respects, the financial position of BioSante Pharmaceuticals, Inc. as of December 31, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2011 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 16, 2011

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BIOSANTE PHARMACEUTICALS, INC.
Balance Sheets
December 31, 2010 and 2009

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

See accompanying notes to the financial statements.

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

	Year Ended December 31,		
	2010	2009	2008
REVENUE			
Licensing revenue	**$ 115,807**	**$ —**	**$ 3,384,091**
Grant revenue	**51,870**	**116,389**	**65,051**

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

See accompanying notes to the financial statements.

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

	Class C Special Shares		Common Stock		Accumulated	
	Shares	Amount	Shares	Amount	Deficit	Total
Balance, January 1, 2008	391,286	$ 391	26,794,607	$ 84,206,583	$ (54,481,482)	$ 29,725,492
Issuance of common shares Warrant exercises - various	—	—	248,157	379,720	—	379,720
Stock option expense	—	—	—	1,102,444	—	1,102,444
Stock warrant expense	—	—	—	104,284	—	104,284
Credit equity financing facility	—	—	—	(60,343)	—	(60,343)
Net loss	—	—	—	—	(17,425,178)	(17,425,178)
Balance, December 31, 2008	391,286	$ 391	27,042,764	$ 85,732,688	$ (71,906,660)	$ 13,826,419
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

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Statements of Cash Flows
Years ended December 31, 2010, 2009 and 2008

	Year Ended December 31,		
	2010	2009	2008
CASH FLOWS (USED IN) OPERATING ACTIVITIES			
Net loss	$ (46,196,216)	$ (47,527,768)	$ (17,425,178)
Adjustments to reconcile net loss to net cash (used in) operating activities			
Acquired in-process research and development	—	9,000,000	—
Excess consideration paid over fair value	—	20,192,194	—
Depreciation and amortization	167,986	137,280	43,137
Employee and director stock-based compensation	992,757	1,254,503	1,102,444
Stock warrant expense - noncash	65,529	64,103	104,284
Loss on disposal of equipment	4,583	—	—
Investment impairment charge	286,000	—	—
Other non-cash items	(65,807)	60,739	—
Convertible note fair value adjustment	1,870,916	(33,163)	—
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	(429,977)	(316,101)	(1,330,491)
Accounts receivable	64,645	285,838	(215,209)
Accounts payable and accrued liabilities	3,142,078	(1,548,535)	2,194,173
Deferred revenue	—	—	(9,091)
Net cash used in operating activities	(40,097,506)	(18,430,910)	(15,535,931)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES			
Redemption of short term investments	—	3,026,334	11,979,642
Proceeds from sale of fixed assets	3,075	—	—
Purchase of fixed assets	(63,441)	(165,724)	(651,116)
Net cash (used in) provided by investing activities	(60,366)	2,860,610	11,328,526
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Cash paid for transaction related costs	—	(2,431,252)	—
Cash received in transaction	—	24,746,346	—
Credit equity financing facility		—	(60,343)
Proceeds from common stock option exercises	2,014	—	—
Proceeds from common stock warrant exercises	—	—	379,720
Proceeds from issuance of common stock by registered direct offerings	48,452,644	11,352,751	—
Net cash provided by financing activities	48,454,658	33,667,845	319,377
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	8,296,786	18,097,545	(3,888,028)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,858,465	11,760,920	15,648,948
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 38,155,251	$ 29,858,465	$ 11,760,920
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Interest paid, including acquired accrued interest	$ 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	$ —	$ —	$ 152,019

See accompanying notes to the financial statements.

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

1. DESCRIPTION OF BUSINESS

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

On October 14, 2009, the Company acquired 100 percent of the common stock of Cell Genesys, Inc. (Cell Genesys) in a direct merger transaction, with the Company being the surviving corporation. The primary reason the Company merged with Cell Genesys was the Company's need for additional funding to continue its Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for the Company to

access capital prior to and at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been the Company's primary method for raising additional financing. Effective October 14, 2009, the balance sheet and net loss of the Company reflect the purchase price allocation and charges resulting from the purchase price allocation related to the merger, which included adjustments to carrying values of the acquired net assets based on their estimated fair values as of that date.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (generally accepted accounting principles). The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reclassifications

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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

Cash and Cash Equivalents

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

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

Short-Term Investments

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

Fair Value of Financial Instruments

The carrying value of certain of the Company's financial instruments, including cash equivalents, accounts receivable and accounts payable, approximate fair value due to their short maturities. Other information about the Company's assets and liabilities recorded at fair value is included in Note 15, "Fair Value Measurements."

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Property and Equipment

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

Long-Lived Assets

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

Convertible Senior Notes

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

Research and Development

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

Legal Costs

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

Basic and Diluted Net Loss Per Share

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

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Stock-Based Compensation

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

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue and are remeasured until the counterparty's performance under the arrangement is complete. Warrants of this nature to purchase an aggregate of 180,000 and 180,000 shares of the Company's common stock were issued in 2010 and 2009, respectively.

Revenue Recognition

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

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

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

Income Taxes

Deferred tax assets or liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates. A valuation allowance is provided against deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is not more likely than not. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2010 and 2009.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Investments

The investments balance of $3,405,807 as of December 31, 2010 and $3,626,000 as of December 31, 2009 consists of the Company's investments that are recorded using the cost method, and substantially represents the Company's investment in Ceregene, Inc., a privately held biotechnology company (Ceregene). As a result of the Company's merger with Cell Genesys, the Company acquired a minority investment in Ceregene. The Company has recorded its investment using the cost method, as no active market exists for this investment, and the Company does not possess significant influence over operating and financial policies of Ceregene, although the Company by virtue of its stock ownership of Ceregene has the right to designate one member on the Ceregene board of directors. During 2010, the Company recorded a $286,000 impairment on this investment. Such impairment was based on a recent third-party investment in Ceregene.

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

Recent Accounting Pronouncements

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

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

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3. LIQUIDITY AND CAPITAL RESOURCES

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

To date, the Company has used primarily equity financings, and to a lesser extent, licensing income, interest income and the cash received from its merger with Cell Genesys, to fund its ongoing business operations and short-term liquidity needs. During 2010, the Company completed three registered direct offerings resulting in net proceeds of approximately $48.5 million as more fully described in Note 9, "Stockholders' Equity." As of

December 31, 2010, the Company had $38.2 million of cash and cash equivalents. In March 2011, the Company completed an offering of an aggregate of 12,199,482 shares of our common stock and warrants to purchase an aggregate of 4,025,827 shares of our common stock, resulting in net proceeds of approximately $23.8 million, after deducting placement agent fees and other offering expenses. See Note 16, "Subsequent Event".

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

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

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

3. LIQUIDITY AND CAPITAL RESOURCES (continued)

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

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

4. ACQUISITION OF NET ASSETS OF CELL GENESYS

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

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

The total purchase price was allocated as follows:

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

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

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

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

5. LICENSE AGREEMENTS

Gel Products

The Company licensed the technology underlying LibiGel, Elestrin and certain of its other gel products, other than Bio-T-Gel, from Antares Pharma, Inc. (Antares). Under the agreement, Antares granted the Company an exclusive license to certain patents and patent applications covering these gel products, including rights to sublicense, in order to develop and market the products in certain territories. Under the agreement, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology and as such, the Company owed Antares $0 as of December 31, 2010 and $18,033 as of December 31, 2009 pursuant to this agreement. The patents covering the formulations used in these gel products are expected to expire in 2022. Bio-T-Gel was developed and is fully-owned by the Company and is not covered under the Antares license.

The Pill Plus

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

CaP Technology

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

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

5. LICENSE AGREEMENTS (continued)

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

Cancer Vaccine Technology

The Company owns development and commercialization rights to its cancer vaccine technology as a result of its transaction with Cell Genesys. The original core patent applications covering the cancer vaccine technology were licensed exclusively to Cell Genesys from Johns Hopkins University and The Whitehead Institute for Biomedical Research in 1992. Rights to additional patents and patent applications were licensed from Johns Hopkins University in 2001. The patents are expected to expire between 2012 and 2026. Under the various agreements, the Company is required to pay Johns Hopkins University and The Whitehead Institute for Biomedical Research certain development and regulatory milestone payments and royalties based on net sales of any products the Company or any sub-licensee sells incorporating the in-licensed technology.

Other License Agreements

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

6. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2010 and 2009 consists of the following:

	2010	2009
Computer equipment	**$ 417,840**	$ 432,625

Office equipment	**163,653**	143,548
Laboratory and equipment	**500,130**	518,775
	1,081,623	1,094,948
Accumulated depreciation and amortization	**(445,847)**	(346,969)
	$ 635,776	$ 747,979

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

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

7. CONVERTIBLE SENIOR NOTES

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

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

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

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

The Company has elected to record the Notes at fair value in order to simplify the accounting for the convertible debt, inclusive of the redemption, repurchase and conversion adjustment features which would otherwise require specialized valuation, bifurcation, and recognition. Accordingly, the Company has adjusted the carrying value of the Notes to their fair value as of December 31, 2010, with changes in the fair value of the Notes occurring since December 31, 2009, reflected in fair value adjustment in the statements of operations. The fair value of the Notes is based on Level 2 inputs. The recorded fair value of the Notes of an aggregate of $18,547,333 and $16,676,417 as of December 31, 2010 and 2009, respectively, differs from their total stated principal amount of $22,016,000 by $3,468,667 and $5,339,583 as of December 31, 2010 and 2009, respectively. The Company recorded fair value adjustments of ($1,870,916) and $33,163 related to the convertible senior notes for the years ended December 31, 2010 and 2009, respectively, to increase its recorded liability and corresponding expense in 2010 and reduce its recorded liability and corresponding expense in 2009.

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BIOSANTE PHARMACEUTICALS, INC.
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7. CONVERTIBLE SENIOR NOTES (continued)

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

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

The assumptions as of December 31, 2010 were:

	2013 Notes	2011 Notes
Average risk-free rate	0.82%	0.29%

Volatility of BioSante common stock	78.7%	61.0%
Discount rate for principal payments in cash	17.0%	17.0%

The assumptions as of December 31, 2009 were:

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

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

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

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

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8. INCOME TAXES

The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The only periods subject to examination by the major tax jurisdictions where the Company does business are the 2007 through 2010 tax years. The Company determined there are no uncertain tax positions existing as of December 31, 2010 or 2009.

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

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

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

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2010, the Company had approximately $123,401,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2018-2030. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, generate deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, the amount management believes is more likely than not to be realized. Additionally, the Company has provided a full valuation allowance against $5,796,148 of research and development credits, which are available to reduce future income taxes, if any, through the year 2030.

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

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

BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
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9. STOCKHOLDERS' EQUITY

Authorized and Outstanding Capital Stock

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

No shares of preferred stock were outstanding as of December 31, 2010 or 2009.

There were 391,286 shares of class C special stock issued and outstanding as of December 31, 2010 and 2009. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of the Company's common stock, at an exchange price of $2.50 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of the Company's assets upon any liquidation, dissolution or winding-up of the Company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

There were 81,391,130 and 53,262,568 shares of common stock issued and outstanding as of December 31, 2010 and 2009, respectively. The Company has presented the par values of its common stock and the related additional paid in capital on a combined basis for all periods presented.

Registered Direct Offerings

On March 8, 2010, the Company completed a registered direct offering of an aggregate of 10,404,626 shares of its common stock and warrants to an aggregate of 5,202,313 shares of its common stock, at a purchase price of $1.73 per share to funds affiliated with two institutional investors resulting in net proceeds to the Company of approximately $17.5 million, after deducting placement agent fees and other offering expenses. The warrants are exercisable beginning on September 9, 2010, have an exercise price of $2.08 per share and will expire on September 8, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 208,093 shares of the Company's common stock at an

BIOSANTE PHARMACEUTICALS, INC.
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9. STOCKHOLDERS' EQUITY (continued)

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

On June 23, 2010, the Company completed an offering of 7,134,366 shares of its common stock and warrants to purchase an aggregate of 3,567,183 shares of its common stock at a purchase price of $2.1025 per share to funds affiliated with certain institutional investors for gross proceeds of $15.0 million. The offering resulted in net proceeds to the Company of approximately $14.1 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately, have an exercise price of $2.45 per share and will expire on June 23, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 214,031 shares of the Company's common stock at an exercise price of $2.63 per share, which warrants are exercisable immediately and will expire on June 9, 2015.

On December 31, 2010, the Company completed an offering of 10,588,236 shares of its common stock and warrants to purchase an aggregate of 5,294,118 shares of its common stock at a purchase price of $1.70 per share to funds affiliated with certain institutional investors for gross proceeds of $18.0 million. The offering resulted in net proceeds to the Company of approximately $16.9 million, after deducting placement agent fees and offering expenses. The warrants are exercisable immediately, have an exercise price of $2.00 per share and expire on December 30, 2015. In connection with the offering, the Company issued the placement agent warrants to purchase an aggregate of 317,647 shares of the Company's common stock at an exercise price of $2.125, which warrants are exercisable immediately and will expire on June 9, 2015.

Acquisition of Net Assets of Cell Genesys

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

were converted into and became warrants to purchase shares of the Company's common stock on terms substantially identical to those in effect prior to the merger, except for

9. STOCKHOLDERS' EQUITY (continued)

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

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

Convertible Senior Notes

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

Committed Equity Financing Facility

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

9. STOCKHOLDERS' EQUITY (continued)

Warrants

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

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

During 2010, the Company issued warrants to purchase 14,803,385 shares of the Company's common stock in connection with registered direct offerings as described above, and warrants to purchase 180,000 shares of the Company's common stock as compensation for investor relations

services as described below. During 2010, no warrants were exercised and warrants to purchase 763,750 shares of the Company's common stock expired unexercised.

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

During 2008, the Company issued warrants to purchase 300,000 shares of the Company's common stock in connection with the CEFF, and warrants to purchase 80,000 shares of the Company's common stock as compensation for investor relations services as described below. Warrants to purchase an aggregate of 176,614 shares of common stock were exercised for total cash proceeds of $379,720. Warrants to purchase an aggregate of 71,543 shares of common stock were exercised on a cashless basis, for which warrants to purchase 74,957 shares of common stock were cancelled by the Company in payment of the exercise price for the exercised warrants. During 2008, warrants to purchase 500 shares of the Company's common stock expired unexercised.

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9. STOCKHOLDERS' EQUITY (continued)

In 2010, 2009 and 2008, the Company issued warrants to purchase 180,000, 180,000 and 80,000 shares of the Company's common stock, respectively, in consideration for various investor relations services. The warrants became exercisable on a ratable basis over a twelve-month period. With respect to the warrants issued in 2008, the Company terminated its relationship with the investor relations firm effective March 31, 2009, at which time 66,667 of the warrants were exercisable, and such warrants remain outstanding at December 31, 2010. The Company uses the Black-Scholes pricing model to value these types of warrants and remeasures the awards each quarter until the measurement date is established. For the years ended December 31, 2010, 2009 and 2008, the Company recorded $65,529, $64,103 and $104,284, respectively, in non-cash general and administrative expense pertaining to consultant warrants.

10. STOCK-BASED COMPENSATION

As of December 31, 2010, the Company has two stockholder-approved equity-based compensation plans under which stock options have been granted — the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan except with respect to options outstanding under the 1998 Plan. As of December 31, 2010, the number of shares of the Company's common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan, was 4,000,000 plus the number of shares subject to options outstanding under the 1998 Plan as of the effective date of the 2008 Plan but only to the extent that such outstanding options are forfeited, expire or otherwise terminate without the issuance of such shares. Of such authorized shares, 1,334 shares had been issued and 1,660,916 shares were subject to outstanding stock options as of December 31, 2010. Outstanding employee stock options generally vest over a period of three years and for more recent 2011 grants, four years, and have 10-year contractual terms. Upon exercise of an option, the Company issues new shares. From time to time, the Company grants employee stock options that have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. None of these options were outstanding as of December 31, 2010. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 Plan and the 2008 Plan was $992,757, $1,254,503 and $1,102,444 for the years ended December 31, 2010, 2009 and 2008, respectively. No income tax benefit was recognized in the Company's statements of operations for stock-based compensation arrangements due to the Company's net loss position.

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10. STOCK-BASED COMPENSATION (continued)

The weighted average fair value of the options at the date of grant for options granted during 2010, 2009 and 2008 was $1.11, $1.04 and $2.41, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

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

The Company uses the simplified method to estimate the life of options meeting certain criteria. The risk-free interest rate used is the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company calculated a volatility rate based on the closing price for its common stock at the end of each calendar month as reported by the NASDAQ Global Market. The Company has

not in the past issued a cash dividend nor does it have any current plans to do so in the future and therefore, an expected dividend yield of zero was used.

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

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

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

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2009	3,006,120	$ 4.24
Granted	758,750	$ 1.64
Exercised	1,334	$ 1.51
Forfeited or expired	46,100	$ 1.57
Outstanding December 31, 2010	3,717,436	$ 3.69
(weighted average contractual term)	*6.74*	
Exercisable at December 31, 2010	2,228,853	4.91
(weighted average contractual term)	*5.46*	

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

10. STOCK-BASED COMPENSATION (continued)

As of December 31, 2010, there was $914,412 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plans. The cost is expected to be recognized over a weighted-average period of 1.81 years.

The intrinsic value of options exercised during the years ended December 31, 2010 was $974. No stock options were exercised during 2009 or 2008. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position. The total fair value of shares vested during the years ended December 31, 2010, 2009 and 2008 was $764,921, $788,461 and $659,898, respectively.

11. RETIREMENT PLAN

The Company offers a discretionary 401(k) Plan to all of its employees. Under the 401(k) Plan, employees may defer income on a tax-exempt basis, subject to IRS limitation. Under the 401(k) Plan, the Company can make discretionary matching contributions. Company contributions expensed in 2010, 2009 and 2008 totaled $179,349, $117,969 and $108,019, respectively.

12. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space which expires in 2014. The future minimum lease payments during 2011, 2012 and 2013 are $353,880, $421,910 and $454,270, respectively.

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

13. COMMITMENTS

Antares Pharma, Inc. License

The Company's license agreement with Antares Pharma, Inc. requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. In 2010, 2009 and 2008, the Company paid or accrued $152,228, $63,749 and $21,830, respectively, to Antares as a result of royalties generated by Elestrin revenues. Pursuant to a separate agreement

with Antares and related to the December 2009 Azur license amendment, the Company paid Antares an aggregate of $268,750 in February 2010, which is recorded in licensing expense. In 2008, the Company also paid $462,500 to Antares as a result of the Azur license of Elestrin.

Wake Forest License

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

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

Year	Minimum Amount Due
2011	80,000
2012	80,000
2013	80,000
2014	80,000
2015	80,000
Thereafter	120,000

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

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

14. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

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

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

information, compared to the income based valuation technique at inception. As of December 31, 2010, the investment continues to be recorded at $3,200,000.

14. FAIR VALUE MEASUREMENTS (continued)

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

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

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

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

15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2010 and 2009 is as follows:

	2010			
	First	Second	Third	Fourth
Revenue	$ 2,279,874	$ —	$ 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	—	—	—
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)

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

16. SUBSEQUENT EVENT

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Management's Report on Internal Control Over Financial Reporting

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

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

Change in Internal Control Over Financial Reporting

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

Item 9B. OTHER INFORMATION

Not applicable.

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PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

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

Executive Officers

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

Code of Conduct and Ethics

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

Changes to Nomination Procedures

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

Audit Committee Matters

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

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Item 11. EXECUTIVE COMPENSATION

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

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

Stock Ownership

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table and notes provide information about shares of our common stock that may be issued under all of our equity compensation plans as of December 31, 2010. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan are within the discretion of the Compensation Committee of our Board of Directors and our Board of Directors; and therefore, cannot be ascertained at this time.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,483,007(1)(2)	$ 2.61	2,337,750(3)
Equity compensation plans not approved by security holders	234,429	$ 19.73	0
Total	3,717,436	$ 3.69	2,337,750

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

(2) Excludes options assumed by us in connection with our merger with Cell Genesys, Inc. As of December 31, 2010, a total of 234,429 shares of our common stock were issuable upon exercise of the assumed options. The weighted average exercise price of the outstanding assumed options as of such date was $19.73 per share and they have an average weighted life remaining of 5.4 years. All of the options assumed and outstanding in

connection with our merger with Cell Genesys were exercisable as of December 31, 2010. No additional options, restricted stock units or other equity incentive awards may be granted under the assumed Cell Genesys, Inc. plans.

