BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 30, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark one)

þ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

o **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____.
Commission file number 001-31812

BIOSANTE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(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 þ

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 þ

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 þ 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. þ

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 o | Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company þ

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

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, 2009 (the last business day of the registrant s second fiscal quarter) as reported by The NASDAQ Global Market on that date was approximately $48.8 million.

As of March 15, 2010, 63,667,194 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 2010 Annual Meeting of Stockholders to be held in June 2010.

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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 , BioLook , BioVant , BioOral , BioAir and GVAX . 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, menopause, contraception and male hypogonadism. In addition, we are evaluating and seeking opportunities for our GVAX cancer immunotherapies, 2A/Furin and other technologies we acquired in our merger with Cell Genesys, Inc. in October 2009. We also are developing our calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery.

Our products for female sexual health, menopause, contraception and male hypogonadism 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 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.

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 one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically, 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, specifically HSDD, in naturally menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

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Currently, three LibiGel Phase III studies are underway and enrolling women: two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months after which time we intend to submit an NDA to the FDA. In February 2010, we announced that based upon the second review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee (DMC) unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. As of such date, there had been no deaths, only six adjudicated cardiovascular events and four breast cancers reported. In view of the DMC recommendation, we will continue the LibiGel Phase III development program as planned. We continue to target submission to the FDA of an NDA by mid-2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

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 which permanently reduced the royalty percentage due to us related to Azur s sales of Elestrin. Upon signing the amended agreement, Azur made a $1.0 million nonrefundable payment in December 2009 in exchange for a permanent reduction in future royalty rates, and received options to make a total of $2.16 million in additional non-refundable payments (which were exercised during the first quarter of 2010) in exchange for the elimination of substantially all remaining future royalties and milestone payments due us under the terms of the original license. The $1.0 million nonrefundable payment was recorded as revenue during the fourth quarter of 2009 as we had no remaining performance obligations with respect to this amount. 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.

As a result of our October 2009 merger with Cell Genesys, we acquired a portfolio of products, including GVAX cancer immunotherapies. GVAX cancer immunotherapies are cancer vaccines designed to stimulate the patient s immune system to effectively fight cancer. Multiple Phase II trials of these technologies which had been ongoing at the date of the acquisition are continuing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer programs, including pancreatic cancer, leukemia and breast cancer.

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. We are pursuing the development of three potential initial applications for our CaP technology. First, CaP technology is being tested in the area of aesthetic medicine. Second, our CaP technology is being tested for its adjuvant activity that enhances the ability of a vaccine to stimulate an immune response. The same nanoparticles allow for delivery of the vaccine via alternative routes of administration including non-injectable routes of administration. Third, we are pursuing the creation of oral, buccal, intranasal, inhaled and longer acting delivery of drugs that currently must be given by injection (e.g., insulin).

The following is a list of our CaP products in development:

- BioLook facial line filler in development using proprietary CaP technology in the area of aesthetic medicine, e.g., a facial line filler.
- BioVant proprietary CaP adjuvant and delivery technology in development for improved vaccines against viral and bacterial infections and autoimmune diseases, among others. BioVant also serves as a delivery system for non-injected delivery of vaccines.

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BioOral a delivery system using CaP technology for oral/buccal/intranasal administration of proteins and other therapies that currently must be injected.

BioAir a delivery system using CaP technology for inhalable versions of proteins and other therapies that currently must be injected.

BioSante s Product Portfolio

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. As part of this process, we merged with Cell Genesys in October 2009. As a result of this transaction, although we will continue to focus primarily on our LibiGel clinical development program, we also will seek future development opportunities for our GVAX cancer immunotherapies, including potential combination with BioVant, our vaccine adjuvant, as well as possible external collaborations, and also will seek to outlicense or sell other technologies acquired from Cell Genesys. In addition, as a result of our merger with Cell Genesys, we acquired an investment equivalent to approximately 16 percent of the total equity of Ceregene, Inc., a privately held biotechnology company focused on the treatment of major neurodegenerative disorders using the delivery of nervous system growth factors.