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(3) As of December 31, 2010, these shares remain available for future issuance under the 2008 Plan. Under the terms of the 2008 Plan, any shares of our common stock subject to outstanding awards under the 1998 Plan as of the approval of the 2008 Plan by our stockholders on June 11, 2010 that are forfeited, expired or otherwise terminated become available for issuance under the 2008 Plan. No awards will be granted or shares issued under the 1998 Plan except upon the exercise of options outstanding as of the effective date of the 2008 Plan.

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

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Our financial statements are included in Item 8 of Part II of this report.

The exhibits to this report are listed on the Exhibit Index to this report. A copy of any of the exhibits listed will be furnished at a reasonable cost, upon receipt from any person of a written request for any such exhibit. Such request should be sent to BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, Attn: Stockholder Information.

The following is a list of each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K pursuant to Item 15(a):

A. Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes (incorporated by reference to Exhibit 10.1 to BioSante's current report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)).

B. Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg (incorporated by reference to Exhibit 10.2 to BioSante's current report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)).

C. Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc. (filed herewith).

D. Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes (filed herewith).

E. BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 contained in BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)).

F. Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 contained in BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)).

G. Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 contained in BioSante's current report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)).

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

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

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

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

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

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

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

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

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

SIGNATURES

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

Dated: March 16, 2011

BIOSANTE PHARMACEUTICALS, INC.

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

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

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

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

John T. Potts, Jr., M.D.		
/S/ EDWARD C. ROSENOW, III, M.D. Edward C. Rosenow, III, M.D.	Director	March 16, 2011
/S/ STEPHEN A. SHERWIN, M.D. Stephen A. Sherwin, M.D.	Director	March 16, 2011

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BIOSANTE PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2010

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)
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

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Exhibit No.	Exhibit	Method of Filing
		the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
3.2	Amended and Restated Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
4.1	Indenture, dated as of October 20, 2004, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to Cell Genesys's Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on December 29, 2004 (File No. 000-19986)
4.2	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of October 20, 2004, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2011	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)

4.3	Indenture, dated as of June 24, 2009, between Cell Genesys, Inc. and U.S. Bank National Association, as trustee	Incorporated by reference to Exhibit 4.1 to Cell Genesys's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 29, 2009 (File No. 000-19986)
4.4	Supplemental Indenture dated as of October 14, 2009 to Indenture dated as of June 24, 2009, by and between BioSante Pharmaceuticals, Inc. and U.S. Bank National Association, Relating to Cell Genesys, Inc. 3.125% Convertible Senior Subordinated Notes due 2013	Incorporated by reference to Exhibit 4.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 14, 2009 (File No. 001-31812)
4.5	Form of Warrant dated as of July 21, 2006 issued by BioSante Pharmaceuticals, Inc. to each of the Subscribers Party to the Subscription Agreements dated July 7, 2006	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 24, 2006 (File No. 001-31812)
4.6	Warrant dated December 15, 2008 issued by BioSante Pharmaceuticals, Inc. to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with

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Exhibit No.	Exhibit	Method of Filing
		the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
4.7	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the August 2009 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
4.8	Form of Replacement Warrant issued to Investors in Cell Genesys, Inc.'s April 2007 Registered Direct Offering	Incorporated by reference to Exhibit 4.9 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
4.9	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to Investors and the Placements Agent in the March 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
4.10	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the June 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
4.11	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placements Agent in the December 2010 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)
4.12	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placement Agent in the March 2011 Registered Direct Offering	Incorporated by reference to Exhibit 4.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 18, 2008

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Exhibit No.	Exhibit	Method of Filing
		(File No. 001-31812)
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed

		with the Securities and Exchange Commission on July 18, 2008 (File No. 001-31812)
10.3	Offer Letter dated April 1, 2008 to Michael C. Snabes from BioSante Pharmaceuticals, Inc.	Filed herewith
10.4	Change in Control and Severance Agreement effective as of July 16, 2008 between BioSante Pharmaceuticals, Inc. and Michael C. Snabes	Filed herewith
10.5	BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
10.6	Form of Incentive Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
10.7	Form of Non-Statutory Stock Option Agreement under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 11, 2010 (File No. 001-31812)
10.8	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.4 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)

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

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Exhibit No.	Exhibit	Method of Filing

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

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Exhibit No.	Exhibit	Method of Filing
10.23	Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 21, 2008 (File No. 001-31812)
10.24	Seventh Amendment to Lease dated as of November 17, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.22 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.25	Eighth Amendment to Lease dated as of September 8, 2009 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.23 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)
10.26	Ninth Amendment to Lease dated as of January 19, 2011 by and between 111 Barclay Associates, the sole beneficiary under Chicago Title Land Trust Company, as successor trustee to LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 27, 2011 (File No. 001-31812)
10.27	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.28	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.29	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.19 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.30	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.31	Amendment No. 4 to the License Agreement, dated August 8, 2002, between	Filed herewith

Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)

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Exhibit No.	Exhibit	Method of Filing
10.32	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Filed herewith
10.33	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.34	License Agreement dated December 3, 2008 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (3)	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.35	Amendment No. 1 to License Agreement and Asset Purchase Agreement dated December 7, 2009 between BioSante Pharmaceuticals, Inc. and Azur Pharma International II, Limited (3)	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.36	Form of Subscription Agreement dated as of July 7, 2006 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 10, 2006 (File No. 001-31812)
10.37	Form of Subscription Agreement dated as of May 25, 2007 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 25, 2007 (File No. 001-31812)
10.38	Common Stock Purchase Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.39	Amendment No. 1 to Common Stock Purchase Agreement dated as of March 24, 2010 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.39 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 (File No. 001-31812)

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Exhibit No.	Exhibit	Method of Filing
10.40	Amendment No. 2 to Common Stock Purchase Agreement dated as of December 15, 2010 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 23, 2010 (File No. 001-31812)
10.41	Registration Rights Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.2 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.42	Amendment to Registration Rights Agreement dated as of dated as of June 26, 2009 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.3 to BioSante's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2009 (File No. 001-31812)
10.43	Form of Securities Purchase Agreement, dated August 13, 2009, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 14, 2009 (File No. 001-31812)
10.44	Form of Securities Purchase Agreement, dated March 4, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
10.45	Form of Securities Purchase Agreement, dated June 20, 2010, by and between	Incorporated by reference to Exhibit 10.1 to

	BioSante Pharmaceuticals, Inc. and each of the investors in the June 2010 registered direct offering	BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
10.46	Form of Securities Purchase Agreement, dated December 27, 2010, by and between BioSante Pharmaceuticals, Inc. and each of the investors in the December 2010 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)

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Exhibit No.	Exhibit	Method of Filing
10.47	Form of Common Stock Purchase Warrant Issued by BioSante Pharmaceuticals, Inc. to the Investors and the Placement Agent in the March 2011 registered direct offering	Incorporated by reference to Exhibit 10.1 to BioSante's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 4, 2011 (File No. 001-31812)
14.1	Code of Conduct and Ethics	Incorporated by reference to Exhibit 14.1 to BioSante's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
23.1	Consent of Deloitte & Touche LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

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

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

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

111 Barclay Boulevard
Lincolnshire, Illinois 60069
Tel: (847) 478-0500 ext. 100
ssimes@biosantepharma.com

Stephen M. Simes
President and CEO

April 1, 2008

Michael C. Snabes
1255 Spruce Street
Winnetka, IL 60093

Dear Mike:

On behalf of BioSante Pharmaceuticals, Inc. (the "Company" or "BioSante"), I am very pleased to offer you employment on the terms and conditions set forth in this letter. We look forward to working with you, continuing to build a successful pharmaceutical company and increasing stockholder value.

The terms of your employment will be as follows, subject to the approval of the BioSante Board of Directors:

1. Title: Vice President, Clinical Development. The "job description" will be a continuation of our working relationship over the last two years; (more job "definition" attached).

2. You will report directly to me, Stephen M. Simes, President and Chief Executive Officer.

3. This position with BioSante is a full-time, on-site-Lincolnshire position and you agree that you will spend substantially all of your business hours on site, on the Company's business.

4. Your annual base salary will be $315,000, less applicable tax withholdings, paid in accordance with Company's normal payroll practices. (This salary is consistent with the same job at "peer" companies).

5. You will be eligible for an annual bonus of up to 30% of your annual base salary, based upon milestones to be defined at a later date. (The only person at higher than 30% is the CEO. Further, the amount at peer companies is 28% for this position). The amount, manner, and time of payment of the bonus will be at the discretion of management with board of directors' concurrence and will not be guaranteed. You must be employed on the date the bonus is paid to be eligible.

6. You will be entitled to 15 days of paid vacation annually.

7. You will receive a monthly car allowance of $600.

8. You will receive reimbursement for reasonable monthly cell phone charges in the range of about $100 per month.

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9. You will be eligible to enroll and participate in the Company's health, life, disability and dental plans under the terms of those plans as in effect from time to time.

10. You will be entitled to participate in the Company's 401(k) plan under the terms of that plan as in effect from time to time, as well as receive any company matching contribution as determined on an annual basis (currently 50% of employee contribution).

11. Subject to the approval of the Company's Board of Directors, you will be granted a ten-year stock option to purchase 100,000 shares of BioSante common stock, (in addition to the 50,000 you already hold; this is consistent with our peer companies), at an exercise price equal to the fair market value of a share of BioSante's common stock on the date of grant. The date of grant will be the first day of your employment or the date the option is approved by the Board of Directors, whichever date occurs later. The option will vest in three equal annual installments over three years from the date of grant. The option will be granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan and will be subject to the terms and conditions of that plan. The option will be an "incentive stock option" under Section 422 of the Internal Revenue Code, to the extent it is eligible.

12. Your employment at BioSante will be "at will" meaning that your employment may be terminated by you or BioSante at any time, with or without cause, with or without notice, and for any reason not prohibited by law. This offer of employment should not be construed as a contract, express or implied, guaranteeing your employment for any specific duration. If your employment is terminated by BioSante for "cause" (as defined below), you will be entitled to receive your base salary through the date of your termination to be paid in accordance with the Company's normal payroll practices. If your employment is terminated by BioSante without cause and other than in connection with your death or disability, you will be entitled to receive severance pay in an amount equal to six months of your base salary at the time of your termination. This severance will be paid, in accordance with the Company's normal payroll practices, less applicable tax withholdings, in the form of salary continuation over a six-month period starting with your termination date. Severance will not commence or be paid to you until you have executed and not rescinded, within the time permitted by law, a Release of claims in a form acceptable to the Company, prepared by the Company, and presented to you and as a condition of receiving severance pay. If your employment is terminated by the Company without cause other than in connection with your death or disability either as a condition to or within one year of a "change in control" (as defined in the Company's stock plan) of the Company, you will be entitled to receive a severance payment in an amount equal to six months of your base salary to be paid over a six month period, subject to the same conditions noted above. For this purpose, "cause" includes, but is not limited to, any of the following: (1) dishonesty or fraud, (2) theft or embezzlement of the

Company's assets, (3) any unlawful or criminal activity of a serious nature, (4) breach of any terms of your Employee Confidentiality and Assignment of Inventions Agreement referred to below; (5) failure to carry out the duties of your position in a competent manner; or (6) failure to comply with the Company's policies and procedures. Whether any of the above events have occurred shall be determined in the complete and sole discretion of the Company.

13. You are also eligible to receive up to $50 per month health club reimbursement and to participate in the BioSante Flex Spending (medical and dependent reimbursement) Program.

This offer of employment is conditioned upon each of the following: (i) your proving your eligibility to work in the United States by way of completion of the I-9 Form; and (ii) your execution of the enclosed Employee Confidentiality and Assignment of Inventions Agreement prior to commencing employment with BioSante.

Please note that the enclosed Employee Confidentiality and Assignment of Inventions Agreement includes confidentiality, assignment of inventions, non-solicitation, non-interference and other provisions and covenants which, among other things, restrict you from engaging in certain activities during and after termination of your employment with BioSante. I am sure you understand that these provisions are necessary to protect BioSante's investment in its confidential information, trade secrets, employee, customer and other third party relationships, and goodwill. Please also note that by signing this offer letter and the enclosed Employee Confidentiality and Assignment of Inventions Agreement you hereby represent that you are not bound by any commitments to third parties that would prevent you from accepting the position described in this offer letter.

Mike, we trust that these terms are acceptable to you and we look forward to you joining our effort on a full time basis commencing as soon as you are able but no later than April 16, 2008, and hope the opportunity will be mutually rewarding. To confirm that you agree to the terms stated in this letter, please sign and date both copies of this letter and return them to me no later than April 4, 2008. Congratulations and welcome!

Kind regards,

/s/ Stephen M. Simes

Stephen M. Simes
President and Chief Executive Officer

Accepted and agreed:

/s/ Michael C. Snabes	April 2, 2008
Michael C. Snabes	Date

CHANGE OF CONTROL AND SEVERANCE AGREEMENT

This Change of Control and Severance Agreement (this "Agreement"), effective as of July 16, 2008, is between BioSante Pharmaceuticals, Inc., a Delaware corporation (the "Company"), located at 111 Barclay Boulevard, Suite 280, Lincolnshire, Illinois 60069 and Michael C. Snabes, M.D., Ph.D. (the "Employee").

A. The Board considers the operation of the Company to be of critical importance to the Company and therefore the establishment and maintenance of a sound and vital management team of the Company is essential to protecting and enhancing the best interests of the Company and its stockholders.

B. In this connection, the Board recognizes that the possibility of a Change in Control may arise and that such possibility and the uncertainty and questions which such transaction may raise among key personnel of the Company could result in the departure or distraction of such personnel to the detriment of the Company and its stockholders.

C. The Board has determined that appropriate steps should be taken to minimize the risk that key personnel of the Company will depart prior to a Change in Control, thereby leaving the Company without adequate key personnel during such a critical period, and to reinforce and encourage the continued attention and dedication of such key personnel to their assigned duties without distraction in circumstances arising from the possibility of a Change in Control.

D. The Board also recognizes that circumstances may arise whereby the Employee's employment is terminated other than in connection with a Change in Control.

E. The Board recognizes that the continuance of the Employee's position with the Company involves a substantial commitment to the Company in terms of the Employee's personal life and professional career and the possibility of foregoing present and future career opportunities, for which the Company receives substantial benefits.

F. To induce the Employee to remain in the employ of the Company, this Agreement, which has been approved by the Board, sets forth the benefits that the Company agrees will be provided to the Employee in the event the Employee's employment with the Company is terminated in connection with a Change in Control or other than in connection with a Change in Control under the circumstances described below

G. The Employee is entitled to certain severance benefits as provided in that certain letter agreement dated April 1, 2008 between the Company and the Employee (the "Prior Agreement") and it is the intention of the parties hereto that this Agreement supersede and replace the obligations of the Company to provide the Employee severance benefits under such Prior Agreement.

H. The Company and the Employee intend that the benefits provided under this Agreement be exempt from the requirements of Section 409A of the Code by reason of the separation pay exception under Treas. Reg. § 1.409A-1(b)(9) or the short term deferral exception under Treas. Reg. § 1.409A-1(b)(4) and this Agreement will be construed and administered in a manner that is consistent with and gives effect to such intention.

I. Certain capitalized terms that are used in this Agreement are defined in Exhibit A, which is an integral part of this Agreement.

Accordingly, the Company and the Employee each intending to be legally bound, agree as follows:

1. Term of Agreement. This Agreement is effective immediately and will continue in effect only so long as the Employee remains employed by the Company. This Agreement will automatically terminate upon the Employee's Termination of Employment with the Company, except for a Termination of Employment contemplated by Section 2 or 3, in which case this Agreement will remain in effect until the date on which the Company's obligations to the Employee arising under or in connection with this Agreement have been satisfied in full.

2. Benefits upon a Change in Control Termination. The Employee will become entitled to the benefits described in this Section 2 on account of a Termination of Employment if and only if (i) the Employee's Termination of Employment is by the Company for any reason other than for Cause and other than the Employee's death or disability, or by the Employee for Good Reason, and (ii) the Termination of Employment occurs either within the period beginning on the date of a Change in Control and ending on the 12th month anniversary date of the Change in Control or prior to a Change in Control if the Employee's Termination of Employment was either a condition of the Change in Control or was at the request or insistence of a Person related to the Change in Control. Any benefits payable pursuant to this Section 2 will be in addition to regular earned pay and accrued vacation benefits, if any, payable to the Employee upon a Termination of Employment.

(a) Cash Payment. The Company will make a lump-sum cash payment to the Employee in an amount equal to the sum of: (i) one-half times the Employee's Base Pay, plus (ii) 100% of the Employee's target bonus (30% of Base Pay) established for the year during which the Change in Control occurs, not more than 10 days following the date of the Employee's Termination of Employment and the Employee's right to rescind the Release referred to below has expired or, if later, not more than 10 days following the date of the Change in Control.

(b) Outplacement Services. The Company shall provide the Employee with reasonable outplacement services at a qualified agency selected by the Employee up to a maximum amount of $15,000 for up to one year following the Employee's Termination of Employment (unless the Employee becomes otherwise employed within such period).

(c) Release. As a condition to receiving benefits under this Section 2, the Employee must within twenty (20) days following the Employee's Termination of Employment sign and not revoke a separation agreement and Release in the form provided to the Employee by the Company within five (5) days of the Employee's Termination of Employment. No amount shall be provided or paid pursuant to this Section 2 if the Employee revokes the Release prior to the payment pursuant to this Section 2 unless the Company has waived the requirement of the separation agreement and Release.

3. Benefits upon a Termination Outside a Change in Control. The Employee will become entitled to the benefits described in this Section 3 on account of a Termination of Employment if and only if the Company terminates the Employee's employment for any reason other than for Cause and other than upon the death or disability of the Employee and other than as provided in Section 2. Any benefits payable pursuant to this Section 3 will be in addition to regular earned pay and accrued vacation benefits, if any, payable to the Employee upon a Termination of Employment. The Company will make cash payments to the Employee in an aggregate amount equal to one-half times the Employee's Base Pay. Such payments will be paid in accordance with the Company's normal payroll practices, in the form of salary continuation over a six-month period commencing not more than ten (10) days following the date of the Employee's Termination of Employment and the Employee's right to rescind the Release as described below has expired. As a condition to receiving the payments under this Section 3, the Employee must within twenty (20) days following the Employee's Termination of Employment sign and not revoke a separation agreement and Release in the form provided to the Employee by the Company within five (5) days of the Employee's Termination of Employment. No amounts shall be paid pursuant to this Section 3 if the Employee revokes the Release prior to the commencement of payments pursuant to this Section 3 unless the Company has waived the requirement of the separation agreement and Release.

4. Limitation on Payments. Notwithstanding any other provisions of this Agreement or any other agreement, contract or understanding heretofore or hereafter entered into between the Employee and the Company, if any "payments" (including, without limitation, any benefits or transfers of property or the acceleration of the vesting of any benefits) in the nature of compensation under any arrangement that is considered contingent on a Change in Control for purposes of Section 280G of the Code, together with any other payments that the Employee has the right to receive from the Company or any corporation that is a member of an "affiliated group" (as defined in Section 1504(a) of the Code without regard to Section 1504(b) of the Code) of which the Company is a member, would constitute a "parachute payment" (as defined in Section 280G(b)(2) of the Code), such "payments" will be reduced to the largest amount as will result in no portion of such "payments" being subject to the excise tax imposed by Section 4999 of the Code; provided, however, that such reduction shall be made only if the aggregate amount of the payments after such reduction exceeds the difference between (A) the amount of such payments absent such reduction minus (B) the aggregate amount of the excise tax imposed under Section 4999 of the Code attributable to any such excess parachute payments. The parachute payments to be reduced under this Agreement will be reduced in the following order: outplacement benefits, lump sum cash severance and option acceleration.

5. Indemnification. Following a Change in Control, the Company will indemnify and advance expenses to the Employee for damages, costs and expenses (including, without limitation, judgments, fines, penalties, settlements and reasonable fees and expenses of the Employee's counsel) (the "Expenses") incurred in connection with all matters, events and transactions relating to the Employee's service to or status with the Company or any other corporation, Benefit Plan or other Person for which the Employee served at the request of the Company to the extent that the Company would have been required to do so under applicable law, corporate articles, bylaws or agreements or instruments of any nature with or covering the Employee, including any indemnification agreement between Company and the Employee, as in effect immediately prior to the Change in Control and to any further extent as may be determined

or agreed upon following the Change in Control.

6. Miscellaneous.

(a) Binding Agreement. This Agreement inures to the benefit of, and is enforceable by, the Employee, the Employee's personal and legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If the Employee dies while employed by the Company or while any amount would still be payable to the Employee under this Agreement if the Employee had continued to live, all such amounts, unless otherwise provided in this Agreement, will be paid in accordance with the terms of this Agreement to the Employee's devisee, legatee or other designee or, if there be no such designee, to the Employee's estate.

(b) No Mitigation. The Employee will not be required to mitigate the amount of any benefits the Company becomes obligated to provide to the Employee in connection with this Agreement by seeking other employment or otherwise. The benefits to be provided to the Employee in connection with this Agreement may not be reduced, offset or subject to recovery by the Company by any benefits the Employee may receive from other employment or otherwise.

(c) No Setoff. The Company has no right to setoff benefits owed to the Employee under this Agreement against amounts owed or claimed to be owed by the Employee to the Company under this Agreement or otherwise.

(d) Taxes. All benefits to be provided to the Employee in connection with this Agreement will be subject to required withholding of federal, state and local income, excise and employment-related taxes. The Company's good faith determination with respect to its obligation to withhold such taxes relieves it of any obligation that such amounts should have been paid to the Employee.

(e) Notices. For the purposes of this Agreement, notices and all other communications provided for in, or required under, this Agreement must be in writing and will be deemed to have been duly given when personally delivered or when mailed by United States registered or certified mail, return receipt requested, postage prepaid and addressed to each party's respective address set forth on the first page of this Agreement (provided that all notices to the Company must be directed to the attention of the President), or to such other address as either party may have furnished to the other in writing in accordance with these provisions, except that notice of change of address will be effective only upon receipt.

(f) Disputes. If the Employee so elects, any dispute, controversy or claim arising under or in connection with this Agreement will be settled exclusively by binding arbitration administered by the American Arbitration Association in Chicago, Illinois in accordance with the Commercial Arbitration Rules of the American Arbitration Association then in effect; provided that the Employee may seek specific performance of the Employee's right to receive benefits under Section 2 of this Agreement until the date of termination during the pendency of any dispute or controversy arising under or in

connection with this Agreement. Judgment may be entered on the arbitrator's award in any court having jurisdiction. If any dispute, controversy or claim for damages arising under or in connection with this Agreement is settled by arbitration, the Company will pay, or if elected by the Employee, reimburse, all fees, costs and expenses incurred by the Employee related to such arbitration unless the arbitrators decide that the Employee's claim was frivolous or advanced by the Employee in bad faith. If the Employee does not elect arbitration, the Employee may pursue all available legal remedies.

(g) Effect of Benefits on Other Severance Plans. In the event the Employee receives any payment under the terms of this Agreement, the Employee will not be eligible to receive benefits under any other severance pay plan sponsored or maintained by the Company or agreement to which the Employee is a party. For the avoidance of doubt, the Employee will not be paid the payments and benefits set forth in the Prior Agreement to the extent that the Employee receives any payment under the terms of this Agreement.

(h) Related Agreements and Other Arrangements. This Agreement, including Exhibit A attached hereto and incorporated as an integral part of this Agreement, constitutes the entire agreement of the parties with respect to the subject matter hereof, and no agreements or representations, oral or otherwise, express or implied, with respect to the subject matter to this Agreement have been made by any party which are not expressly set forth in this Agreement. To the extent that any provision of any Other Arrangement limits, qualifies or is inconsistent with any provision of this Agreement, then for purposes of this Agreement, while such Other Arrangement remains in force, the provision of this Agreement will control and such provision of such Other Arrangement will be deemed to have been superseded, and to be of no force or effect, as if such Other Arrangement had been formally amended to the extent necessary to accomplish such purpose. Nothing in this Agreement prevents or limits the Employee's continuing or future participation in any Other Arrangement for which the Employee may qualify, and nothing in this Agreement limits or otherwise affects the rights the Employee may have under any Other Arrangement. Amounts that are vested benefits or which the Employee is otherwise entitled to receive under any Other Arrangement at or subsequent to the date of termination will be payable in accordance with such Other Arrangement.

(i) No Employment or Service Contract. Nothing in this Agreement is intended to provide the Employee with any right to continue in the employ of the Company for any period of specific duration or interfere with or otherwise restrict in any way the Employee's rights or the rights of the Company.

(j) Payment; Assignment. Benefits payable under this Agreement will be paid only from the general assets of the Company. No Person has any right to or interest in any specific assets of the Company by reason of this Agreement. To the extent benefits under this Agreement are not paid when due to any individual, he or she is a general unsecured creditor of the Company with respect to any amounts due. Benefits payable pursuant to this Agreement and the right to receive future benefits may not be anticipated, alienated, sold, transferred, assigned, pledged, encumbered or subject to any charge.

(k) Late Payments. Benefits not paid under Section 2 or Section 3 of this Agreement when due will accrue interest at the rate of 10% per year, or, if lesser, the maximum rate permitted under applicable law, and shall be paid on the 5th day of the month next following the month during which such interest accrued.

(l) Survival. The respective obligations of, and benefits afforded to, the Company and the Employee which by their express terms or clear intent survive termination of the Employee's employment with the Company or termination of this Agreement, as the case may be, will survive termination of the Employee's employment with the Company or termination of this Agreement, as the case may be, and will remain in full force and effect according to their terms.

(m) Amendments; Waivers. No provision of this Agreement may be modified, waived or discharged unless such modification, waiver or discharge is specifically agreed to in a writing that makes express reference to this Agreement as the subject of such amendment, waiver or discharge and is manually signed by the Employee and a duly authorized officer of the Company. No waiver by any party to this Agreement at any time of any breach by another party to this Agreement of, or of compliance with any condition or provision of this Agreement to be performed by such party will be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

(n) Governing Law. This Agreement and the legal relations among the parties as to all matters, including, without limitation, matters of validity, interpretation, construction, performance and remedies, will be governed by and construed exclusively in accordance with the internal laws of the State of Delaware (without regard to the conflict of laws principles of any jurisdiction).

(o) Further Assurances. The parties to this Agreement agree to perform, or cause to be performed, such further acts and deeds and to execute and deliver or cause to be executed and delivered, such additional or supplemental documents or instruments as may be reasonably required by the other party to carry into effect the intent and purpose of this Agreement.

(p) Interpretation. The invalidity or unenforceability of all or any part of any provision of this Agreement will not affect the validity or enforceability of the remainder of such provision or of any other provision of this Agreement, which will remain in full force and effect.

(q) Counterparts. This Agreement may be executed in several counterparts, each of which will be deemed to be an original, but all of which together will constitute one and the same instrument. Facsimile execution and delivery of this Agreement shall be legal, valid and binding execution and delivery for all purposes.

(r) Severability and Judicial Modification. If any portion of this Agreement is adjudicated to be invalid or unenforceable, then a court of competent jurisdiction shall amend, modify or delete that portion thus adjudicated invalid or unenforceable. If any

portion is deemed unenforceable by virtue of its scope or limitation, the Company and the Employee agree that a court of competent jurisdiction shall modify such provision to make it enforceable to the fullest extent permitted by Delaware law.

IN WITNESS WHEREOF, the Company and the Employee have executed this Agreement effective as of the date first above written.

BIOSANTE PHARMACEUTICALS, INC.		**EMPLOYEE:**
By:	/s/ Stephen M. Simes	/s/ Michael C. Snabes, M.D., Ph.D.
Name:	Stephen M. Simes	Michael C. Snabes, M.D., Ph.D.
Title:	Vice Chairman, President and Chief Executive Officer	

Exhibit A

DEFINITIONS

For purposes of the Agreement, the following terms will have the meaning set forth below in this Exhibit A unless the context clearly requires otherwise. Terms defined elsewhere in the Agreement will have the same meaning throughout the Agreement.

1. "Affiliate" means any person with whom the Company would be considered a single employer under Sections 414(b) and 414(c) of the Code, namely (i) any corporation at least eighty percent (80%) of whose outstanding securities ordinarily having the right to vote at elections of directors is owned directly or indirectly by the Company or (ii) any other form of business entity in which the Company, directly or indirectly, owns eighty percent (80%) or more of the controlling interests in such entity.

2. "Base Pay" means the Employee's annual base salary from the Company at the rate in effect immediately prior to a Change in Control or at the time of termination, whichever is greater. Base Pay includes only regular cash salary and is determined before any reduction for deferrals pursuant to any nonqualified deferred compensation plan or arrangement, qualified cash or deferred arrangement or cafeteria plan.

3. "Benefit Plan" means any

(a) employee benefit plan as defined in Section 3(3) of ERISA;

(b) cafeteria plan described in Code Section 125;

(c) plan, policy or practice providing for paid vacation, other paid time off or short-or long-term profit sharing, bonus or incentive payments or perquisites; or

(d) stock option, stock purchase, restricted stock, phantom stock, stock appreciation right or other equity-based compensation plan with respect to the securities of any Affiliate

that is sponsored, maintained or contributed to by the Company or the Company for the benefit of employees (and/or their families and dependents) generally or the Employee in particular (and/or the Employee's family and dependents).

4. "Board" means the board of directors of the Company duly qualified and acting at the time in question. On and after the date of a Change in Control, any duty of the Board in connection with this Agreement is nondelegable and any attempt by the Board to delegate any such duty is ineffective.

5. "Cause" means:

(a) the Employee's dishonesty or fraud;

(b) theft or embezzlement by the Employee of the Company's assets;

(c) any unlawful or criminal activity of a serious nature by the Employee;

(d) breach by the Employee of any terms of the Employee's Employee Confidentiality and Assignment of Inventions Agreement with the Company;

(e) the Employee's failure to carry out the duties of the Employee's position in a competent manner; or

(f) the Employee's failure to comply with the Company's policies and procedures.

6. "Change in Control" shall mean a Change in Control of the Company, as defined in the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan, after the date of this Agreement.

7. "Code" means the Internal Revenue Code of 1986, as amended (including, when the context requires, all regulations, rulings and authoritative interpretations issued thereunder). Any reference to a specific provision of the Code includes a reference to such provision as it may be amended from time to time and to any successor provision.

8. "Company" means BioSante Pharmaceuticals, Inc., any Successor and any Affiliate.

9. "ERISA" means the Employee Retirement Income Security Act of 1974, as amended. Any reference to a specific provision of ERISA includes a reference to such provision as it may be amended from time to time and to any successor provision.

10. "Exchange Act" means the Securities Exchange Act of 1934, as amended. Any reference to a specific provision of the Exchange Act or to any rule or regulation thereunder includes a reference to such provision as it may be amended from time to time and to any successor provision.

11. "Good Reason" means:

(a) a material diminution in the Employee's authority, duties or responsibilities as in effect immediately prior to the Change in Control (other than, if applicable, any such change directly attributable to the fact that the Company is no longer publicly owned);

(b) a material diminution in the Employee's base compensation;

(c) a material diminution in the authority, duties, or responsibilities of the supervisor to whom the Employee reports as in effect immediately prior to the Change in Control;

(d) a material change in the geographic location at which the Company requires the Employee to be based as compared to the location where the Employee was based immediately prior to the Change in Control; or

An act or omission will not constitute a "Good Reason" unless the Employee gives written notice to the Company of the existence of such act or omission within 90 days of its initial existence and the Company fails to cure the act or omission within 30 days after the notification.

12. "Other Arrangement" is any Benefit Plan or other plan, policy or practice of the Company or any other agreement between the Employee and the Company, other than this Agreement.

13. "Person" means any individual, corporation, partnership, group, association or other person, as such term is used in Section 13(d) or Section 14(d) of the Exchange Act, other than the Company, any Affiliate or any Benefit Plan(s) sponsored by the Company or an Affiliate.

14. "Release" is a written instrument, prescribed by the Company and signed by the Employee, under which the Employee releases the Company and its Affiliates, and their directors, officers and employees from any and all claims the Employee may have against any of them by reason of his or her employment or the termination of such employment. The Release will waive all claims the Employee may have under the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Americans with Disabilities Act, the Employee Retirement Income Security Act of 1974, and such other statutes and rules of law as the Company may deem advisable.

15. "Successor" means any Person that succeeds to, or has the practical ability to control (either immediately or solely with the passage of time), the Company's business directly, by merger, consolidation or other form of business combination, or indirectly, by purchase of the Company's outstanding securities ordinarily having the right to vote at the election of directors or all or substantially all of its assets or otherwise.

16. "Termination of Employment" means a termination of Employee's employment relationship with the Company and all Affiliates or such other change in the Employee's employment relationship with the Company and all Affiliates that would be considered a "separation from service" under Section 409A of the Code. The Employee's employment relationship will be treated as remaining intact while the Employee is on a military leave, a sick leave or other bona fide leave of absence (pursuant to which there is a reasonable expectation that the Employee will return to perform services for the Company or an Affiliate) but only if the period of such leave does not exceed six (6) months, or if longer, so long as the Employee retains a right to reemployment by the Company or an Affiliate under applicable statute or by contract, provided, however, a twenty-nine (29) month period of absence may be substituted for such six (6) month period of absence where the Employee's leave is due to any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than six (6) months and such impairment causes the Employee to be unable to perform the duties of his or her position of employment or any substantially similar position of employment. In all cases, the Employee's Termination of Employment must constitute a "separation from service" under Section 409A of the Code and any "separation from service" under Section 409A of the Code shall be treated as a Termination of Employment.

Exhibit 10.14

BIOSANTE PHARMACEUTICALS, INC.

DESCRIPTION OF NON-EMPLOYEE DIRECTOR COMPENSATION ARRANGEMENTS

Retainer and Meeting Fees. The cash compensation paid to our non-employee directors consists of annual cash retainers paid to each Board member, our Chairman of the Board and each Board committee chair and member. The following table sets forth the annual cash retainers currently paid to our non-employee directors:

Description	Annual Cash Retainer
Board Member	$ 25,000
Chairman of the Board (in addition to Board member retainer)	12,500
Audit and Finance Committee Chair	15,000
Compensation Committee Chair	10,000
Nominating and Corporate Governance Committee Chair	7,000
Audit and Finance Committee Member (other than Chair)	7,500
Compensation Committee Member (other than Chair)	5,000
Nominating and Corporate Governance Committee Member (other than Chair)	3,500

The annual cash retainers are paid on a quarterly basis in the beginning of each calendar quarter. For example, the retainers paid in the beginning of the first calendar quarter are for the period from January 1 through March 31.

The table below sets forth the per meeting fees currently paid to our non-employee directors:

Description	Meeting Fees
Board Meeting (in person)	$ 2,000
Board Meeting (telephonic)	1,000
Board Committee (in person or telephonic)	1,000

We do not compensate Mr. Simes separately for serving on the Board of Directors or any of the Board committees.

Stock Options.

Each of our non-employee directors receives an automatic grant of options to purchase shares of our common stock upon the director's initial election to the Board of Directors and on an annual basis on the last business day of March each year. In addition, our Chairman of the Board receives an additional automatic option grant. The options have a ten-year term and an exercise price equal to the fair market value of our common stock on the grant date. The initial options vest and become exercisable in four equal annual installments and the annual options vest and become exercisable in full on the one-year anniversary of the grant date.

The table below sets forth the number of options granted to each of our non-employee directors as initial and annual grants and the additional option grant to our Chairman of the Board:

Description	Number of Shares Underlying Option Grants
New Board Member (initial grant)	50,000
Board Member (annual basis)	25,000
Chairman of the Board (annual basis)	10,000

Reimbursement of Expenses. We reimburse each member of our Board of Directors, including Mr. Simes, for out-of-pocket expenses incurred in connection with attending Board and Board committee meetings.

Exhibit 10.27

LICENSE AGREEMENT

between

PERMATEC TECHNOLOGIE, AG

and

BIOSANTE PHARMACEUTICALS, INC.

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Exhibit intact has been filed separately with the Securities and Exchange Commission.]

INDEX

[Portions of this Index have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Exhibit with this Index intact has been filed separately with the Securities and Exchange Commission.]

LICENSE AGREEMENT

This agreement is entered into, effective this 13th day of June, 2000, by and between PERMATEC TECHNOLOGIE, AG, a corporation of Switzerland ("PERMATEC"), and BIOSANTE PHARMACEUTICALS, INC., a Wyoming corporation ("BIOSANTE").

Background

WHEREAS, PERMATEC has begun formulation and development of several new pharmaceutical products based on proprietary know-how, and desires to grant BIOSANTE an exclusive license in defined geographical areas under the terms and conditions set forth hereinafter to continue the development of and to market these products;

WHEREAS, BIOSANTE desires to take from PERMATEC such a license to continue the development and to market these products;

THE PARTIES ARE HEREBY AGREED AS FOLLOWS:

1. **Definitions**

1.1 "Affiliate" shall mean, with respect to either party hereto, any corporation, partnership or other entity controlled by, controlling or under common control with, such party, with "control" meaning direct or indirect beneficial ownership of more than 50% of the voting power of, or more than 50% of ownership interest in, such corporation, partnership or other entity.

1.2 "Approval" shall mean the first effective date on which sales of a new drug may begin, in accordance with a new drug approval received from FDA, and any equivalent approval from the respective Regulatory Authority in any other country of the Territory.

1.3 "Develop" or "Development" shall mean and include to undertake any and all activities to investigate, research, conduct clinical trials, perform market research, prepare and submit applications for Approval, negotiate with government entities (including the FDA and Regulatory Authorities), or conduct any other activities ordinarily undertaken, or necessary or required or advisable to be undertaken, by the sponsor of a pharmaceutical product in the process of being prepared for marketing or being marketed and to be granted Approvals, on the same basis as if it were the owner of the Products.

1.4 "Development Plan" shall mean the Development Plan for each Product pursuant to Section 5.6 below.

1.5 "FDA" shall mean the US Food and Drug Administration.

1.6 "Know-How" shall mean all information and data, which are not generally known including, but not limited to, patent claims and related information not yet disclosed to the public, formulae, procedures, protocols, techniques and results of experimentation and testing, which (a) relate to any of the Products, and (b) are necessary or useful to the Development or Marketing of any of the Products in the Territory, all to the extent as of the effective date of this Agreement owned or otherwise controlled by and at the free disposition of PERMATEC.

1.7 "Market" or "Marketing" shall mean any and all activities ordinarily associated with efforts to interest a given market in a product and to induce and further sales, including, but not limited to, sales, sales support, continuing medical education, advertising, promotion, publicity and media relations.

1.8 "Net Sales" shall mean the aggregate arms-length gross price invoiced by BIOSANTE and, if applicable, invoiced by the sublicensees of BIOSANTE, for the sale for commercial use of Products to non-affiliated third parties during the relevant period, less deductions for (i) normal and customary trade and cash discounts, credits and allowances (for rejection or return of Products), rebates or refunds incurred or granted; and (ii) sales, use or excise taxes and duties, and freight and insurance, to the extent included in the gross price charged.

1.9 "Patents" shall mean all patents and patent applications filed or having presently or in the future legal force in any country in the Territory owned by PERMATEC which claim any of the Products, or the process to manufacture any of the Products, including but not limited to the patents and patent applications listed in **Exhibit A** hereto, together with all patents that in the future issue therefrom in any country of the Territory, including utility, model and design patents and certificates of invention, and all divisionals, continuations, continuations-in-part, reissues, renewals, extensions, substitutions, confirmations or additions to any such patents and patent applications.

1.10 "Products" shall mean the four pharmaceutical products developed by PERMATEC, either dermal gel or patch, for application on the skin, intended for pharmaceutical use with humans for any indication now known or known in the future, and with defined active compounds, all as listed in **Exhibit B**.

1.11 "Regulatory Authority" shall mean any governmental authority in any country of the Territory competent to approve pharmaceutical products for manufacturing, marketing, distribution and sale in any country of the Territory and/or to approve the price for pharmaceutical products to be sold in any country of the Territory.

1.12 "Specifications" shall mean the specifications, recipes and manufacturing instructions for Products as known at the effective date of this Agreement and from time to time during the term of this Agreement changed, altered, amended or repealed by mutual consent of the parties.

1.13 "Supply Agreement" shall mean the written agreement between BIOSANTE PHARMACEUTICALS, INC. and PERMATEC TECHNOLOGIE, AG, executed by the parties at or about the same time as this License Agreement.

1.14 "Territory" shall mean the United States of America and those of its territories and possessions over which the FDA has regulatory authority (the "USA"); Canada; Australia; New Zealand; South Africa; Israel; Mexico; The People's Republic of China (including Hong Kong) ("China"); Malaysia; and Indonesia. The countries are classified according to **Exhibit C** in three tiers.

1.15 "Good Manufacturing Practices" or "GMP" shall mean the then-current requirements of FDA relating to the manufacture of pharmaceutical products and related activities in the United States, as set forth in applicable FDA regulations and Guidance Documents, and any and all equivalent rules and regulations applicable to such activities in any other country of the Territory.