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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, testosterone and a combination of estradiol and testosterone: Elestrin, Bio-T-Gel and LibiGel, and 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, The Pill-Plus. 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 hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue and to dry in under one to two minutes. We believe our gel products have a number of benefits over competitive products, including the following:

- our transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus transdermal patches;
- our transdermal gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;
- our transdermal gels have been shown to be well absorbed, thus allowing clinical hormone 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.

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 due to aging or following surgical menopause. LibiGel successfully has completed a Phase II clinical trial, and three Phase III safety and efficacy clinical studies are currently underway and 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 one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of 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 indicates that these agreed measures will serve as the basis for regulatory review and any decision by the FDA to approve an NDA for LibiGel. These SPA trials use our validated instruments to measure the clinical endpoints. We have three SPA agreements 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 LibiGel for the treatment of FSD, specifically, HSDD in naturally menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

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Currently, three LibiGel Phase III studies are underway and enrolling women: two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months after which time we intend to submit an NDA to the FDA. In February 2010, we announced that based upon the second review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. As of such date, there had been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. In view of DMC recommendation, we will continue the LibiGel Phase III development program as planned. We continue to target submission to the FDA of an NDA by mid-2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

There is no pharmaceutical product currently approved in the United States for FSD, specifically HSDD. While several therapies have been tested to treat FSD, thus far testosterone therapy appears to be the only treatment that results in a consistent significant increase in the number of satisfying sexual events in women, which represents one of the two key efficacy endpoints chosen by the FDA for pivotal clinical trials of FSD therapies. We are not aware of another testosterone therapy product for the treatment of FSD in active clinical development in the U.S. other than LibiGel.

Although generally characterized as limited to men, testosterone also is present in 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 18-59, 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) and 26 percent could not experience orgasm. Furthermore, according to a study published in the *New England Journal of Medicine*, 43 percent of American women between the ages of 57-85 experience low sexual desire. Importantly, according to IMS data, two million testosterone prescriptions were written off-label for women by U.S. physicians in 2007. 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.

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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.

In December 2006, we received FDA approval for the marketing of Elestrin in the United States. 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 that delivers 0.87 grams of gel per actuation, thereby allowing for precise titration from dose to dose. Two doses of Elestrin, 0.87 grams per day and 1.7 grams per day, were approved by the FDA. The 0.87 gram dose of Elestrin, which delivers 12.5 mcg of estradiol per day, 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. In addition, we received three years of marketing exclusivity for Elestrin.

In December 2008, we entered into 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. Under the license agreement, Azur was to pay us royalties on sales of Elestrin ranging from 10 percent to 20 percent depending primarily upon the annual sales levels and additional sales-based milestone payments. In April 2009, we announced the initiation of sales and marketing activity of Elestrin by Azur. In December 2009, we entered into an amendment to our original licensing agreement with Azur which permanently reduced the royalty percentage due to us related to Azur s sales of Elestrin. Upon signing the amended agreement, Azur made a $1.0 million nonrefundable payment in December 2009 in exchange for a permanent reduction in future royalty rates, and received options to make a total of $2.16 million in additional non-refundable payments (which were exercised during the first quarter of 2010) in exchange for the elimination of substantially all remaining future royalties and milestone payments due us under the terms of the original license. The $1.0 million nonrefundable payment was recorded as revenue during the fourth quarter of 2009 as we had no remaining performance obligations with respect to this amount. 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.

In December 2008, we signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. In June 2009, PharmaSwiss submitted a new drug application to the Israeli authorities based on our approved U.S. NDA and manufacturing information.

According to The North American Menopause Society, there are more than 40 million postmenopausal women in the U.S., and this group is expected to grow 25 percent by 2010. Menopause begins when the ovaries cease to produce estrogen, or when both ovaries are surgically removed prior to natural menopause. The average age at which women experience natural menopause is 51 years. The average age of surgical menopause is 41 years. The most common physical symptoms of natural or surgical menopause and the resultant estrogen deficiency are hot flashes, vaginal atrophy and osteoporosis. According to the North American Menopause Society, studies show that hot flashes occur in approximately two-thirds of menopausal women. Hormone therapy in women decreases the chance that women will experience the symptoms of menopause due to estrogen deficiency. According to industry estimates, approximately six million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy. According to IMS Health, the current market in the U.S. for single-entity estrogen products was approximately $1.5 billion in 2009, of which the transdermal segment, mostly patches, is reported at about $316 million. As the baby boomer generation ages, the number of women reaching menopause, a large percentage of whom may need estrogen or combined estrogen therapy, is between 5,000 and 6,000 women per day in the U.S.

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There are several treatment options for women experiencing menopausal symptoms, which vary according to which symptoms a woman experiences and whether or not she has had a hysterectomy. Estrogen is most commonly given orally in pill or tablet form. There are several potential side effects, however, with the use of oral estrogen, including insufficient absorption by the circulatory system, upset stomach, gallstones, blood clots as well as an increase in C-reactive protein, a possible marker for cardiovascular inflammation. Reports suggest that oral estrogen causes an increase in strokes and blood clots. Although transdermal, or skin, patches have been shown to avoid some of these problems or effects, transdermal patches have a physical presence, can fall off, and can result in skin irritation. However, transdermal delivery of estrogen via patches or gels may reduce the risks associated with oral estrogen, including having no effect on C-reactive protein and potentially reduce the risk of breast cancer and cardiovascular disease.

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.

In December 2002, we entered into a development and license agreement, which was subsequently amended, with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA 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.

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. According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 28 percent in 2009 to $968 million from $755 million in 2008.

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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) and three issued U.S. patents pertaining to triple component contraception. The Pill-Plus adds a third component, an androgen, to the normal two component (estrogen and progestogen) oral contraceptive to prevent androgen deficiency which often leads to a decrease in sexual desire, sexual activity and mood changes. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousabilty and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to improve female sexual dysfunction in oral contraceptive users, among other potential benefits.

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.

In May 2007, we announced that we sublicensed U.S. rights to The Pill-Plus to 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.

Other Products. In September 2000, we sublicensed the marketing rights to our gel products in Canada to 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. If and when we receive FDA approval for any of our gel products in the United States, Paladin may be able to use this information to obtain the appropriate regulatory approvals of such products in Canada.

In August 2001, we entered into a sublicense agreement with Solvay Pharmaceuticals, B.V. (which was purchased by Abbott Laboratories in February 2010) covering the U.S. and Canadian rights to the estrogen/progestogen combination therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sublicenses our estrogen/progestogen combination therapy gel product for an initial payment of $2.5 million, future milestone payments (of which $950,000 has been received to date) and sales-based royalties. Solvay has been responsible for all costs of development to date. We believe that the product licensed to Solvay is not in active development by Solvay, and we do not expect its active development to occur at any time in the near future.

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Description of GVAX Cancer Immunotherapies and Other Technologies Acquired in the Cell Genesys Merger

GVAX Cancer Immunotherapy Technology. GVAX cancer immunotherapies are cancer vaccines designed to stimulate the patient s immune system to effectively fight cancer. GVAX cancer immunotherapies 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 GVAX cancer immunotherapies 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 immunotherapy 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 a GVAX immunotherapy potentially can result in the destruction of tumor cells that persist or recur following surgery, radiation therapy or chemotherapy treatment. GVAX cancer immunotherapies 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. GVAX cancer immunotherapies are being tested as patient-specific, or autologous, products and as non patient-specific, or allogeneic, products. Multiple Phase II trials of these technologies which had been ongoing at the date of the acquisition are continuing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer programs, including pancreatic cancer, leukemia and breast cancer.

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.

Oncolytic VirusTechnology. Our 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.