2. License Grant

2.1 License: PERMATEC hereby grants to BIOSANTE an exclusive license, with the right to grant sublicenses as provided in this Agreement, to Develop the Products in the Territory (except for the E2-NETA Combi Gel or any other product substituted under section 2.5 of this Agreement, the Territory for which is restricted to USA and Canada) as "applicant" and "owner" of Products, as those terms are defined in applicable regulations, for purposes of obtaining Approvals, and upon receipt of the Approvals, to Market and sell the Products, in the Territory, and to use the Patents and Know-How exclusively for that purpose, all in accordance with the provisions contained in this Agreement. It is the parties' intention that any product characterized by its marketing approval, as opposed to Products, developed by BIOSANTE and based on PERMATEC's technology will be and remain the property of BIOSANTE but BIOSANTE will not be allowed to use or market the products in case the License Agreement between PERMATEC and BIOSANTE is terminated.

2.2 Sub-Licenses: In the event that BIOSANTE grants a sublicense under its license to any Affiliate or third party for any part of the Territory, then BIOSANTE shall be responsible for any and all acts, deeds and undertakings of its sub-licensee(s) and shall continue to be bound by all terms and provisions under this Agreement throughout its term. BIOSANTE shall assume any and all obligations and undertakings in lieu and place of its sub-licensee(s) and shall be held responsible for these obligations, including but not limited to the confidentiality obligations set forth hereinafter. Furthermore, BIOSANTE undertakes that any and all sub-license agreements shall provide for inspection and audit

provisions identical to the provisions set forth below in order to enable PERMATEC to control and audit and receive any and all payments due as provided in this Agreement. BIOSANTE shall provide PERMATEC promptly with copies of all agreements with such sub-licensee(s) (with only the commercial terms redacted).

2.3 Assistance: PERMATEC agrees during the term of this Agreement to provide technical and scientific assistance to BIOSANTE (i) without any additional charge to the extent mutually agreed upon in the Development Plan, and (ii) against reimbursement applying a rate of USD 150 per man-hour spent by PERMATEC personnel in addition to the mutually agreed upon assistance pursuant to sub-section (i) hereinabove, provided in each case that BIOSANTE undertakes and agrees to reimburse any and all reasonable out-of-pocket expenses incurred by PERMATEC in connection with any such assistance. Such assistance shall be provided by PERMATEC within a reasonable time in response to requests in connection with BIOSANTE's efforts to obtain Approvals for the Products, including, without limitation, providing the chemistry, manufacturing and control components of any application needed to obtain Approvals.

2.4 No further or Trademark License: It is understood and acknowledged by BIOSANTE that the license granted hereunder shall under no circumstances encompass any further license grant, including without limitation any further license with respect to the Know-How or the Patents or any products other than Products, or with respect to any trademark or trade-name of PERMATEC, including without limitation its internationally registered trademark "Permatec".

2.5 E2-NETA Combi Gel: BIOSANTE has ninety (90) days to exchange the E2-NETA Combi Gel with another progestative from the following list: Levonorgestrel, Medroxyprogesterone or Progesterone. BIOSANTE shall use its best efforts to decide on a change in a shorter period of time. Without written notice from BIOSANTE requesting a change, PERMATEC will assume that E2-NETA Combi Gel remains the originally selected progestative. In the meantime, the Development Plan will be established based on E2-NETA Combi Gel. If PERMATEC has a potential interested party for one of the mentioned Combi gels, excluding E2-NETA Combi Gel, with proposed commercial terms, PERMATEC shall inform BIOSANTE in writing and BIOSANTE has fifteen (15) business days to decide on a change.

3. Consideration

3.1 Initial payment: Upon the mutual execution of this Agreement, BIOSANTE shall pay to PERMATEC the sum of One Million Dollars (USD 1,000,000) of which Two Hundred and Fifty Thousand Dollars (USD 250,000) is creditable against future royalty payments and/or sublicense up front payments as described in Section 3.4 of this Agreement, pursuant to section 3.5.2 below.

3.2 Royalty payments: Commencing with the first commercial sale of any of the Products, and thereafter during the entire term of this Agreement, BIOSANTE shall pay a

royalty of six percent (6%) of the aggregate Net Sales invoiced for sales of the Products, calculated on a country-by-country basis as described in Section 3.5.2.2. PERMATEC and BIOSANTE agree that BIOSANTE will make royalty payments for each respective Product during a period (the "Royalty Term") computed on a country-by-country basis starting with the first commercial sale of such Product in such country and ending upon the later of (i) the expiration of the last to expire Patents applicable to such Product in such country, and (ii) the tenth (10^{th}) anniversary of the first commercial sale of such Product in such country. However, if PERMATEC obtains a patent during the term of this Agreement that achieves exclusivity in the market for any Product, then the Royalty obligation regarding that Product shall continue for the life of that patent. Upon the expiration of the Royalty Term in any given country for any Product, BIOSANTE shall have a fully paid-up exclusive license regarding the applicable Product in such country.

3.3 Milestone payments: In addition, BIOSANTE shall pay to PERMATEC the milestone payments described below in the amounts and at the occurrence of the events described below **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**:

3.3.1 Manufacture of first Product: Upon the start of manufacturing by PERMATEC in response to an order by BIOSANTE to PERMATEC pursuant to Section 4.1 below to manufacture the first batch of GMP-compliant finished Product for use in a clinical trial of the first Product to be subjected to such clinical trial, or pursuant to Section 3.3.6 below, BIOSANTE shall pay to PERMATEC the sum of One Hundred Twenty Five Thousand Dollars (USD 125,000).

3.3.2 Manufacture of second Product: Upon the start of manufacturing by PERMATEC in response to an order by BIOSANTE to PERMATEC pursuant to Section 4.1 below to manufacture the first batch of GMP-compliant finished Product for use in a clinical trial of the second Product to be subjected to such clinical trial, or pursuant to Section 3.3.6 below, BIOSANTE shall pay to PERMATEC the sum of One Hundred Twenty Five Thousand Dollars (USD 125,000).

3.3.3 Start of clinical trial of E2-NETA Combi Gel: Upon the start of the first clinical trial of E2-NETA Combi Gel in the USA, BIOSANTE shall pay to PERMATEC the sum of Five Hundred Thousand Dollars (USD 500,000).

3.3.4 XXXXXXXXXXXXXXX: Upon the XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX,

or pursuant to Section 3.3.7 below, BIOSANTE shall pay to PERMATEC up to XXXXX Dollars (USD XXXXX), XXXXXXXXXXXX, for E2-NETA Combi Gel respectively, as follows:

3.3.4.1 XXXXXXXXXXXXXXXXX. BIOSANTE shall pay up to USD XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXX (depending upon whether payments have previously been made pursuant to paragraphs 3.3.4.2 and/or 3.3.4.3).

3.3.4.2 XXXXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay USD XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

3.3.4.3 XXXXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay USD XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

3.3.4.4 E2-NETA Combi gel: BIOSANTE shall pay to PERMATEC USD XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

3.3.5. Approvals: Upon receipt of the first Approval to market from FDA or from any other Regulatory Authority in any other country of the Territory for, respectively, each of the Products, as follows:

3.3.5.1	Gel Testosterone	up to USD XXXXX
3.3.5.2	Gel E2	up to USD XXXXX
3.3.5.3	Patch E2	up to USD XXXXX
3.3.5.4	E2-NETA Combi Gel	up to USD XXXXX

The following payments shall be made:

XXXXXXXXX: Up to USD XXXXX for Gel Testosterone, USD XXXXX for Gel E2 and USD XXXXX for Patch E2, USD XXXXX for E2-NETA Combi Gel, depending upon whether payments have previously been made for XXXXXXXXXXXX as set forth below.

XXXXXXXXXXXX: USD XXXXX XXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXX

XXXXXXXXXXXX: USD XXXXX XXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXX

If a patent exists that prevents BIOSANTE from introducing any Product into commercial sale, notwithstanding Approval, the Approval payments described in this subsection will be delayed until such time as the patent in issue ceases to prevent such sale.

3.3.6 BIOSANTE failure to order: In the event that BIOSANTE fails to issue either of the orders pursuant to Section 3.3.1 or 3.3.2 above at the time as provided in the Development Plan for the respective Product, and such failure to issue either such order continues for more than thirty (30) days after BIOSANTE receives from PERMATEC the respective notice to do so, then the respective milestone payment under

Section 3.3.1 and 3.3.2 above, respectively, shall nonetheless become due and payable upon the expiration of the thirty (30) day period provided for in PERMATEC's notice.

3.3.7 BIOSANTE failure to file: In the event that BIOSANTE fails to file an NDA or ANDA (as the case may be) or the equivalent filing for Approval with any other Regulatory Authority for any of the Products pursuant to Section 3.3.4 above within twelve (12) months after the completion of the Phase III clinical trials or bio-equivalency studies (as the case may be) for the respective Product and the respective country, and such failure to file such NDA or ANDA or equivalent filing in any other country of the Territory (only if such phase III trials or bio-equivalency trials are applicable in such other country) continues for more than thirty (30) days after BIOSANTE receives from PERMATEC the respective notice to do so, then the respective milestone payment under Section 3.3.4 above shall nonetheless become due and payable upon the expiration of such thirty (30) day period provided for in PERMATEC's notice.

3.4 Sub-licensee payments: Should BIOSANTE in its sole discretion, but always in accordance with Section 2.2 above, sub-license any of the Products, in any portion of the Territory, BIOSANTE shall pay to PERMATEC twenty five percent (25%) of any up-front or sublicense or milestone payments received from such sub-licensees, in addition to royalties, except for up-front or milestone or sublicense payments related to a sublicense in China, Hong Kong, Malaysia or Indonesia for which BIOSANTE will pay PERMATEC thirty five percent (35%) of such payments from sub-licensees.

3.5 Mode of Payments, related reports

3.5.1 Initial and Milestone Payments: The initial payment and all milestone payments due PERMATEC under this Agreement shall be paid in U.S. Dollars (USD), within thirty (30) days of the triggering event of the initial payment and each milestone, respectively, by confirmed wire transfer to a bank account of PERMATEC reasonably notified to BIOSANTE.

3.5.2 Royalty payments: All royalty payments due to PERMATEC under this Agreement shall accrue and be paid to PERMATEC quarterly, in U.S. Dollars (USD), within sixty (60) days of the end of each calendar quarter (each quarter being a period of three consecutive calendar months commencing January, April, July and October), by confirmed wire transfer to a bank account of PERMATEC reasonably notified to BIOSANTE from time to time.

3.5.2.1 Withholding: Any and all withholding taxes or similar charges assessable to BIOSANTE on royalties payable hereunder for sales outside of the United States will be deducted from such amount due, will be paid by the payer to the proper taxing authority, and proof of payment of said tax, as well as any other documents or confirmations reasonably required by PERMATEC to recover any such withholding taxes or parts thereof from the proper tax authorities, will be secured and sent to PERMATEC as evidence of such payment.

3.5.2.2 Calculation of royalties: Any conversions into U.S. Dollars (USD) from the currency in which the corresponding Net Sales for any royalties were made, are to be made by applying an exchange rate equal to the applicable buying rate reported by The Wall Street Journal for the currency of the country in question for the last business day of the calendar quarter in question.

3.5.2.3 Reports: Each such royalty payment shall be accompanied by a statement showing on a country-by-country and Product-by-Product basis the amount of Net Sales of each Product achieved during such quarter and the amounts of royalty due on such Net Sales of Products. With respect to any calendar quarter for which no payment is due for any given Product in any given country, BIOSANTE shall nonetheless include such Product and/or country in each such quarterly statements. Each such statement shall be certified by the CFO or other authorized officer of BIOSANTE to be complete, true and accurate.

3.5.2.4 Books and records: BIOSANTE shall keep full, true and accurate books of account containing all particulars and reasonable supporting documentation which may be necessary for the purpose of determining the Net Sales of Products, royalties due thereon and the statements provided by BIOSANTE pursuant to Section 3.5.2.3 above. Such records shall be kept at BIOSANTE's principal place of business, and shall be open at all reasonable times and upon reasonable advance notice to the inspection of PERMATEC or an independent certified public accounting firm retained by PERMATEC, and reasonably acceptable to BIOSANTE, for the purpose of verifying any payment made under this Agreement. PERMATEC shall bear the full cost of any such audit, unless the audit discloses that the amount due during any period audited exceeds the amount paid by (i) ten percent (10%) or more during the first two (2) years following first commercial sale of a Product in any country; or (ii) five percent (5%) or more thereafter, in which case BIOSANTE shall bear the full cost of such audit. Any additional royalty found in such audit to be due PERMATEC shall be paid by BIOSANTE within thirty (30) days after such finding.

4. PERMATEC production of Products

4.1 Production of Clinical Batches: PERMATEC will formulate and produce and supply the Products in sufficient quantities for all purposes of Development as reasonably needed for BIOSANTE to perform its Development obligations under this Agreement, as follows:

4.1.1 Orders: PERMATEC will supply Products for clinical studies in response to written orders from BIOSANTE to be issued in accordance with the Development Plan for each Product. Any order for such clinical batch shall provide for lead times of at least one-hundred-eighty (180) days, and will allow for quantities of +/- 10% of the quantity of Product ordered. BIOSANTE agrees to purchase from PERMATEC all supplies of Products so ordered for all Development purposes hereunder.

4.1.2 Production costs: PERMATEC shall bear the costs, up to an aggregate of One Hundred Fifty Thousand Dollars (USD 150,000) per Product (for a potential aggregate maximum of Six Hundred Thousand Dollars (USD 600,000) for all four products), associated with the formulation and production of such clinical batches of the Products including, without limitation, the preparation of the chemistry, manufacturing and control components of any application needed to obtain Approval(s), with any additional cost of the formulation and

production of such clinical batches of Products in excess of USD 150,000 per Product to be borne exclusively by BIOSANTE.

4.1.3 Further provisions: Any and all further provisions governing the production and supply of clinical batches of Products shall be mutually agreed upon by the parties at the appropriate time and, absent such mutual agreement, the respective provisions of the Supply Agreement shall apply mutatis mutandis to such production and supply of clinical batches.

4.1.4 Repayment of production milestones: In the event that PERMATEC, within the one-hundred-eighty (180) days minimum lead time for the order of any Product for clinical studies from BIOSANTE under Section 4.1.1 above, may not reasonably demonstrate its ability to produce or have produced the ordered clinical batch of the respective Product in time and in compliance with applicable GMP, then BIOSANTE may request PERMATEC to repay the respective production milestone payment paid by BIOSANTE for the production of the clinical batches of such Product under Section 3.3.1 and 3.3.2, respectively, upon receipt of which request PERMATEC shall be fully released from its obligation under Sections 4.1.1 through 4.1.3, but with respect to the affected Product only. In that case, PERMATEC shall repay to BIOSANTE 25% of USD XXXXX per product up to a total of XXXXX Dollars (USD XXXXX). **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

4.2 Production of Commercial Supply: The terms and conditions governing the ordering, manufacturing and supply of any Product for commercial use shall be mutually agreed upon by the parties in a separate Supply Agreement.

5. Development obligations of BIOSANTE and PERMATEC

5.1 Non-Territory development: PERMATEC shall retain all rights to the Products, the Know-How and the Patents in geographical areas not included within the Territory, and PERMATEC shall have all rights, but no obligation whatsoever, to develop, market and sell or license out to a third party any Product with respect to any and all countries outside the Territory.

5.2 Data sharing: BIOSANTE and PERMATEC agree to provide one another immediate, full and free access to the clinical data and results generated by or on behalf

of each with respect to the Products, and each agrees that the other may utilize all such data and results, directly or through permitted (sub-) licenses in pursuit of Product Approval in their respective geographical areas (the Territory for BIOSANTE, all other areas for PERAMATEC), provided that (i) BIOSANTE undertakes to include such obligation in any and all of its sub-license agreements in accordance with Section 2.2 above, and (ii) PERMATEC will use its best efforts to obtain access to such data from other licensees or sublicensees, but PERMATEC shall have no obligation to share or provide any such information and data regarding Products with BIOSANTE under this Section 5.2, if such information and data is not freely available to PERMATEC.

5.3 BIOSANTE's Development and Marketing obligations/United States: BIOSANTE agrees and undertakes to diligently use all its commercially reasonable efforts to (1) Develop the Products in the Territory, and to (2) obtain Approval from the FDA to market the Products as applicant and owner, consistent with the Development efforts undertaken by other companies similarly situated within the industry for similar drug products used for similar indications, all in accordance with the respective Development Plan for each Product. As Approvals for each respective Product are obtained, BIOSANTE shall proceed diligently to (1) use all its commercially reasonable efforts to sell the Product[s] in the applicable jurisdictions of the Territory, (2) Market, advertise and promote the sale of and otherwise employ marketing and sales techniques reasonably designed to develop a demand for the Product[s] in order to achieve the projected sales. Toward these ends, BIOSANTE shall take appropriate steps including but not limited to:

(a) preparation and filing of an Investigational New Drug Application with FDA concerning each Product as applicant; and
(b) establishing and maintaining a program reasonably designed and funded to obtain information adequate to enable BIOSANTE to file a New Drug Application or Abbreviated New Drug Application, as applicable, for each Product; and
(c) investing and making available any and all necessary financial, Marketing, sales and human resources required to achieve in time the projected sales of each Product as provided for in the Development Plan.

5.4 BIOSANTE's Development and Marketing obligations/Non-US: In all other countries of the Territory, BIOSANTE agrees to use all its commercially reasonable efforts to Develop and Market, or have Developed and Marketed by sub-licensees in accordance with Section 2.2 above, the Products and to obtain the necessary Approvals, consistent with the Development and Marketing efforts undertaken by other companies similarly situated within the industry for similar drug products used for similar indications in any country of the Territory, all in accordance with the respective Development Plan for each Product, in order to achieve in time the projected sales of each Product as provided for in the Development Plan.

5.5 Protocol review: The parties agree that before either begins a clinical trial of a Product, whether conducted by or on behalf of such party, it will give the other party the opportunity to review the protocol for such trial, along with the opportunity to

provide comments. The reviewing party shall have fourteen (14) days to complete such review. Notwithstanding any such consultation, the party conducting such clinical trial shall maintain full and sole responsibility regarding any such study protocol.

5.6 Development Plan

5.6.1 Agreed Development Plan: As soon as possible, but in any event within ninety (90) days of entering into this Agreement, BIOSANTE shall prepare and provide to PERMATEC, for each Product, a Development Plan containing sales projections, its best good faith projection of a Development timetable (including projected timetables for clinical studies and the FDA new drug application process), and projected date of launch. BIOSANTE and PERMATEC will consult and agree on this Development Plan by written acknowledgement by each party on a copy of the plan, provided to the other party.

5.6.2 Material deviations: Material deviations from the Development Plans, including without limitation deviations from the timetable contained therein, shall require the prior written consent by PERMATEC, which consent shall not be unreasonably withheld, except that in no event shall PERMATEC's approval be withheld if BIOSANTE may demonstrate that such deviation is required, due to, or caused by, any material technical, scientific or clinical reason encountered by BIOSANTE during the Development of such Product.

5.7 Development Reporting: BIOSANTE undertakes to provide PERMATEC regularly, but at least twice yearly (within sixty (60) days of the start of the calendar year and July 1, respectively), with an update reasonably detailing the steps and actions performed and results achieved or gained by BIOSANTE in pursuing the Development pursuant to the Development Plan, including without limitation information on the status of any filing for Approvals for each Product.

6. Representations, warranties and covenants; indemnification

6.1 PERMATEC's: PERMATEC, as an inducement to BIOSANTE to enter into this Agreement, represents, warrants and covenants to BIOSANTE as follows:

6.1.1 Right to license: PERMATEC has full right, power and authority to grant an exclusive license to BIOSANTE in the Territory pursuant to the terms of this Agreement to practice the technology covered by any and all patents listed in Exhibit A, and Know-How, and to Develop, Market and sell the Products, free and clear of any mortgage, lien, encumbrance or

other third-party interest of any kind. As of the effective date of this Agreement, PERMATEC is not aware of any fact or circumstances that the Products are, in or with respect to the Territory, subject to any restrictions, covenants, licenses other than this Agreement, or judicial and administrative orders of any kind, which detract in any material respect from the value of the Products, or which could interfere with the use thereof by BIOSANTE in the Territory as contemplated by this Agreement.

6.1.2 No inability to receive Approval: As of the effective date of this Agreement, PERMATEC is aware of no facts that would reasonably lead it to conclude that any of the Products will be unable to receive the contemplated Approval from the FDA or Approval from any other Regulatory Authority upon satisfactory completion of clinical trials, and PERMATEC has no knowledge of any facts which would reasonably lead it to conclude that satisfactory completion of clinical trials is not likely.

6.1.3 Clear rights: As of the effective date of this Agreement, PERMATEC has not received any notice and has no knowledge that (i) the rights to Develop, Market and sell the Products have been challenged in any judicial or administrative proceeding, or (ii) any person, entity or product has infringed or will infringe any patent rights encompassed by the Patents and applicable to the Products, or (iii) any patent rights or other intellectual property rights, including but not limited rights of trade mark, trade dress and copyright, have been infringed by PERMATEC or will be infringed by BIOSANTE by virtue of performing the activities contemplated by this Agreement.

6.1.4 Right to execute and perform: PERMATEC has full right, power and authority to execute and deliver this Agreement, and to perform its obligations under it, and has taken all necessary action to authorize such execution, delivery and performance. This Agreement constitutes the legal, valid and binding obligation of PERMATEC, enforceable against it in accordance with its terms.

6.1.5 Compliance with law: PERMATEC will comply with all applicable laws in connection with performance of its obligations under this Agreement. The execution, delivery and performance of this Agreement by PERMATEC does not violate any provision of applicable law or of any regulation, order, decree of any court, arbitration or governmental authority, or any other agreement to which PERMATEC is a party. No consents, approvals or authorizations, registrations or filings are required in connection with the execution, delivery, performance, validity or enforceability of this Agreement, except as have been obtained or set forth in this Agreement.

6.1.6 No further representation: Except for the specific representations and warranties given by PERMATEC in this Section 6.1, PERMATEC does not give any further or other warranty and makes no other or further representation, whether express or implied. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, PERMATEC DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS AND/OR THE KNOW-HOW, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF, IN PARTICULAR WITH RESPECT TO THE INTENDED PURPOSE OF SUCCESSFUL APPLICATION FOR APPROVAL(S) IN ANY COUNTRY OF THE TERRITORY.

6.2 BIOSANTE's: As an inducement to PERMATEC to enter into this Agreement, BIOSANTE represents and warrants to PERMATEC as follows:

6.2.1 Right to execute and perform: BIOSANTE has full right, power and authority to execute and deliver this Agreement, and to perform its obligations under it, and has taken all necessary action to authorize such execution, delivery and performance. This Agreement constitutes the legal, valid and binding obligation of BIOSANTE, enforceable against it in accordance with its terms.

6.2.2 Compliance with law: BIOSANTE will comply with all applicable laws in connection with performance of its obligations under this Agreement. The execution, delivery and performance of this Agreement by BIOSANTE does not and will not violate any provision of applicable law or of any regulation, order, decree of any court, arbitration or governmental authority, or any other agreement to which BIOSANTE is a party. No consents, approvals or authorizations, registrations or filings are required in connection with the execution, delivery, performance, validity or enforceability of this Agreement, except as have been obtained or set forth in this Agreement.

6.2.3 Best efforts: BIOSANTE represents and warrants that it will use its best efforts to perform and pursue all steps and actions required for, and apply for and pursue the Approvals for Product in accordance with the Development Plans and within the time-limits set forth therein, and, upon such granting of any such Approvals, to Market the Products throughout the Territory during the term of and in accordance with this Agreement.

6.2.4 Compliance with Approvals: BIOSANTE represents and warrants that in addition to complying with and respecting any and all applicable laws, rules, regulations and orders, it shall also comply with all terms and

conditions of the Approvals (if any), when Developing, Marketing and selling Products in any country of the Territory.

6.2.5 No further representation: Except for the specific representations and warranties given by BIOSANTE in this Section 6.2, BIOSANTE does not give any further or other warranty and makes no other or further representation, whether express or implied. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, BIOSANTE DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS AND/OR THE KNOW-HOW, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF, IN PARTICULAR WITH RESPECT TO THE INTENDED PURPOSE OF SUCCESSFUL APPLICATION FOR APPROVAL(S) IN ANY COUNTRY OF THE TERRITORY.

6.3 Indemnification by BIOSANTE: Without affecting any other remedies available under this Agreement, BIOSANTE shall defend, indemnify and hold PERMATEC and its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including reasonable fees, costs and expenses of attorneys and other professionals and court costs, but excluding consequential damages for lost profits) arising from or relating to the negligence or willful misconduct of BIOSANTE or its Affiliates or its sub-licensees in connection with the subject matter of this Agreement.

6.4 Indemnification by PERMATEC: Without affecting any other remedies available under this Agreement, PERMATEC shall defend, indemnify and hold BIOSANTE and its directors, officers and employees, harmless from and against any and all claims, suits or demands for liability, damages, costs and expenses (including reasonable fees, costs and expenses of attorneys and other professionals and court costs, but excluding consequential damages for lost profits) arising from or relating to the negligence or willful misconduct of PERMATEC in connection with the subject matter of this Agreement.

7. Confidentiality

7.1 Obligation of confidentiality: Except to the extent expressly authorized by this Agreement, or otherwise agreed in writing, the parties agree that, at all times during the term of this Agreement and for five (5) years thereafter, the receiving party shall keep completely confidential, shall not publish or otherwise disclose and shall not use directly or indirectly for any purpose, any information furnished, disclosed, delivered or otherwise made available to it by the other party pursuant to this Agreement (including

without limitation Know-How), except to the extent that it can be established by the receiving party by competent proof that such information:

(a) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure by the other party;
(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party;
(c) became generally available to the public or otherwise part of the public domain after its disclosure, other than through any act or omission of the receiving party in breach of this Agreement; or
(d) was disclosed to the receiving party, other than under an obligation of confidentiality, by a third party who had no obligation to the disclosing party not to disclose such information to others.

7.2 Exceptions: Each party may disclose the other's information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, pursuing or defending litigation, or complying with applicable governmental regulations, provided that if a party intends to make any such disclosure, it shall give reasonable advance written notice to the other party of such intended disclosure, and shall take reasonable steps to restrict or limit such disclosure or require confidential treatment thereof.

7.3 When consent needed: Except as otherwise provided in Section 7.2 above, neither party shall disclose any terms or conditions of this Agreement to any third party without the prior consent of the other party. Notwithstanding the foregoing, prior to the execution of this Agreement, the parties shall agree upon the substance of information that can be used to describe the terms of this transaction, and the parties may disclose only such information without the other party's consent.

8. Proprietary Right and Patents

8.1 Title: PERMATEC shall retain title to and full ownership in the Products, the Patents and the Know-How including, but not limited to, any and all developments and inventions related thereto, if any (hereinafter collectively referred to as "PERMATEC IPR"). BIOSANTE does not by virtue of this Agreement, directly or indirectly through its officers, directors, employees, agent, Affiliates, customers or other controlled or associated third parties, acquire any proprietary interest in or other right to PERMATEC IPR, other than provided in this Agreement.

8.2 Infringement by third parties: PERMATEC and BIOSANTE recognize that they each have an interest in the protection of the PERMATEC IPR. Either or both may wish to take steps to protect or defend their respective interests in specific circumstances. In addition:

8.2.1 Notice: If either PERMATEC or BIOSANTE becomes aware of (i) any product or activity of any kind that involves or may involve an

infringement or violation of PERMATEC IPR with respect to Products and/or the Territory, or (ii) any third-party action, claim or dispute (including, but not limited to, actions for declaratory judgement alleging invalidity or non-infringement) based upon or arising out of PERMATEC IPR with respect to Products and/or the Territory, then each agrees to promptly so notify the other in writing.

8.2.2 Independent decisions to act: Each party shall, in its sole discretion, have the right but no obligation to determine the most commercially appropriate course of action, if any, for it to follow to enforce, or otherwise abate the infringement of, or defend third-party actions regarding, PERMATEC IPR with respect to Products and the Territory, including whether to request status as an additional party to any such action. Each party deciding to take any such course of action shall do so at its own risk, benefit, cost and expense. Notwithstanding anything contained herein, BIOSANTE shall not accept any settlement or award in any such action which has or may have a negative impact on the proprietary or other legitimate rights of PERMATEC in any of the PERMATEC IPR, without the prior written consent of PERMATEC, which consent shall not be withheld unreasonably.

8.2.3 Reduction in Royalty: In the instance in which an A/B rated generic equivalent or substitute of a Product on sale in any part of the Territory is reasonably notified by either party under Section 8.2.1 above to infringe a Patent available for such Product in such country of the Territory, and PERMATEC takes no action against the third party, but BIOSANTE does, and BIOSANTE may give evidence that the marketing of such competitive product has led to a reduction in sales of the affected Product in such country of the Territory of more then fifteen percent (15%), then the Royalty payable by BIOSANTE to PERMATEC for that Product after such reasonable notice pursuant to Section 8.2.1 in that country of the Territory will be XXXX percent (XXXX%) for as long as (1) such competing product is on sale, and (2) BIOSANTE's Royalty obligation exists under this Agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

8.2.4 Cooperation: In addition to the above, each party, regardless of whether it joins in a legal action, agrees to cooperate with the other to provide reasonable assistance in the prosecution or defense of any actions regarding PERMATEC's IPR. Each party shall keep the other regularly informed on developments in any such action in which it participates or obtains information, if the other party is not involved.

9. Term and Termination

9.1 Term: This Agreement shall be effective on the date first written above and shall expire, unless earlier terminated by either party pursuant to this Section 9, on a country-by-country and Product-by-Product basis upon the expiration of the respective Royalty Term, subject to BIOSANTE's continuing fully-paid up exclusive license pursuant to Section 3.2 above.

9.2 Termination: At any time, this Agreement may be terminated by giving written notice to that effect, as follows:

(a) by either party, if the other party is in material default or in material breach of any term or provision hereof, including without limitation to the terms and deadlines incorporated into the parties' agreed Development Plan, which termination shall apply only to the Product(s) and Country(ies) involved, or material breach of any representation or warranty in this Agreement or material breach of the confidentiality obligations hereof, and such material default or material breach continues and is not remedied within thirty (30) days upon the other party's written request to remedy such default or breach; or

(b) by either party, if the other party goes into liquidation, voluntarily or otherwise, other than for the sole purpose of reorganisation, or goes into bankruptcy or makes an assignment for the benefit of creditors, or in the event of a receiver being appointed of a substantial part of the other party's property; or

(c) by either party in its sole discretion, with respect only to the involved Product or Products, or country or countries of the Territory, respectively, and without prejudice to any other rights conferred on it by this Agreement and in addition to any other remedies available to it by law or in equity, if such party terminates the Supply Agreement for material breach or insolvency or other material reason caused or set by the other party as provided for in such Supply Agreement, with the effect of such being the termination of this Agreement upon the effective date of the termination of the Supply Agreement; or

(d) by PERMATEC, with respect only to the involved Product or Products, or country or countries of the Territory, respectively, if BIOSANTE, (A) within six (6) months after the delivery of clinical supplies has not initiated with respect to each Product and for each country of the Territory reasonable steps, including sub-licensing in case BIOSANTE shall not wish to Develop and Market itself the Product in certain countries of the Territory, to Develop and thereafter Market such Product pursuant to the provisions of this Agreement, it being understood the development work done in the USA may be applicable in all countries of the Territory or (B) within three (3) months after receipt of commercial quantities after receipt of any Approval for a Product in any given country of the Territory has not launched such Product in such country of the

Territory, or (C) within eighteen (18) months after receipt of the first Approval for any given Product by any Regulatory Authority, does not either (i) file a request for Approval for such Product in all countries of the Territory only if the first approval is useful for approval purposes, or (ii) sublicense such Product in such other country(ies) of the Territory, or (D) ceases the Marketing and sale of any Product in any country of the Territory after the Approval from the respective Regulatory Authority has been received, in each case with respect to the affected Product and the affected country(ies) only, and in each case only if BIOSANTE does not cure such situation within three (3) months after PERMATEC's written request to do so, subject always to Section 11.10 below; or

(e) by BIOSANTE prior to the granting of an Approval for any given Product in any given country of the Territory, in case of material technical, scientific or regulatory problems or, if the results and data achieved and generated during the Development of any given Product in reasonable determination show that Approval for such Product will be unlikely to be granted, with respect to the affected Product only and in a specific country of the Territory, and provided that prior to such termination, the parties have discussed in all details the problems encountered and not agreed on a mutually acceptable change of the Development Plan pursuant to Section 5.6.2 above; or

(f) by BIOSANTE, if any Regulatory Authority has finally denied the Approval (or any material part thereof) for any given Product in any country of the Territory, with respect to the affected Product and such country or countries only; or

(g) by BIOSANTE if in its reasonable discretion it determines that it would not be economically viable to develop and market a Product in any country of the Territory, with respect to a specific product and country only. In this case, BIOSANTE shall inform PERMATEC immediately of this decision and shall provide in writing and within 30 days a detailed explanation including market research data and projections and calculation for such a decision. Following this decision and on a country-by-country basis, PERMATEC has the right to use free of charge all the development data, registration file for marketing or licensing purposes in that specific country and for that specific Product. In that case the repayment of the costs to generate data by PERMATEC to BIOSANTE as defined in paragraph 9.4 does not apply. The approvals obtained by BIOSANTE in these countries will be transferred free of charge to PERMATEC upon request.

9.3 No prejudice to rights: The termination of this Agreement shall be without prejudice to any rights and obligations of either party accrued prior to the effective date of such termination, unless explicitly otherwise agreed. BIOSANTE shall forthwith make all payments due and outstanding to PERMATEC at the date of termination. Except as explicitly otherwise stated in this Agreement or otherwise agreed in writing, PERMATEC shall not be obliged to refund upon termination of this Agreement to BIOSANTE any payments, including without limitation the milestone payments or

royalties made by BIOSANTE to PERMATEC prior to such termination pursuant to the provisions of this Agreement.

9.4 Termination of license, return of information: In the event of termination of this Agreement for whatsoever reason, then the license granted hereunder shall immediately be terminated and BIOSANTE shall immediately refrain from using directly or indirectly in any way the Patents, Know-How and confidential information of PERMATEC. Furthermore, BIOSANTE shall return to PERMATEC all materials, documentation, information, data and other things furnished by PERMATEC in connection with this Agreement, including without limitation any and all information on PERMATEC IPR, together with all copies thereof in BIOSANTE's possession or under its control, which were achieved, produced or received hereunder, all free of any charge. Furthermore, BIOSANTE shall deliver to PERMATEC any and all studies, data, results and protocols achieved, produced or gained by BIOSANTE in performing the Development and not previously delivered to PERMATEC pursuant to Section 5.2 above. PERMATEC shall have the right, but no obligation, to use, at its sole discretion, any and all such material for its own purposes. In case PERMATEC shall use such information in applying and receiving marketing approval and launching the Product, then at launch, PERMATEC shall reimburse the costs to generate such information to BIOSANTE excluding development costs that were paid by BIOSANTE to PERMATEC under this Agreement. In case PERMATEC shall use such information to enter a license agreement with a third party, then PERMATEC shall reimburse the costs to generate such information to BIOSANTE excluding development costs that were paid by BIOSANTE to PERMATEC under this agreement. The reimbursement to BIOSANTE will occur at the execution of the license agreement and shall not exceed the net payments (upfront, milestones and royalty payments excluding development costs) received by PERMATEC from a third party under a license agreement. BIOSANTE's costs to generate such information which is to be reimbursed by PERMATEC is to be agreed between BIOSANTE and PERMATEC at the time of termination or when the information is to be transferred to PERMATEC

9.5 Partial termination: In the event that any termination hereunder is limited to one or more, but not all, countries of the Territory and/or to one Product only, but not all Products, as provided for in Sections 9.2(d), (e) and (f) above, then the effects of such termination shall only apply to such country or countries and/or the affected Product, but shall not affect in any way the validity of this Agreement with respect to any other country of the Territory with respect to the affected Product and/or any other Product.

9.6 Remedies not limited: The termination of this Agreement by either party shall not limit remedies which may be otherwise available under this Agreement or in law or equity to either party.

10. Options to extend Territory or Products

10.1 Option to extend Territory: During a period of 180 days after the effective date of this Agreement (the "Exercise Period"), BIOSANTE shall have a free option, exercisable in its sole discretion, to add any or all of the nations of Denmark, Finland, Norway, Sweden and Japan (the "Option Countries") to the Territory that is the subject of this Agreement, with respect to the Products provided and to the extent that the Products are available for license for the considered countries. The option may be exercised by BIOSANTE during the Exercise Period by giving written notice of exercise to PERMATEC as provided in this Agreement. The parties recognizing that they may or may not desire to abide by identical terms to those in this Agreement with respect to the extended portions of the Territory, upon receipt by PERMATEC of BIOSANTE's written notice of exercise, the parties agree to negotiate in good faith and determine the specific terms to apply to BIOSANTE's Development and Marketing in the extended portions of the Territory. Notwithstanding anything contained in this Section 10.1, PERMATEC, during the Exercise Period, if it has negotiated with a third party commercial terms of a license (including, without limitation license fees, milestone payments, royalties and allocation of development costs) in any Option Country, may request BIOSANTE in writing to elect whether or not to exercise its option under this Section 10.1 with respect to the same country or countries that are the subject of the terms negotiated with the third party, in which case BIOSANTE shall have thirty (30) days from such notice from PERMATEC to exercise that option. In the event that

BIOSANTE does not exercise its option under this Section 10.1 within the thirty (30) day period after receipt of PERMATEC's notice hereunder, then the option under this Section 10.1 shall lapse and fall away, irrespective of any part of the Exercise Period remaining.

10.2 Right of first offer: During a period starting on the ninety-first (91st) day after the effective date of this Agreement and ending on the first (1st) anniversary of the effective date of this Agreement (the "Offering Period"), BIOSANTE shall have an exclusive right of first offer to Develop and Market in the United States, Canada, Japan, and any other country of the Territory not already licensed to third parties or subject to a third party's right of first refusal, and to enter into a respective license therefor, any non-proprietary sexual hormone product or related hormonal product, including tamoxifen and its derivatives, that PERMATEC may have formulated, invented, developed, licensed or otherwise obtained rights with respect to, and which PERMATEC intends to, but has not prior to such Offering Period committed to, license out for the Territory or parts thereof. Exercise of the right of first offer shall commence with PERMATEC notifying BIOSANTE at any time during the Offering Period of its intention to license out such product, which notice shall in reasonable detail describe the product and Territory or parts thereof in question and the commercial terms of such license (including without limitation license fees, milestone payments, royalties and allocation of development cost). BIOSANTE shall have forty five (45) days to accept the offer on identical terms as contained in such notice, during which forty five (45) days PERMATEC and BIOSANTE agree to negotiate in good faith all terms of such contemplated license and development agreement on the basis of PERMATEC's notice, unless otherwise agreed by the Parties. Notice and exercise under this Section 10.2 shall be made by written notice. In the event that BIOSANTE shall not accept the commercial terms notified by PERMATEC, then PERMATEC shall be free to grant such license to any third party, irrespective of any part

of the Offering Period remaining. In the event that PERMATEC has the ability to license the products described to a third party within the first ninety (90) days of this Agreement, PERMATEC shall immediately so notify BIOSANTE, and BIOSANTE shall have fifteen (15) business days within which to exercise its right of first offer as described elsewhere in this paragraph.

10.3 Option regarding the XXXXX Combi Gel

10.3.1 License Agreement: PERMATEC will not license XXXXX Combi Gel to any company other than the one company identified by PERMATEC to BIOSANTE during negotiation of this Agreement in the first ninety (90) days of the effectiveness of this Agreement. If no license agreement is reached in that ninety (90) day period with the company described, then during a period starting on the ninety-first (91st') day after the effective date of this Agreement and ending on the first (1st') anniversary of the effective date of this Agreement (the "Offering Period") PERMATEC will offer and BIOSANTE hereby agrees to accept an exclusive license on the XXXXX Combi Gel pursuant to the terms and conditions set forth below. . **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

10.3.2 Terms: PERMATEC will license to BIOSANTE XXXXX Combi Gel in the countries of the United States of America and Canada and any other part of the Territory not already licensed to third parties except Japan on the following basic terms: for a license fee of XXXXX Dollars (USD XXXXX), which license fee is not refundable, non-recoverable and payable as set forth below, and a XXXXX percent (XXXXX%) royalty on Net Sales of XXXXX Combi Gel, calculated in the same manner as royalties for the Products under this Agreement, and BIOSANTE to bear all costs of development (including without limitation clinical study cost), and otherwise on substantially identical terms as set forth in this Agreement. The costs associated with the production of clinical batches of XXXXX Combi Gel will be borne equally by PERMATEC and BIOSANTE up to XXXXX Dollars (USD XXXXX), with any amounts in excess thereof to be borne by BIOSANTE. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

10.3.3 Payments: **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

10.3.3.1 Execution of License Agreement: Upon execution of a separate license agreement concerning XXXXX Combi Gel, BIOSANTE shall pay to PERMATEC a milestone payment of XXXXX Dollars (USD XXXXX).