Description of Our CaP Technology and Products in Development

We believe our CaP technology can serve as a facial line filler in the area of aesthetic medicine and as an effective vehicle for delivering drugs and vaccines and enhancing the effects of vaccines. Our CaP nanoparticles successfully have passed the first stage of toxicity studies for administration orally, into muscles, under the skin, and into the lungs by inhalation. We successfully have completed a Phase I human clinical safety trial of CaP. We have entered into several subcontract or development agreements with various corporate partners and governmental entities concerning our CaP technology.

Overview of CaP Technology. Research and development involving our CaP technology originated under an agreement dated April 6, 1989 between the University of California and one of our predecessor companies, relating to viral protein surface absorption studies. The discovery research was funded at UCLA School of Medicine and was based, in essence, on the use of extremely small, solid, uniform particles as components that could increase the stability of drugs and act as systems to deliver drugs into the body. Research in these areas at UCLA or our laboratory has resulted in the issuance of a number of patents, which we either license from the University of California or own.

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These ultra fine particles are made from inert, biologically acceptable materials, such as ceramics, pure crystalline carbon or biodegradable calcium phosphate-like particles. The size of the particles is in the nanometer range. A nanometer is one millionth of a millimeter and typically particles measure approximately 300 nanometers (nm). Because the size of these particles is measured in nanometers, we use the term nanoparticles to describe them. We use the nanoparticles as the basis of a delivery system. The critical property of these nanoparticles is that biologically active molecules, proteins, peptides or pharmacological agents, for example, vaccine components like bacterial or viral antigens or proteins like insulin, attached to them, retain their activity and can be protected from natural alterations to their molecular structure by adverse environmental conditions. It has been shown in studies conducted by us and confirmed by others that when these combinations are injected into animals, the attachment can enhance the biological activity as compared to injection of the molecule alone.

We believe our CaP technology has a number of benefits, including the following:

- it is biodegradable (capable of being decomposed by natural biological processes) and non-toxic and therefore potentially safe to use and introduce into the human body;
- it is fast, easy and inexpensive to manufacture, which should keep costs down and potentially lead to higher profit margins compared to other delivery systems;
- the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays, inhalation or intranasally, instead of using often painful and inconvenient injections; and
- it has excellent loading capacity the amount of molecules that can bond with the nanoparticles thereby potentially decreasing the dose needed to be taken by patients while enhancing the release capabilities.

Potential Commercial Applications for CaP. We plan to develop commercial applications of our CaP technology and any proprietary technology developed as a result of our ongoing research and development efforts. Initially, we plan to pursue primarily the development of:

- a facial line filler using CaP technology in the area of aesthetic medicine;
- injected and non-injected vaccines using CaP as a delivery system and vaccine adjuvant; and
- drug delivery systems, including a method of delivering proteins (e.g., insulin) orally or buccally, or through intranasal and subcutaneous routes of administration.

Our pre-clinical research team in our laboratory in Doylestown, Pennsylvania currently is pursuing the development of our CaP technology in these areas as well as exploring other areas.

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CaP Products in Development. The following is a list of our CaP products in development:

BioLook a facial line filler in development using proprietary CaP technology in the area of aesthetic medicine.

BioVant proprietary CaP adjuvant and delivery technology in development for improved versions of current vaccines and new vaccines against viral and bacterial infections and autoimmune diseases, among others. BioVant also serves as a delivery system for non-injected delivery of vaccines.

BioOral a delivery system using CaP technology for oral/buccal/intranasal administration of proteins and other therapies that currently must be injected.

BioAir a delivery system using CaP technology for inhalable versions of proteins and other therapies that currently must be injected.

Aesthetic Medicine. In November 2007, we signed a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial line filler in aesthetic medicine (BioLook). Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received an ownership position in MATC of approximately five percent of the common stock of MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

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 2010.

Vaccine Adjuvant and Delivery System. We believe that our CaP nanoparticles may offer a means of preparing new vaccines that are equal or better in their safety and immunogenicity, that is, in their capacity to elicit an immune response, compared to alum-formulated (the vaccine adjuvant used in the vast majority of adjuvanted vaccines in the United States) and non-adjuvanted vaccines but may be injected in lower concentrations and less often which could result in certain benefits, including cost savings and improved patient compliance. Further, we believe that CaP will allow for vaccines to be delivered by alternate routes of administration such as intranasally rather than by injection. Our nanoparticles when combined with vaccine antigens have been shown in animal studies conducted by us and others to possess an ability to elicit a higher immune response than non-adjuvanted vaccines and an immune response of the same magnitude as alum-formulated vaccines. These preclinical studies also have shown that our CaP nanoparticles also may sustain higher antibody levels over a longer time period than both alum-formulated vaccines and non-adjuvanted vaccines. Because our CaP nanoparticles are made of calcium phosphate-like material, which has a chemical nature similar to normal bone material and therefore is natural to the human body, as opposed to aluminum hydroxide, or alum, which is not natural to the human body, we believe that our nanoparticles may be safer to use than alum especially for intranasal delivery. In our animal studies, we observed no material adverse reactions when our CaP nanoparticles were administered at effective levels.

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We filed an investigational new drug, or IND, application with the FDA and have conducted a Phase I human clinical trial of CaP as a vaccine adjuvant and delivery system, which we call BioVant. As discussed in more detail under the heading Government Regulation, the purpose of a Phase I trial is to evaluate the metabolism and safety of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. The Phase I trial of our CaP specifically looked at safety parameters, including local irritation and blood chemistry changes. The Phase I trial was a double blind, placebo controlled trial, in 18 subjects to determine the safety of CaP as a vaccine adjuvant. The trial results showed that there was no apparent difference in side-effect profile between CaP and placebo. Phase I and or Phase II clinical trials will need to be repeated for each CaP/vaccine and CaP/protein drug developed.

Drug Delivery Systems. The third field of use in which we are exploring applying our CaP technology involves creating novel and improved forms of delivery of drugs, especially proteins (e.g., insulin). The attachment of drugs to CaP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We have shown pre-clinical efficacy in the oral delivery of insulin in normal and diabetic mouse models.

We were awarded a $150,000 Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) to support our development of formulations for the pulmonary delivery of interferon alpha (IFN-α) using our CaP technology. The grant was used to fund product development for IFN-α formulated with CaP particles for administration via inhalation. The desired outcome is safe and effective treatment of hepatitis B and C. An inhaled product may allow for convenient self treatment which would be an improvement over the current injectable IFN-α. We are in the process of applying for additional government grants to help fund our CaP drug delivery development.

License and Development Activities. In addition to continuing our own research and development in the potential commercial applications of our CaP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CaP technology. We believe these collaborations may enable us to accelerate the development of potential improved vaccines and the delivery of injectable drugs by other routes of administration, such as orally, buccally, intranasally or through needle-free administration. Our out-licensing activities with respect to our CaP vaccine adjuvant and delivery system for use in other companies vaccines, have to date included meeting with target sub-licensees and, in some cases, agreeing that the target sub-licensee will test our CaP adjuvant or delivery system in their animal models. Thereafter, the target sub-licensee may send to us its vaccine antigen or DNA that we will then formulate with our nanoparticles and return for use in the target sub-licensee s animal models. Once this is completed, if the results are positive, we would seek to negotiate an out-license agreement with the target sub-licensee.

It is important to point out that vaccine development is an expensive and long-term process. We have used our strategy of utilizing primarily outside resources to fund CaP s development in order to leverage the expertise of other companies and the United States government and to minimize our spending on this expensive and long-term development work. Our strategic plan is to focus on our nearer-term products and to seek collaborations and funding for our CaP technology.

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.