10.3.3.2 XXXXXXXXXXXXX: Upon XXXXXXXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay to PERMATEC a milestone payment of XXXXX Dollars (USD XXXXX).

10.3.3.3. XXXXXXXXXXXXX: Upon XXXXXXXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay to PERMATEC a milestone payment of up to XXXXX Dollars (USD XXXXX), as follows: XXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

10.3.3.4 XXXXXXXXXXXXX: Upon XXXXXXXXXXXXXXXXXXXXXXXXXXXXX, BIOSANTE shall pay to PERMATEC a milestone payment of up to XXXXX Dollars (USD XXXXX), as follows: XXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

10.4 Termination of option rights: In the event that this Agreement is terminated by PERMATEC pursuant to Section 9.2 above prior to the expiration of any of the rights contained in this Section 10, then all such rights shall terminate and fall away as per the effective date of such termination without any liability on the side of PERMATEC.

11. Miscellaneous

11.1 Governing Law: This Agreement is governed by and construed in all respects in accordance with the laws of the State of Illinois, USA and the United States of America (without regard to conflicts of laws principles), excluding the United Nations Convention on Contracts for the International Sale of Goods.

11.2 Dispute Resolution:

(a) Conciliation. The parties wish first to seek an amicable settlement of all disputes, controversies or claims arising out of or relating to this Agreement by conciliation in accordance with the UNCITRAL Conciliation Rules now in force. The conciliation shall take place in Chicago, Illinois (USA) before a conciliator. If assistance is needed in connection with the appointment of a conciliator or other administrative matters, JAMS Endispute, Inc., 222 S. Riverside Plaza, Chicago, Illinois, USA (telephone 312-739-0200), shall be the institution to render such assistance. The language to be used in the conciliation proceedings shall be English.

(b) Arbitration. Subject to possible court proceedings under Section 11.2(d) of this Agreement, if any conciliation proceedings under Section 11.2(a) of this Agreement are terminated in accordance with Article 15 of the UNCITRAL Conciliation Rules or rejected in accordance with Article 2 of those Rules, without resolution of the disputes, controversies or claims, then all said disputes, controversies or claims shall be determined by arbitration in accordance with the UNCITRAL Arbitration Rules now in force, as supplemented by the IBA Rules on the Taking of Evidence in International Commercial Arbitration, as adopted June 1, 1999, insofar as said IBA Rules are not inconsistent with the express provisions of this Agreement. The language to be used in the arbitral proceedings shall be English. There shall be three (3) arbitrators, the place of arbitration shall be Chicago, Illinois (USA) and the appointing authority shall be JAMS Endispute, Inc. In rendering the award, the arbitrator shall follow and apply the substantive laws of the State of Illinois (without regard to conflict or choice of laws principles). The arbitrator shall have the authority to award compensatory damages only, subject to the limitations described in this Agreement. Each party shall pay the fees of its own attorneys, expenses of witnesses and all other expenses and costs in connection with the presentation of such party's case (collectively, "Attorneys' Fees"). The remaining costs of the arbitration, including without limitation, fees of the arbitrator, costs of records or transcripts and administrative fees (collectively, "Arbitration Costs") shall be borne equally by the parties. Notwithstanding the foregoing, the arbitrator in the award may apportion said Attorneys' Fees and Arbitration Costs, pursuant to articles 38 through 40 of the UNCITRAL Arbitration Rules. The award rendered by the arbitrator shall be final, and judgment may be entered in accordance with the applicable law by any court having jurisdiction thereof.

(c) Confidentiality. The existence and resolution of any conciliation and/or arbitration shall be kept confidential, and the parties, the conciliator and the arbitrator shall not disclose to any person any information about such arbitration.

(d) Court Proceedings. Notwithstanding the arbitration provisions in Section 11.2(c) of this Agreement, PERMATEC shall have the right to sue in any court of competent jurisdiction to collect from BIOSANTE funds due and owing PERMATEC hereunder. Section 11.2(c) of this Agreement shall not be construed to prevent either party from seeking injunctive relief against the other party from any judicial or administrative authority of competent jurisdiction to enjoin that party from breaching this Agreement pending the resolution of a dispute by arbitration, pursuant to said Section 11.2(c). Any action to confirm an arbitration award or any other legal action related to this Agreement between the parties may be instituted in any court of competent jurisdiction. PERMATEC and BIOSANTE each waive their right to a trial by jury in any such court proceedings.

11.3 Notice: All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission, mailed by registered or certified mail (return receipt requested, postage prepaid) or sent by overnight courier service to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

If to PERMATEC

Permatec Technologie, AG
c/o Permatec Pharma AG
Hardstrasse 18
CH-4132 Muttenz, Switzerland
Attn.: **President**
Fax No: +41 61 465 92 91

with copy to: Rinderknecht Klein & Stadelhofer
Beethovenstrasse 7
CH-8022 Zurich, Switzerland
Fax No: ++41 1 287 24 00

If to BIOSANTE:

Stephen M. Simes
President and CEO
BioSante Pharmaceuticals, Inc.

175 Olde Half Day Road
Lincolnshire, Illinois 60069
Tel: (847) 793-2434
Fax: (847) 793-2435

with copy to: Eric F. Greenberg
Ungaretti & Harris
3500 Three First National Plaza
Chicago, Illinois 60602-4283
Tel: (312) 977-4647
Fax: (312) 977-4405

11.4 Entirety: The terms and conditions of this Agreement, together with the Exhibits referred to herein, constitute the entire agreement and understanding of the parties, and supersede all previous communications whether oral or written between the parties, including any previous agreement or understanding varying or extending the same.

11.5 Modification: This Agreement may be released, discharged, abandoned, changed or modified only by an instrument in writing of equal formality, signed by the duly authorized officer or representative of each of the parties.

11.6 Severability: Each party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the parties agree that it is their intent that the remainder of the Agreement shall continue in effect, and shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the parties would have entered into this Agreement with such valid provisions.

11.7 Waiver: The failure of either party at any time or from time to time to exercise any of its rights or to enforce any of the terms, conditions or provisions under this Agreement shall not be deemed to be a waiver of any such rights nor shall it prevent such party from subsequently asserting or exercising any such rights.

11.8 Relationship of Parties: Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency or joint venture relationship between the parties.

11.9 Assignment: Neither this Agreement nor any interest hereunder shall be assignable by either party without the prior written consent of the other party (provided

that this shall not restrict or prevent BIOSANTE from sublicensing its rights or responsibilities hereunder). Notwithstanding the foregoing, PERMATEC may subcontract any and all of its obligations hereunder to any third party, and the parties may assign this Agreement or any of its respective rights or obligations hereunder to any Affiliate or successor by merger or sale of substantially all of their business; provided in each case, however, that such party shall remain jointly and severally liable for the performance of all of its duties and obligations hereunder.

11.10 Force Majeure: Neither party hereto shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party, including but not limited to fire, floods, embargos, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labour disturbances, acts of God, omissions or delays in acting by any governmental authority (including the FDA and Regulatory Authorities) or the other party hereto.

11.11 Interest: In the event any amount due and payable under this Agreement is not paid by the due date, then the party owing such amount shall pay to the other party, without being requested by such other party, interest on the total outstanding amount at the rate equal to the U.S. Prime Rate, as reported by the Wall Street Journal on the date that such payment falls due, increased by three percent (3%), in United States Dollars and adjusted on the first day of every subsequent calendar quarter.

11.12 Interpretation: The Parties will execute or have executed a Supply Agreement at or about the same time as this License Agreement, which has as its initial subject matter the same Products that are the subject of this License Agreement. It is the Parties' intent and understanding that there are no conflicts or contradictions between the two Agreements, as the License Agreement is intended to control the licensing (including supply of products for development), Development and Marketing of the Products, and the Supply Agreement is intended to control the supply of commercial quantities of Products. In the event and to the extent any direct conflict or contradiction between the two Agreements is identified, it is the Parties' intent that the terms of the License Agreement shall govern.

IN WITNESSETH WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the date first above written.

PERMATEC TECHNOLOGIE, AG

/s/ Dr. Jacques Gonella
By: Dr. Jacques Gonella
Its: Executive Chairman

/s/ Dr. Philippe Dro

By: Dr. Philippe Dro
Its: President and COO

BIOSANTE PHARMACEUTICALS, INC.

/s/ Stephen M. Simes

By: Stephen M. Simes
Its: President and CEO

EXHIBIT A

PATENTS

A Novel Composition for transdermal administration of an Estrogen, A Progestin or a mixture thereof (Combi Gel)

Ref.: PRE.001

Country	Application Date	Number	Patent Date	Number	Expiration Date
Argentina	06.06.1997	P970102497			06.06.2017
Australia	05.06.1997	24729/97			05.06.2017
Canada	05.06.1997	2,207,144			05.06.2017
Europe	04.06.1997	97108989.1			04.06.2016
Italy	06.06.1996	MI96A001152	07.04.1998	1283102	06.06.2016
Japan	05.06.1997	9-185695			05.06.2017
Korea, Rep.	04.06.1997	97-236704			04.06.2017
New Zealand	05.06.1997	328021	19.03.1998	328021	05.06.2017
South Africa	05.06.1997	974981	25.03.1998	97/4981	05.06.2017
Taiwan	06.06.1997	86107807			
U.S.A	05.06.1997	08/869.982	06.04.1999	5,891,462	05.06.2017

Administration System for Estradiol (Estradiol Patch)

Ref.: GPH.001

Country	Application Date	Number	Patent Date	Number	Expirat. Date
Australia	07.05.1993	38459/93	05.11.1996	670273	07.05.2013
Austria	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Belgium	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Denmark	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Europe	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Europe/It.	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
France	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Germany	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Greece	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Ireland	07.05.1993	93810336.3	05.08.1999	0569338	07.05.2013
Japan	28.04.1993	102325/1993	30.07.1999	2960832	28.04.2013
Korea, Rep.	07.05.1993	93-7877			07.05.2013
Luxembourg	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Netherlands	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
New Zealand	05.05.1993	247549	11.04.1996	247549	05.05.2013
Portugal	07.05.1993	93810336.3	05.08.1998	569338	07.05.2013
South Africa	06.05.1993	93/3180	31.08.1994	93/3180	06.05.2013
Spain	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Sweden	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Switzerland	07.05.1993	93810336.3	05.08.1998	0569338	07.05.2013
Taiwan	08.05.1993	82103602	27.11.1995	NI072551	07.05.2013
U.K.	07.05.1993	93810336.3	05.08.1998	569338	07.05.2013
Canada	07.05.1993	2,095,789			07.05.2013
U.S.A.	03.05.1993	08/058,517			

Administration System for Estradiol (followed)

Ref.: GPH.001/A und /CON1

Country	Application Date	Number	Patent Date	Number	Expirat. Date
GPH.001/A					
Switzerland	08.05.1992	1487/92			08.05.2012
GPH.001/CON 1					
U.S.A.	19.12.1994	08/358,897	09.09.1997	5,665,377	09.09.2014

EXHIBIT B

PRODUCTS

[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]

Gel E2 (where estradiol is the sole active ingredient, and where the gel is applied to the skin)

Gel Testosterone (where testosterone is the sole active ingredient and where the gel is applied to the skin)

Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin)

E2-NETA Combi Gel (where estradiol and norethindrone acetate are the two active ingredients and where the gel is applied to the skin)

Option regarding XXXX Combi gel

XXXX Combi Gel (where XXXX and XXXX are the two active ingredients and where the gel is applied to the skin)

EXHIBIT C

COUNTRY CLASSIFICATION

First Tier: USA

Second Tier Canada; China

Third Tier: All other countries of the Territory

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

Amendment No. 1

to the

License Agreement
dated 13th of June 2000 (the "Agreement")

by and between

Antares Pharma IPL AG, Zug, Switzerland as Licensor
(formerly known as Permatec Technologie AG)

and

BioSante Pharmaceuticals, Inc., Lincolnshire, IL, U.S.A. as Licensee

Recitals:

WHEREAS, Permatec Technologie AG has changed its corporate name into Antares Pharma IPL AG ("ANTARES"); and

WHEREAS, "ANTARES" has secured a third party being interested in a license package which package would — *inter alia* — include the rights to certain Products (all capitalized terms used herein but not defined shall have such meaning as ascribed to such terms in the Agreement) in specified countries of the Territory as licensed to BioSante Pharmaceuticals, Inc. ("BIOSANTE") under the Agreement; and

WHEREAS, BIOSANTE is prepared to return such rights to certain Products in specified countries included in the license under the Agreement for the consideration described and under the terms and conditions set forth herein below.

NOW THEREFORE, the Parties hereby agree pursuant to this Amendment No. 1 to the License Agreement dated 13th of June 2000 (the "Agreement") ("Amendment No. 1") to amend the Agreement as follows:

1. Change of Corporate Name

Following the change of corporate name from Permatec Technologie AG into Antares Pharma IPL AG effective as of 15th February 2001, the Agreement is hereby amended as follows for clarification and to make the Agreement consistent with this Amendment No. 1.

(a) all references in the Agreement to Permatec Technologie AG shall be substituted by Antares Pharma IPL AG; and

(b) all references in the Agreement to PERMATEC shall be substituted by ANTARES.

2. Return of Rights

2.1 BIOSANTE hereby returns its rights granted under the Agreement as part of the license (including without limitation rights to Develop, apply and receive Approval as applicant, Market, use and sell) to ANTARES with respect to:

(a) all rights to the Product Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin) for all countries of the Territory; and

(b) the rights to the Product Gel E2 (where estradiol is the sole active ingredient and where the gel is applied to the skin), for the countries Australia and Malaysia; and

(c) the rights to the Product Gel Testosterone (where testosterone is the sole active ingredient and where the gel is applied to the skin), for the countries Australia and Malaysia.

All such rights returned to ANTARES as described in this Section 2.1 shall be collectively referred to hereinafter as the "Returned Rights").

2.2 In order to give effect to the waiver and return of the Returned Rights, the parties agree to amend the Agreement as follows:

(a) the Product Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin) is deleted from the list of Products attached to the Agreement as Exhibit B, and all references to Patch E2 in the Agreement are deleted and eliminated without substitution; and

(b) the definition of the term "Territory" in Section 1.14 of the Agreement is deleted in its entirety and substituted by the following definition:

1.14 "Territory" shall mean the United States of America and those of its territories and possessions over which the FDS has regulatory authority (the "USA"); Canada; Australia; New Zealand; South Africa; Israel; Mexico; The People's Republic of China (including Hong Kong) ("China"); Malaysia; and Indonesia, except for the Products Gel E2 and Gel Testosterone, for which

Products the term "Territory" shall mean the United States of America and those of its territories and possessions over which the FDS has regulatory authority (the "USA"); Canada; New Zealand; South Africa; Israel; Mexico; The People's Republic of China (including Hong Kong) ("China"); and Indonesia. The countries are classified according to **Exhibit C** in three tiers.

3. Data Sharing

3.1 In order to secure the mutual exchange and sharing of data relating to the Products in the Territory (as amended hereby) by BIOSANTE and its sub-licensees, and outside the Territory (as amended hereby) by ANTARES and/or its third party licensees, the parties hereby agree that Section 5.2 of the Agreement shall in particular also include the use of any data and results generated in the Territory by BIOSANTE or any of its sub-licensees (if any) for use by ANTARES or any licensee with respect to the Returned Rights outside the Territory, and any data and results generated by ANTARES or any licensee with respect to the Returned Rights for use by BIOSANTE or its sub-licensees in the Territory.

3.2 ANTARES undertakes to include a respective obligation giving effect to such data sharing also with respect to the Returned Rights in any eventual license agreement with a third party on the Returned Rights (or any part thereof).

4. Changes in Payment Obligations

4.1 As consideration for the Returned Rights by BIOSANTE, the parties agree to eliminate certain payment obligation of BIOSANTE under the Agreement as specified herein below:

(a) the payment obligation of BIOSANTE under Section 3.3.1 of the Agreement in the amount of USD 125,000 upon start of manufacturing of the first batch of GMP-compliant finished Product for use in a clinical trial of the first Product to be subjected to such clinical trial (which is either the Product GEL E2 or GEL Testosterone) shall be eliminated from the Agreement; and

(b) the payment obligation of BIOSANTE under Section 3.3.2 of the Agreement in the amount of USD 125,000 upon start of manufacturing of the first batch of GMP-compliant finished Product for use in a clinical trial of the second Product to be subjected to such clinical trial (which is either the Product GEL E2 or GEL Testosterone) shall be eliminated from the Agreement; and

(c) the milestone payment obligation of BIOSANTE under Section10.3.3.1 of the Agreement in the amount of XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX, shall be eliminated from the Agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

4.2 As further consideration for the Returned Rights by BIOSANTE, ANTARES agrees that its obligation under Section 4.1.3 of the Agreement is not diminished by this Amendment No. 1, such that ANTARES remains obligated to expend funds for the formulation and production of the Products remaining under the Agreement, up to a potential maximum of Six Hundred Thousand Dollars ($600,000), and such that the funds it was to have expended on the Product Patch E2, up to One Hundred Fifty Thousand Dollars ($150,000), will be allocated as additional formulation and production expenditures for Product Gel E2 and Product Gel Testosterone.

4.3 The parties hereby confirm that the consideration described above is sufficient and adequate for the Returned Rights.

5. No Further Changes

5.1 The parties hereby agreed and acknowledge that the Agreement shall, except for and in due incorporation of the changes agreed upon in this Amendment No. 1, remain in full force and effect and, subject to Section 5.2 below, not be otherwise changed, altered or amended.

5.2 The parties further agree that in the event that any further amendment, change or alteration of the language or wording of any Section of the Agreement would be required to give full effect to any of the changes agreed upon in this Amendment, then such further amendment, change or alteration of the language or wording shall be made upon reasonable request of either party.

5.3 This Amendment is agreed to be subject to the provisions of the Agreement of 11.1. (Governing Law) and 11.2 (Dispute Resolution) by reference.

IN WITNESS WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the 20th day of May, 2001.

Antares Pharma IPL AG

/s/ Dario Carrara

By: Dario Carrara
Its: Executive Director

By:
Its:

BIOSANTE PHARMACEUTICALS, INC.

/s/ Stephen M. Simes

By: Stephen M. Simes
Its: President and CEO

EXHIBIT C

COUNTRY CLASSIFICATION

First Tier:	USA
Second Tier:	Canada; China
Third Tier:	All other countries of the Territory

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

AMENDMENT NO. 3

to the

License Agreement dated 13th of June, 2000 (the "Agreement")

by and between

ANTARES Pharma IPL AG, Zug, Baarerstrasse 95, 6301 Zug, Switzerland as Licensor (formerly known as Permatec Technologie AG) as **Licensor**

and

BioSante Pharmaceuticals, Inc., Lincolnshire, IL, U.S.A. as **Licensee**

Recitals:

WHEREAS, ANTARES Pharma IPL AG ("ANTARES") and BioSante Pharmaceuticals, Inc. ("BIOSANTE") have entered into that certain License Agreement dated of June 13, 2000 (the "Agreement"), regarding the grant of a license with the right to sublicense products as defined in the Agreement;

WHEREAS, ANTARES Pharma IPL AG ("ANTARES") and BioSante Pharmaceuticals, Inc. ("BIOSANTE") have entered into a Supply Agreement dated of June 13, 2000 (the "Supply Agreement") regarding the manufacturing and the supply of products (according to Exhibit D of the Supply Agreement);

WHEREAS, ANTARES and BIOSANTE have concluded some alterations to the Agreement in Amendment No. 1 of May 20, 2001 ("Amendment No. 1");

WHEREAS, ANTARES has granted BIOSANTE the licensing of XXXX Combi-Gel which is set out in Amendment No. 2 of July 5, 2001 ("Amendment No. 2") **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

WHEREAS, the parties have negotiated this third set of terms and conditions in alteration of the Agreement;

NOW, THEREFORE, the Parties agree according to this Amendment No. 3 ("Amendment No. 3") to amend the Agreement as follows:

---

1. Royalties

(a) Royalty payment

BIOSANTE will receive from ANTARES in modification of section 3.2 of the "Agreement" a commission on royalty for the sale of the combination product "Estradiol plus Norethindrone Acetate ("E2-NETA Combi Gel"). The commission on royalties for the said product will be 5% for sales amounting up to USD 75,000,000 (Seventy five million US-dollars) and 7% for sales over USD 75,000,000 (Seventy five million US-dollars). This modification comes into effect as per the date of signature (effective date) of this Amendment No. 3. However, this modification of the royalties does not apply for the products "Estradiol single gel", "Testosterone single gel" and the combination product "Estradiol plus Testosterone" but only and exclusive for E2-NETA Combi Gel.