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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 trials of our products, including in particular LibiGel. We spent approximately $13.7 million in 2009, $15.8 million in 2008 and $4.8 million in 2007 on research and development activities. We spent an average of approximately $1.1 million per month on our research and development activities during 2009. The decrease in 2009 research and development expenses compared to 2008 was primarily the result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study to conserve cash. We reinitiated screening and enrollment in our safety study in August 2009. We expect our monthly research and development expenses to increase significantly in 2010 compared to 2009. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash and cash equivalents, available; (2) our development schedule, including the timing of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our products; and (5) 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 clinical studies and Elestrin for commercial supplies are 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 LibGel, 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. 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. Bio-T-Gel was developed and is fully-owned by us and not covered under the Antares license.

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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 are expected to expire in 2016.

GVAX Cancer Immunotherapy Technology. We own development and commercialization rights to our GVAX cancer immunotherapy technology as a result of our merger with Cell Genesys in October 2009. The original core patent applications covering our GVAX cancer immunotherapy 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 GVAX patent estate broadly covers our GVAX cancer immunotherapy products and pipeline. The GVAX patent estate includes 17 patent families, comprising over 60 issued US and foreign patents, directed to various aspects of the GVAX cancer immunotherapy technology. The patents are expected to 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 are expected to expire between 2023 and 2026.

Oncolytic Virus Technology. We also own development and commercialization rights to our oncolytic virus technology as a result of our merger with Cell Genesys in October 2009. The oncolytic virus patent estate includes eight patent families, comprising over 24 issued US and foreign patents, directed to various aspects of the oncolytic virus technology, including CG0070 which has completed a Phase 1 trial for non-muscle, invasive transitional cell bladder cancer. The patents are expected to expire between 2018 and 2023.

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. Importantly, we 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.

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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.

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 the marks BIOSANTE®, LIBIGEL®, BIO-E-GEL®, BIOAIR and GVAX . 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), BIO-T-GEL , BIOVANT and covering goods that include or are closely related to products, vaccines and vaccine adjuvants and drug delivery platforms. 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 , BIO-E/P-GEL , BIOLOOK , CAP-ORAL , BIOVANT , BIOAIR and GVAX . For those trademarks for which registration has been sought, registrations have issued for some of those trademarks in certain jurisdictions and others currently are in the application/prosecution phase.

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

Competition

There is intense competition in the biopharmaceutical industry, 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.

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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 CaP technology, the international vaccine industry is dominated by three companies: GlaxoSmithKline plc, Sanofi-aventis (through its subsidiaries, including Institut Merieux International S.A., Pasteur Merieux Serums et Vaccins, S.A., Connaught Laboratories Limited and Connaught Laboratories, Inc.) and Merck & Co., Inc. The larger, better known pharmaceutical companies generally have focused on a traditional synthetic drug approach, although some have substantial expertise in biotechnology. During the last decade, however, significant research activity in the biotechnology industry has been completed by smaller research and development companies, like us, formed to pursue new technologies.

With regard to our GVAX cancer immunotherapy 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 immunotherapies and oncolytic virus therapies 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 immunotherapies and oncolytic virus therapies including early-stage and established biotechnology companies, pharmaceutical companies, academic institutions, government agencies and research institutions. Examples in the cancer immunotherapy area include Dendreon Corporation, which has completed a Phase III trial for its product in prostate cancer and has filed a Biologics License Application (BLA) with the FDA, and Onyvax Ltd., which has commenced Phase II trials in prostate cancer. Antigenics, Inc., Oncothyreon Inc., Warner Chilcott plc and Boerhinger Ingelheim USA Corporation also are developing immunotherapy 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 process of seeking and obtaining FDA approval for a previously unapproved new human pharmaceutical product generally requires a number of years and involves the expenditure of substantial resources.

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Following drug discovery, the steps required before a drug product may be marketed in the United States include:

- completion of preclinical laboratory and animal testing;
- the submission to the FDA of an investigational new drug application, commonly known as an IND application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- the completion of clinical and other studies to assess safety and parameters of use;
- the completion of multiple adequate and well-controlled human clinical trials to establish the safety and effectiveness of the drug product for its intended use;
- the submission to the FDA of a new drug application, commonly known as an NDA, or an abbreviated NDA, commonly known as an ANDA;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities at which the drug product is produced, and potentially other involved facilities as well, to assess compliance with current good manufacturing practice, or cGMP, regulations and other applicable regulations; and
- FDA approval of the NDA or ANDA prior to any commercial sale or shipment of the product.