(b) Reduction in Royalty Payments

Consistent with the principles in the BIOSANTE-SOLVAY agreement, in the instance in which an A/B rated generic equivalent or substitute of E2-NETA Combi Gel ("Product") is reasonably notified by BIOANTE, SOLVAY or ANTARES to infringe a patent available for such product in the United States or Canada, and SOLVAY may give evidence that the marketing of such competitive product has led to a reduction in sales of the product in either such country of more than fifteen percent (15%) in an average three (3) month period, then the Royalty payable by BIOSANTE to ANTARES for E2-NETA Combi-Gel after such reasonable notice in that country of the Territory will be three and one half percent (3 ½%) up to total sales of Seventy Five Million Dollars (USD 75,000,000) and five percent (5%) for sales over Seventy Five Million Dollars (USD 75,000,000), for as long as (1) such competing product is on sale, and (2) BIOSANTE's Royalty obligation exists under this Agreement.

(c) Books and records

Pertaining to E2-NETA Combi Gel BIOSANTE shall keep full, true and accurate books of accounting containing all particulars and reasonable supporting documentation which may be necessary for the purpose of the accurate determination of the Net Sales achieved by SOLVAY. The inspection of the books and records will be carried out according to the terms and conditions of the Agreement.

(d) Audits

ANTARES has the right to notify BIOSANTE that it would like to audit the books and records of SOLVAY to inspect the accuracy of SOLVAY Net Sales reported to BIOSANTE, in which instance BIOSANTE will in turn notify SOLVAY that it would like to exercise its right to audit pursuant to the agreement between BIOSANTE and SOLVAY. SOLVAY shall permit a firm of certified

public accountants, acceptable to ANTARES, BIOSANTE and SOLVAY, upon request by ANTARES, to examine all books and records relating to the sales of E2-NETA Combi Gel, at all reasonable times and upon reasonable notice, to verify BIOSANTE's reports and accountings determining the correctness of the sublicense royalties. The expenses for such audit will be borne by ANTARES as per the BIOSANTE-SOLVAY agreement.

2. Reallocation of USD 150,000

As consideration for the successful sub-license of the E2-NETA Combi Gel (see 3), hereinafter, ANTARES reallocates as follows the USD 150,000 (One hundred fifty thousand US-Dollars) obligation (as per section 4.1.2 of the Agreement) corresponding to E2-NETA Combi Gel formulation and production costs: USD 75,000 (Seventy five thousand US-dollars) for "Estradiol single gel" and additional USD 75,000 (Seventy five thousand US-dollars) for "Testosterone single gel". The reallocation will take effect as per the date of signature (effective date) of this Amendment No. 3. This reallocation is in addition to the reallocation stipulated in section 4.2 of Amendment No. 1. The net effect of these reallocations is that ANTARES is obliged to expend funds for the formulation and production of Product Gel E2 ("Estradiol single gel") and of Product Gel Testosterone ("Testosterone single gel") up to a potential maximum of USD 600,000 (Six hundred thousand US Dollars).

3. Manufacturing rights (Sublicense)

ANTARES grants to BIOSANTE the right to grant manufacturing of E2-NETA Combi Gel exclusively to Solvay Pharmaceuticals, B.V. ("SOLVAY"). In the event of termination of the Agreement between ANTARES and BIOSANTE, BIOSANTE's rights under the BIOSANTE-SOLVAY Agreement will be assigned to ANTARES, except that BIOSANTE will continue to receive its share of milestone and royalty payments paid by SOLVAY pursuant to the terms of the BIOSANTE-SOLVAY Agreement.

4. Assistance of ANTARES

The parties agree to draft and sign a separate **Manufacturing Assistance Agreement** within a period of 60 days after the signing of this Amendment No. 3. As pertains E2-NETA Combi Gel, the Manufacturing Assistance Agreement shall: (1) Replace the Supply Agreement for E2-NETA Combi-Gel; (2) Eliminate any and all ANTARES obligations contained in the Supply Agreement for E2-NETA Combi-Gel; and (3) Govern all manufacturing aspects related to E2-NETA Combi Gel.

The Manufacturing Assistance Agreement shall inter alia contain the following points:

ANTARES agrees during the term of the Manufacturing Assistance Agreement to provide technical and scientific assistance to BIOSANTE or its sublicensee against reimbursement applying a rate of USD 150 (One hundred fifty US-Dollars) per man-hour spent by ANTARES personnel. BIOSANTE further undertakes and agrees to reimburse any and all reasonable out-of-pocket expenses incurred by ANTARES and agreed to in advance in writing by BIOSANTE in connection with any such assistance to BIOSANTE. Such assistance shall be provided by

ANTARES within a reasonable time in response to requests in connection with BIOSANTE's or the sublicensee's efforts to manufacture the product.

5. Discount of USD 125,000

ANTARES grants a discount to BIOSANTE of USD 125,000 (One hundred twenty five thousand US-Dollars) for its development work already performed on "Estradiol single gel" and "Testosterone single gel". This discount may be implemented by reduction of the invoice of ANTARES to BIOSANTE dated June 30, 2001. Nothing herein shall prevent the parties from negotiating or entering into further agreements on adjustments to the June 30, 2001 invoice.

6. No Further Funding for E2-NETA Combi-Gel

After the execution of this Amendment 3 including the execution of the Manufacturing Assistance Agreement, ANTARES has no further obligation to financially fund, develop, market, assist or otherwise support E2-NETA Combi Gel as outlined in the Agreement and the Supply Agreement except for those obligations contained in this Amendment 3.

7. No Further Changes

The parties hereby agree and acknowledge that the Agreement shall, except for and in due incorporation of the changes agreed upon in Amendment No. 1, Amendment No. 2 and this Amendment No. 3, remain in full force and effect and, subject to the following, not be otherwise altered or amended.

The amendments and changes to the Agreement as set forth in this Amendment No. 3 shall upon execution become an integral part of the Agreement.

The parties further agree that in the event that any further amendment, change or alteration of the language or wording of any Section of the Agreement would be required to give full effect to any of the changes agreed upon in this Amendment, then such further amendment, change or alteration of the language or wording shall be made upon reasonable request of either party.

8. Governing Law

This Amendment No. 3 is construed under and governed by Illinois Law.

IN WITNESSETH WHEREOF, the Parties have duly executed this Amendment effective as of the day of , 2001.

ANTARES Pharma IPL AG

Allschwie August 28, 2001
Place and Date

/s/ Dario Carrara
By: Dr. Dario Carrara
Its: Managing Director, Swiss Operations

BioSante Pharmaceuticals, Inc.

Lincolnshire, IL August 30, 2001
Place and Date

/s/ Stephen M. Simes
By: Stephen M. Simes
Its: President and CEO

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 406 of the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

Amendment No. 4
to the
License Agreement
dated 13th of June 2000 (the "Agreement") by and between
Antares Pharma IPL AG, Zug, Switzerland as Licensor
(formerly known as Permatec Technologie AG)
and
BioSante Pharmaceuticals, Inc., Lincolnshire, IL, U.S.A. as Licensee

WHEREAS, Antares Pharma IPL AG, Zug, Switzerland ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante") have previously entered into a License Agreement dated June 13, 2000 ("Agreement"), regarding the grant of a license with the right to sublicense specified products, as well as a Supply Agreement of the same date; and

WHEREAS, Antares and BioSante have also entered into a series of three amendatory agreements subsequent to June 13, 2000, each of which has made specified amendments to the terms of the Agreement, as follows: Amendment No. 1, dated May 20, 2001; Amendment No. 2, dated July 5, 2001; and Amendment No. 3, dated August 30, 2001; and

WHEREAS, Antares and BioSante each acknowledge that the other is, as of this date, in material compliance with all aspects of the License Agreement and Supply Agreement, but that Antares and BioSante have identified issues involving interpretation of the Agreement and the amendments regarding which they disagree, including issues relating to the Products covered by the Agreement, and desire to resolve those differences and continue their business relationship subject to some altered terms; and

WHEREAS, in order to effectuate these purposes, Antares and BioSante desire to enter into an agreement that will effectuate a fourth set of amendments to the Agreement, with the terms set forth below;

NOW THEREFORE, the Parties hereby agree pursuant to this Amendment No.4 to the License Agreement dated 13th of June 2000 ("Amendment No. 4") to amend the Agreement as follows:

I. Amendments to Agreement

[I-1] Covered Products

Paragraph 2.1 License, as amended by Amendment No. 1, is further modified to provide that BioSante is granted a license, with the right to grant sublicenses, to Develop the Products and any improvements or modifications thereof created, developed or devised by BioSante or Antares. It therefore follows that:

A. The Products include all estrogen gels, all testosterone gels, all E+T gels, and all E+P gels, whether or not their formulations contain lauryl alcohol, except as noted in B below;

B. BioSante owns, on an exclusive worldwide basis all rights to Bio-T-Gel, XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX, and has no obligation to share any information regarding Bio-T-Gel with Antares, including data generated during development; **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this section that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

[I-2] Assistance

I-2-1 Paragraph 2.3 Assistance: Paragraph 2.3 Assistance of the Agreement is amended by the addition of an alternative means for Antares to provide assistance, as follows: if and when requested by BioSante in its sole discretion, provision of assistance will be negotiated on a project basis with an agreed-upon budget before the work commences. The final charges will be based on this budget only and will be invoiced at +/- 10% of the agreed upon budget. No additional work beyond the agreed project will commence, nor charges reimbursed, without the written agreement of Antares and BioSante.

I-2-2 Manufacturing Assistance Agreement: The parties acknowledge and agree that the Manufacturing Assistance Agreement between the parties creation of which was provided for by Amendment No.3 has not been created, and that, as a result of different agreements of the parties embodied in this Amendment no.4, the parties no longer desire that such a Manufacturing Assistance Agreement should be created or entered into between them.

[I-3] Royalty

Paragraph 3.2 Roya1ty Payments of the Agreement, as amended by Amendment No. 3, is further amended to provide that BioSante's obligation to pay a royalty is amended from XXXXXX (XXXX) to XXXXXX (XXXX) in the case of licensed Products, and BioSante will pay to Antares a royalty of XXXX of the royalty received by BioSante, up to a maximum of XXXX of net sales, in the case of sub-licensed Products. **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

[I-4] Sub-licensee up-front, sublicense or milestone payments

Paragraph 3.4 of the Agreement is amended to provide that:

A. Upon sub-license by BioSante of any Product covered in this Agreement or Amendments Nos. 1, 2, or 3 (other than E/Neta), BioSante will pay to Antares the proportion of such upfront payments defined in C below or Milestone Payments defined in paragraph 3.3 actually received, as follows: a) where the payments received by BioSante are XXXXXXXXXXXX from BioSante to Antares then XXXXXXXXXX will be due to Antares, b) where the payments to BioSante are XXXXXXXXXXXXXXX above the commitment to Antares, the additional amount payable to Antares will be XXX of this excess, and c) where payments received by BioSante are XXXXXXXXXXX the amounts due to Antares, then BioSante will pay Antares XXX of this excess. (For example, if a Milestone Payment of XXXXXX is due from BioSante to Antares, and a sub-licensee pays BioSante a Milestone Payment upon the same milestone of XXXXXX, BioSante will pay Antares XXX of the amount from XXXXXX to XXXXXX (that is, XXXXXX) and BioSante will pay Antares XXX of the XXXXXX excess over XXXXXXXXXXX the XXXXXX Milestone Payment, or XXXXXX) for a total of XXXXXX; **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

B. In the case of E/Neta, BioSante will pay to Antares XXX of all sums received from sub-licensees for the same Milestone in excess of the Milestone Payment payable under paragraph 3.3; **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

C. For purposes of calculating the appropriate amount of upfront payments, Antares and BioSante agree that the $1.0 million BioSante paid upfront to Antares is deemed to be attributed XXXXXXX to each of Bio-E-Gel, LibiGel and E/Neta (XXXXXXXX); **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

D. BioSante has no obligation to pay to Antares any portion of payments made to it for equity investments by sub-licensees, except to the extent that such equity investment incorporates payment of a per-share premium over the then-current market price, in which case BioSante shall pay Antares XXX of such premiums received. **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

[I-5] BioSante's Development and Marketing obligations/United States and Non-US

Paragraphs 5.3 BioSante's Development and Marketing obligations/United States and 5.4 BioSante's Development and Marketing obligations/Non-US are amplified by the agreement that at its risk, BioSante will make final decisions as to data requirements for US submissions.

[I.6] Reduction in Royalty

Paragraph 8.2.3 Reduction in Royalty is amended to provide that in the instance in which arise the triggering circumstances described in that Paragraph 8.2.3, relating to the existence an A/B rated generic equivalent, the royalty owing is to be reduced from XXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX. **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

[I-7] Terms

Paragraph 10.3.2 Terms, regarding XXX Combi Gel is amended to provide that

A. the license fee totals XXXXXXXXXXXXXXXXXXXXXXXXXX (XXXXXX); and

B. XXXXXXXXXXXXXXXXXXXXXXXX (XXXXXX) of the license fee has been satisfied by Amendment No. 1, and royalty to XXXXX from XXXXX.

[A portion of these sections have been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of these sections with the portion intact has been filed separately with the Securities and Exchange Commission]

[I-8] Payments

I-8-1 10.3.3.2 Manufacturing of clinical batches: The provisions of sub-paragraph 10.3.3.2 of the Agreement are entirely deleted, extinguished and eliminated.

I-8-2 10.3.3.3 Filing of the product: The provisions of sub-paragraph 10.3.3.3 are amended to provide that the maximum milestone payment owed by BioSante upon filing of the product is XXXXXXXXXXXXXXXXXXXX (XXXXXX). **[A portion of this section has been omitted pursuant to a request for confidential treatment under Rule 406 under the Securities Act of 1933, as amended. The confidential portions of this Exhibit that have been omitted are marked with "XXXX." A copy of this section with the portion intact has been filed separately with the Securities and Exchange Commission]**

II. Supply Agreement

[II-1] Supply Agreement Termination

The Supply Agreement between Antares (formerly known as Permatec Technologie, AG) and BioSante dated June 13, 2000, by agreement of Antares and BioSante, is hereby terminated, extinguished an eliminated in its entirety pursuant to Article 18 (Modification) of the Supply Agreement. Antares and BioSante acknowledge that all manufacturing is being transferred to a U.S. based GMP manufacturer and that Antares has no similar capacity. Any assistance in manufacturing will be governed by Paragraph 2.3 as amended above. Antares and BioSante each acknowledge that (a) neither has accrued any rights to its benefit under the Supply Agreement prior to this date, and that (b) neither has any obligations under the Supply Agreement that survive this termination

[II-2] Antares to Involve BioSante in Manufacturing Communications

In order to maintain efficiency and accuracy in manufacturing, which will benefit both Antares and BioSante, Antares agrees to assure that BioSante will be fully involved and informed in conversations and communications with DPT regarding BioSante products, Bio-E-Gel, LibiGel, LibiGel E/T and any other product that may be developed.

III. General

[III- 1] Package Development

In the event that another Antares licensee uses a package or labeling developed by BioSante, BioSante will be reimbursed by Antares for development expenses in an amount to be negotiated by the parties in good faith. In the event another Antares licensee uses packaging for which BioSante provides dies, tooling, and similar equipment, BioSante will be reimbursed by Antares for the expense of such equipment.

[III-2] Governance

In addition to and preceding the mechanisms in 11.2 Dispute Resolution of the Agreement, the parties agree that Steering Committee, made up of Dario Cararra, Roger Harrison, Stephen Simes and Leah Lehman or replacements to be named by the respective companies. The Operational Committee will be Holger, Doris and Lisa or replacements to be named by the respective companies.

[III-3] Continued effect

The parties agree that the Agreement shall, except for and in due incorporation of the amendments agreed upon in Amendment No. 1, dated May 20,2001; Amendment No. 2 dated July 5,2001; and Amendment No.3, dated August 30, 2001, and this Amendment No. 4, remains in full force and effect and are not otherwise changed, altered or amended. The parties further agree that in the event that any further amendment, change or alteration to the language or wording if any section of the Agreement or this Amendment No.4 is determined by the parties to

be required to give full effect to any of the changes agreed upon in this Amendment No. 4, then the parties agree to execute in writing any such further amendment, change or alteration.

IN WITNESSETH WHEREOF, the Parties have duly executed this Amendment effective as of the 8th day of August, 2002.

Antares Pharma IPL AG

	/s/ Roger G. Harrison
Place and Date	By: Roger G. Harrison
	Its: CEO and President

BioSante Pharmaceuticals, Inc.

Lincolnshire, IL 8/8/02	/s/ Stephen M. Simes
Place and Date	By: Stephen M. Simes
	Its: President and CEO

Amendment No. 5
to the
License Agreement dated 13th of June 2000 (the "Agreement")
by and between

Antares Pharma IPL AG
Zug, Switzerland
as Licensor
(formerly known as Permatec Technologie AG)

and

BioSante Pharmaceuticals, Inc.
Lincolnshire, IL, U.S.A.
as Licensee

WHEREAS, Antares Pharma IPL AG, Zug, Switzerland ("Antares") and BioSante Pharmaceuticals, Inc., Lincolnshire, Illinois ("BioSante") have previously entered into a License Agreement dated June 13, 2000 ("Agreement"), regarding the grant of a license with the right to sublicense specified products, as well as a Supply Agreement of the same date;

WHEREAS, Antares and BioSante have also entered into a series of four amendatory agreements subsequent to June 13, 2000, each of which has made specified amendments to the terms of the Agreement, as follows: Amendment No. 1, dated May 20, 2001; Amendment No. 2, dated July 5, 2001; Amendment No. 3, dated August 30, 2001; and Amendment No. 4, August 8, 2002;

WHEREAS, Antares and BioSante each acknowledge that Antares and BioSante have identified issues involving interpretation of the Agreement and the amendatory agreements regarding which they disagree, specifically as to the appropriate timing of the milestone payment provided for in paragraph 3.3.3 of the Agreement, as modified by section 1-4(B) of Amendment No. 4, and the agreed geographical location of product development activities; and

WHEREAS, Antares and BioSante each desire to resolve their differences without acknowledging the accuracy or validity of the assertions of the other, except as may be set forth herein, and desire to continue their business relationship subject to some altered terms;

NOW THEREFORE, Antares and BioSante hereby agree pursuant to this Amendment No. 5 to the License Agreement dated 13th of June 2000 ("Amendment No. 5") to amend the Agreement as follows:

A. MILESTONE

In order to perform its obligations under paragraph 3.3.3 of the Agreement, as modified by paragraph 1-4(B) of Amendment No. 4, Antares and BioSante agree that BioSante shall pay

(1) the sum of Two Hundred Thousand Dollars (USD 200,000), upon execution of this Amendment No. 5; and

(2) an additional Three Hundred Thousand Dollars (USD 300,000) upon the start of a clinical trial of E2-Neta Combi Gel in the USA or upon filing of a New Drug Application with the US Food and Drug Administration for E2-NETA Combi Gel by Solvay Pharmaceuticals, whichever occurs first.

The Parties agree and acknowledge that the above sums are in full and complete performance of the obligations in paragraph 3.3.3 of the Agreement, as modified by paragraph 1-4(B) of Amendment No. 4, and in full and complete settlement and resolution of their differences with respect to such paragraphs, and that payment of such sums are in addition to and different than payment of any other sums provided for in the Agreement and any of the four prior amendments to it.

B. GEOGRAPHY OF DEVELOPMENT ACTIVITIES

In order to resolve the Parties' disagreement regarding the proper geographical location of development activities for defined Products:

(1) BioSante hereby acknowledges and agrees that its license from Antares regarding E2-Neta Combi Gel includes marketing rights only in the United States and Canada, and regarding other Products, only in countries specifically enumerated in the Agreement and/or one or more of the amendments to it, and hereby reaffirms that it has no intention of undertaking or sublicensing development activities for any purposes other than achieving regulatory approval and making subsequent sales and undertaking related support activities in the countries with respect to which it has received such licenses from Antares; and

(2) Antares and BioSante hereby acknowledge and agree that, under the terms of the Agreement and the five amendments to it, activities constituting Development of any Product may be undertaken in any geographical location inside or outside the agreed and defined Territory for such Product, whether undertaken by BioSante or its sublicensee Solvay Pharmaceuticals regarding E2-Neta Combi Gel, or any other sublicensee regarding any other Product, or any future sublicensee, assignee or designee. The choices of location of such activities are in the sole discretion of BioSante, Solvay or its assignee or designee, and such entities will not, by virtue of their choice of location alone, be considered to be in breach of the Agreement or any amendment to it. As in section B(1) above, it is acknowledged that all such activity will be directed toward achieving regulatory

approval and making subsequent sales and undertaking related support activities in the territories in which BioSante, its current or future sub licensees, or any

future sub licensees, designees or assignees have rights to the Products as specified in the Agreement and all amendments.

C. MISCELLANEOUS

The parties agree that the Agreement shall, except for and in due incorporation of the amendments agreed upon in Amendment No. 1, dated May 20, 2001; Amendment No. 2, dated July 5, 2001; Amendment No. 3, dated August 30, 2001; Amendment No. 4, dated August 8, 2002, and this Amendment No. 5, remain in full force and effect and is not otherwise changed, altered or amended.

IN WITNESSETH WHEREOF, the Parties have duly executed this Amendment effective as of the 30th day of December, 2002.

Antares Pharma IPL AG

PA 12/30/02	/s/ Roger G. Harrison
Place and Date	By: Roger G. Harrison
	Its: President and CEO

BioSante Pharmaceuticals, Inc.

Lincolnshire, IL 12/27/02	/s/ Stephen M. Simes
Place and Date	By: Stephen M. Simes
	Its: President and CEO

Exhibit 10.33

Execution Version

[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. THE CONFIDENTIAL PORTIONS OF THIS EXHIBIT THAT HAVE BEEN OMITTED ARE MARKED WITH "XXXX." A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

Amendment No. 6

to the

License Agreement
dated 13th of June 2000

by and between

Antares Pharma IPL AG, Zug, Switzerland as Licensor
(formerly known as Permatec Technologies AG)

and

BioSante Pharmaceuticals, Inc., Lincolnshire, IL, USA as Licensee

WHEREAS, Antares Pharma IPL AG, Zug, Switzerland ("Antares") and BioSante Pharmaceuticals, Inc., Lincolnshire, Illinois, United States of America ("BioSante") have previously entered into a License Agreement dated June 13, 2000 ("License Agreement"), as amended in a series of five amendments, as follows: Amendment No. 1, dated May 20, 2001; Amendment No. 2, dated July 5, 2001; Amendment No. 3, dated August 30, 2001; Amendment No. 4, dated August 8, 2002; and Amendment No. 5, dated December 30, 2002 (collectively the Amendments and with the License Agreement, the "Agreement"); and

NOW THEREFORE, Antares and BioSante agree pursuant to this Amendment No. 6 dated October 20, 2006 to the Agreement ("Amendment No. 6") to amend the Agreement as follows:

1. License Grant. The licenses granted under the Agreement are hereby amended as follows:

(a) Paragraph 1.10 of the Agreement is hereby amended and restated in its entirety as follows:

"Products" shall have the meaning set forth in Exhibit B of this License Agreement."

(b) Exhibit B of this Agreement is hereby amended and replaced in its entirety as follows:

"A. Products shall include all estrogen gels, all testosterone gels, all E and T gels, and all E and P gels, whether or not if any of the above gel formulations contain lauryl alcohol, except as noted in Section B below.

B. BIOSANTE owns on an exclusive worldwide basis, free and clear of any claims by ANTARES, its product and formulation currently known as and referred to as Bio-T-Gel (XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX), and has no obligation to share information regarding Bio-T Gel with ANTARES, including data generated during development. **[PORTIONS OF THIS SECTION HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. THE CONFIDENTIAL PORTIONS OF THIS EXHIBIT THAT HAVE BEEN OMITTED ARE MARKED WITH "XXXX." A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]**

C. Notwithstanding the above, AP-108l (gel containing norelgestromin and ethinyl estradiol and which is a competitor to Ortho Evra) shall not be included in Products.

D. Notwithstanding the above, Nestorone (gel formulation made pursuant to Joint Development Agreement with The Population Council) shall not be included in Products.

E. Notwithstanding the above, Antares shall retain its rights to testosterone gels for prevention or treatment of diseases in males in the Territory but only for products for which regulatory approval is sought and obtained by submission of (what in the United States would be known as) a full New Drug Application, and not an Abbreviated New Drug Application, "paper NDA" under section 505(b)(2) of the United States FD&C Act, or other form of application that relies on clinical studies conducted by others as to which the applicant does not have a right of reference."

(c) Paragraph I-1 of Amendment No. 4 to the License Agreement is no longer applicable and is deleted in its entirety.

(d) Paragraph 2.1 of the Agreement is hereby amended and replaced in its entirety as follows:

"2.1.1 ANTARES hereby grants to BIOSANTE an exclusive license, with the right to grant sublicenses as provided in this License Agreement, to Develop the Products in the field of transdermal gel preparations ("Field") in the Territory for purposes of obtaining Approvals, and upon receipt of the Approvals, to Market and sell the Products in the Field in the Territory, and to use the Patents and Know-How exclusively for that purpose, all in accordance with provisions contained in this Agreement. It is the parties' intention that any product characterized by its

marketing approval, as opposed to Products, developed by BIOSANTE and based on PERMATECH'S Technology will be and remain the property of BIOSANTE but BIOSANTE will not be allowed to use or market the products in case this License Agreement between ANTARES and BIOSANTE is terminated.

2.1.2 ANTARES hereby grants to BIOSANTE a non-exclusive license, with the right to grant sublicenses as provided in this License Agreement, under the Patents and Know-How, to make and have made Bio-E-Gel in the Territory.

2.1.3 ANTARES additionally grants to BIOSANTE a non-exclusive license with the right to grant sublicenses as provided in this License Agreement, to conduct the following activities: investigation, research, conduct clinical trials and perform market research in any country outside of the Territory. For purposes of clarity the above license shall not include a license or right to apply or seek any regulatory approval/marketing authorization for any Product outside the Territory."

(e) Paragraph B(2) of Amendment No. 5 to the License Agreement is no longer applicable and is deleted in its entirety.

(f) Paragraph 2.2 of the Agreement is hereby amended by the deletion of "(with only the commercial terms redacted)" from the last sentence therein.

(g) Paragraph 2.2 of the Agreement is hereby further amended by the insertion of the following sentence after the end of the sentence beginning with "Furthermore, BIOSANTE undertakes . . ." with the following sentence:

"Additionally, BIOSANTE covenants that any and all sublicense agreements, in which Bio-E-Gel is sublicensed, shall provide that (i) all up-front, sublicense and milestone payments due from such sublicense agreement shall be paid into an interest bearing escrow account established for the benefit of both ANTARES and BIOSANTE and shall be the account designated by both ANTARES and BIOSANTE ("Escrow Account") and (ii) that ANTARES is a third party beneficiary of such sublicense agreement solely with respect to subsection (i) above. The parties agree that the terms of the Escrow Account shall provide that (a) ANTARES is responsible for all costs and fees to establish and maintain the Escrow Account, (b) seventy-five (75%) of funds deposited shall immediately be released to BIOSANTE, and (c) the remaining twenty-five (25%) of funds deposited plus any and all interest accrued shall be released to ANTARES upon thirty days from deposit."

2. Credit for Sublicense Payments for Bio-E-Gel. In the event that BioSante (i) terminates a sublicense agreement for Bio-E-Gel ("Sublicense Agreement") prior to February 15, 2007 and where such termination is based on BioSante failing to receive regulatory approval for Bio-E-Gel by the FDA (as defined below) and (ii) has to return all or a portion of the upfront consideration received pursuant to such Sublicense Agreement, then Antares will credit the pro rata portion of such upfront consideration that it received to future payments due by BioSante for Bio-E-Gel.

3. Disclosure of Confidential Information. Each party may disclose non-public confidential information of the other party to subcontractors or potential licensees who are under a binding obligation of confidentiality to such party, at least as strict as in the Agreement and so long as such party remains responsible for the potential licensees' compliance.

4. Patent Prosecution and Maintenance. From the effective date of this Amendment No. 6, Antares will, at its cost and expense, file, prosecute, and maintain the Patents, including, but not limited to, those listed on Appendix A hereto. If Antares determines to abandon or not file any Patent, then Antares shall provide BioSante with written notice at least thirty (30) days or if less, as long as reasonably practicable, prior to the date such abandonment or failure to file would become effective for BioSante to act in its stead, provided, that BioSante has received from Antares any and all reasonable documentation and information it reasonably needs to make a decision and take the necessary action in reasonable sufficient time to avoid abandonment. For purposes of clarity, discontinuance shall be elected on a country-by-country basis. BioSante may elect at its sole discretion to continue prosecution or maintenance of any discontinued Patent at its sole expense. BioSante shall then own any such Patent, and Antares shall execute such documents and perform such acts, at BioSante's cost, as may be reasonably necessary for BioSante to continue prosecution or maintenance, including assigning and transferring ownership of such Patent to BioSante and directing its counsel to transfer the complete file to BioSante or its counsel as BioSante may request. Upon the assignment or transfer of any Patent to BioSante, Antares shall not be thereafter entitled to any royalties from sales of a Product sold in a country where such Patent was abandoned and where such Patent claims such Product.

5. Patent Reports and Updates. Antares will (at its sole cost and expense) provide BioSante with a complete paper, organized file set of material prosecution documents for each of the Patents. Going forward, Antares will at its sole cost and expense copy BioSante on all material communications with respective patent offices in the Territory and provide BioSante with twice-yearly update summaries reviewed by its patent counsel regarding each of the Patents (including filing, prosecution, and maintenance status in each country in the Territory). Additionally, Antares will, at BioSante's expense, make its counsel reasonably available to consult with BioSante and potential licensees regarding the status of the Patents.

6. Patent Enforcement. To the extent BioSante consents in writing, BioSante's exclusive sublicensee(s) in the United States shall have those rights possessed by BioSante as set forth in section 8.2.2 and 8.2.4 of the Agreement.

7. LibiGel Package. BioSante will promptly provide Antares with a copy of all material filings and submissions submitted to date to the United States Food and Drug Administration ("FDA") regarding LibiGel and the minutes from the BioSante LibiGel meeting held with the FDA on or about April 2006 (collectively, the "LibiGel Package").

8. XXXXXXXXXXXXXX. BioSante consents to Antares' engagement of XXXXXXXXXXXXXX in Europe for work on testosterone gel for women; provided that Antares agrees that no BioSante confidential information is used or disclosed in connection with the engagement. **[PORTIONS OF THIS SECTION HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. THE CONFIDENTIAL PORTIONS OF THIS**

EXHIBIT THAT HAVE BEEN OMITTED ARE MARKED WITH "XXXX." A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

9. Steering Committee. Antares and BioSante will each send at least one representative who is an officer to a steering committee meeting to be held on a twice-yearly basis alternating between Antares' facility and BioSante's facility. Each party will provide a summary update twice-yearly to the other of its activities being conducted to establish that it is in substantial compliance with its material obligations under the Agreement.

10. Further Sublicensing. BioSante may, in connection with the exercise of its sublicense rights under the Agreement, authorize (i) its sublicensee(s) to solely grant a further sublicense to their contract manufacturer(s) for the sole purpose of manufacturing Product for such sublicensee(s) to the extent that BioSante has such license right itself or (ii) an exclusive sublicensee of BioSante ("Sublicensee") the right to further sublicense Bio-E-Gel subject to Antares' written consent (not to be unreasonably withheld), provided, that all payments due to BioSante from its Sublicensee, directly or indirectly, for the grant of such further sublicense by the Sublicensee shall be paid into the Escrow Account and disbursed in accordance with the procedures and allocation percentages provided in Paragraph 2.2 of the Agreement.

11. Audits of Sublicensees. With respect to any audits that Antares may conduct of sublicensees pursuant to Sections 2.2 and 3.5.2.4 of the Agreement, Antares agrees that it and any independent certified public accounting firm retained by Antares to conduct the audit will treat any information obtained from the sublicensee during the course of the inspection and audit as confidential pursuant to Section 7 of the Agreement, and if requested by the sublicensee will execute a commercially reasonable confidentiality agreement before beginning the audit in which Antares and such public accounting firm agree to maintain the confidentiality of the sublicensees' books and records and to use all information received from the sublicensee only for such audit purpose.

12. Effect of Termination on Sublicensee. Antares agrees that if so provided in a sublicense agreement signed by BioSante and its sublicensee of its rights hereunder and where such sublicense has been granted in accordance with the Agreement, then a termination of the Agreement due to BioSante's breach that is not caused by the sublicensee will not terminate the sublicensee's license rights and that in such case the sublicense agreement (and all future payments and performance under the sublicense agreement by the sublicensee) will continue between the sublicense and Antares. In the event the aforesaid termination was caused by BioSante's non-payment of monies due to Antares, such continuation of the sublicense agreement between sublicense and Antares shall not effect BioSante's obligation to pay Antares for any and all monies due from BioSante to Antares as of the date of termination.

13. Representation. Antares hereby represents that, to its knowledge as of the effective date of this Amendment No. 6, Bio-E-Gel does not infringe any patent or other proprietary right of any third party in the United States.

14. Amended and Restated Agreement. The parties will exercise good faith efforts to prepare and execute an amended and restated agreement of this Agreement as it exists as of the execution

of this Amendment No. 6 as soon as practicable, and no later than within 90 days, following execution of this Amendment No. 6, with ANTARES to prepare a full and complete initial draft of same at its expense. After preparation of such initial draft by ANTARES, each party will be responsible for its own costs and expenses incurred in the completion of such amended and restated agreement. For clarity, such amended and restated agreement shall strictly conform in all respects to this Agreement as it exists as of the execution of this Amendment No. 6.

15. Headings. The captions to the paragraphs/section in this Amendment No. 6 are not a part of this Amendment No. 6 or the Agreement, and are included merely for convenience of reference only and shall not affect its meaning or interpretation.

16. Counterparts. This Amendment may be signed in any number of counterparts with the same effect as if the signatures thereto and hereto were upon the same instrument.

17. Construction. This Amendment No. 6 (i) was drafted by both parties and thus any rule of contract interpretation calling for documents to be construed against the drafter shall not apply to the construction of this Amendment, and (ii) shall not affect the construction of the Agreement as it existed before the effective date of this Amendment.

18. Miscellaneous. Antares and BioSante confirm and acknowledge that the Agreement is in full force and effect, that there have been no uncured events of breach to date, and that each is in material compliance with the Agreement. Nothing in this Amendment No. 6 shall constitute an admission of wrongdoing by either party vis a vis the other and each party expressly denies any wrongdoing. Except for the changes made by this Amendment No. 6 to the Agreement, the Agreement remains in full force and effect without modification.

IN WITNESS WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the 20th day of October, 2006.

Antares Pharma IPL AG

By:	/s/ Jack E. Stover	/s/ Dario Carrara
Name:	Jack E. Stover	Dario Carrara
Title:	President & CEO	Managing Dir. Swiss Operations
Date:	10/20/06	10/20/06

BioSante Pharmaceuticals, Inc.

By: /s/ Stephen M. Simes

Name: Stephen M. Simes

Title: President * CEO

Date: 10/20/06

Appendix A
Patents

1. U.S. Appl. No. 10/798,111
2. U.S. Appl. No. 10/343,570
3. U.S. Appl. No. 10/798,161
4. U.S. Appl. No. 11/371,042
5. U.S. Patent. No. 5,891,462
6. U.S. Appl. No. 11/441,311
7. U.S. Prov. Appl. No. 60/794,015

BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, IL 60069

October 27, 2006

Antares Pharma IPL AG
c/o Antares Pharma Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard, Suite 290
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to clarify paragraph 12 of Amendment No. 6 (dated as of October 20, 2006) of the Agreement. Specifically, it is BioSante's understanding that in the event that a sublicense agreement is assigned to Antares under that paragraph 12, any moneys that the sublicensee owed BioSante as a result of events (such as sales or milestone-triggering events) that occurred before the effective date of the termination of the Agreement would still be owed and paid to BioSante, even if the actual payment date were to fall after the effective date of the termination.

If this clarification is agreeable to Antares, please countersign below and return a copy of this letter to me. Thank you.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer

Agreed and Accepted:

ANTARES PHARMA IPL AG

By: /s/ Jack E. Stover
Jack E. Stover
President and CEO

DATED: October 27, 2006

BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, IL 60069

November 6, 2006

Antares Pharma IPL AG
c/o Antares Pharma Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard, Suite 290
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to seek clarification of two paragraphs of Amendment No. 6 (dated as of October 20, 2006) of the Agreement.

With respect to paragraph 6, BioSante would like to clarify that in the event that it and/or its sublicensee assert any of the Patents listed in Appendix A to Amendment No. 6 against an infringer, Antares would agree if commercially reasonable and if requested to join as a coplaintiff (to assure standing) at the sole cost and expense of the party making the request (BioSante or the sublicensee, as the case may be).

With respect to paragraph 12, BioSante we would like to clarify that the provisions of this paragraph would also apply if the Agreement is terminated due to BioSante's bankruptcy, by inserting the phrase "or bankruptcy" after the phrase "BioSante's breach" in the third line.

If this is agreeable, please countersign below and return a copy of this letter to me.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Name and title:
Stephen M. Simes
President & CEO

Agreed and Accepted:

ANTARES PHARMA IPL AG

By: /s/ Jack E. Stover
Name and title:
Jack E. Stover
President & CEO

DATED: November 6, 2006

BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, IL 60069

November 7, 2006

Antares Pharma IPL AG
c/o Antares Pharma Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard, Suite 290
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to provide language to embody a clarification and amendment to the Agreement.

With respect to the proposed sublicense of Bio-E-Gel to Bradley Pharmaceuticals, Inc. ("Sublicensee") by BioSante ("Sublicense Agreement"), BioSante and Antares agree that Antares shall receive twenty-five percent (25%) of all up-front, sublicense and milestone payments due from such Sublicense Agreement as provided in Amendment No. 6 of the Agreement dated October 20, 2006 ("Amendment No. 6"), and in the event that BioSante is to receive at least seven million dollars upon the regulatory approval of Bio-E-Gel in the United States, then BioSante shall not be obligated to pay any additional milestone payments on the regulatory approval of Bio-E-Gel for the United States other than twenty-five percent (25%) of the payment it receives for regulatory approval of Bio-E-Gel from Sublicensee for the United States. For purposes of clarity, if Sublicensee is obligated to pay seven million dollars to BioSante upon regulatory approval of Bio-E-Gel in the United States, then Antares shall receive twenty-five percent of such amount - $1,750,000 to be paid as provided in paragraph 1(g) in Amendment No. 6.

Additionally, because the escrow account contemplated by Amendment No. 6 has not been established and we are on the verge of executing the Sublicense Agreement for Bio-E-Gel with the Sublicensee, we ask Antares' agreement that the escrow requirement of Amendment No. 6 is satisfied if the Sublicensee pays directly upon signing to Antares twenty-five percent (25%) of all payments due to BioSante or its Affiliates upon signing by wire to the following account:

Bank name and address:
Wells Fargo Bank, N.A.
6th and Marquette
Minneapolis, MN 55479
Account name: Antares Pharma, Inc.
Account number: 323-869-1379
ABA: 121000248

Except for the changes made by this letter, the Agreements remains in full force and effect without modification.

If this is agreeable, please countersign below and return a copy of this letter to me.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Name: Stephen M. Simes
Title" President & CEO

Agreed and Accepted:

ANTARES PHARMA IPL AG
`

By: /s/ Robert Apple
Name: Robert Apple
Title: CFO

DATED: November 7, 2006

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-168842, 333-151660, 333-151663, 333-109474, 333-100238 and 333-53384 on Form S-8 and in Registration Statement Nos. 333-156276, 333-166859, 333-159606, 333-144665, 333-136852, and 333-64218 on Form S-3 of our reports dated March 16, 2011, relating to the financial statements of BioSante Pharmaceuticals, Inc., and the effectiveness of BioSante Pharmaceuticals Inc.'s internal control over financial reporting, appearing in this Annual Report on Form 10-K of BioSante Pharmaceuticals, Inc. for the year ended December 31, 2010.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 16, 2011

Exhibit 31.1

CERTIFICATION OF CEO PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Stephen M. Simes, certify that:

1. I have reviewed this annual report on Form 10-K of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2011

/s/ Stephen M. Simes

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

Exhibit 31.2

CERTIFICATION OF CFO PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 AND SEC RULE 13a-14(a)

I, Phillip B. Donenberg, certify that:

1. I have reviewed this annual report on Form 10-K of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2011

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

Exhibit 32.1

Certification of CEO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen M. Simes, Vice Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen M. Simes
Stephen M. Simes
Vice Chairman, President and Chief Executive Officer
March 16, 2011

Exhibit 32.2

Certification of CFO Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip B. Donenberg, Senior Vice President of Finance, Chief Financial Officer and Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Senior Vice President of Finance, Chief Financial Officer and Secretary
March 16, 2011