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.

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

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

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

New Drug Applications. Upon the successful completion of clinical testing, an NDA is submitted to the FDA for approval. This application requires detailed data on the results of preclinical testing, clinical testing and the composition of the product, specimen labeling to be used with the drug, information on manufacturing methods and samples of the product. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. 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. Further, there is no assurance that the FDA will ultimately approve an NDA.

During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA may refuse to approve an NDA and issue a not approvable letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical or other data, including one or more additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaboration partners interpret data. If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. The FDA may withdraw drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the FDA-approved indications and in accordance with the FDA-approved label. Further, if there are any modifications to the drug, including changes in indications, other labeling changes, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may

require us to develop additional data or conduct additional preclinical studies and clinical trials.

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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. 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. 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.

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

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

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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 25 employees as of December 31, 2009, including 20 in product development and five 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 press 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, possib potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, 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:

- 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;
- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes and licensure or acquisition of new products;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market size and market acceptance of our products;
- the effect of new accounting pronouncements and future health care, tax and other legislation;

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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 1996. In October 2009, we acquired Cell Genesys, Inc. through a direct merger. Our principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Our telephone number is (847) 478-0500, and our Internet web site address is www.biosantepharma.com. The information contained on our web site or connected to our web site is not incorporated by reference into and should not be considered part of this annual report on Form 10-K.

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

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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 incurred a net loss of $47.5 million for the year ended December 31, 2009 and as of December 31, 2009, our accumulated deficit was $119.4 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 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 successfully our own products or enter into collaborative agreements with others who can commercialize them successfully. Even if our products are introduced commercially, they may never achieve market acceptance and we may not generate additional revenues or ever achieve profitability.

We may need to continue to raise substantial additional capital to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

We currently do not have sufficient resources to obtain regulatory approval of LibiGel or any of our other products or to complete the commercialization of any of our products. We expect the Phase III clinical study program of LibiGel to continue to require significant resources. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;
- subject recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;
- our ability to license LibiGel or our other products for development and commercialization;
- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts, to continue to evaluate various strategic alternatives available with respect to our GVAX cancer immunotherapics 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;
- the rate of technological advances;
- the commercial success of our products;
- our general and administrative expenses;

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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 $29.9 million at December 31, 2009 and the additional $17.5 million in net proceeds we received from our March 2010 registered direct offering will be sufficient to meet our liquidity requirements through at least the next 12 months, this estimate may prove incorrect or we may decide to raise additional financing earlier.

We have on file an effective shelf registration statement that allows us to raise up to $75.0 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, as of March 15, 2010, we had used approximately $46.8 million of this amount and under applicable SEC rules, if we have a public float of less than $75.0 million, we can only offer to sell under the registration statement up to one-third of our public float during any 12 month period. We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, 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 GVAX immunotherapies, 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 equity securities may cause dilution to existing stockholders, raising additional funds by issuing additional debt financing may restrict our operations and raising additional funds by through licensing arrangements may require us to relinquish proprietary rights.

If we raise additional funds through the issuance of 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 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 GVAX immunotherapies, 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 2010. 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 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. 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 and we did not have an effective registration statement registering the resale of shares of our common stock issued or issuable to Kingsbridge under the 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 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 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 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 indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If we do not comply with the covenants in the 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.

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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 GVAX immunotherapy 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 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, 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 development stages and likely will not be introduced commercially for several years, if at all.

Our products are in the 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 nor do we expect them to be for several years. Some of our products are not in active development. For example, at this time and as previously disclosed, we believe that our estrogen/progestogen combination transdermal gel product licensed to Solvay is not in active development by Solvay (now owned by Abbott Laboratories), and we do not expect its active development to occur at any time in the near future. We cannot assure you that any of our products 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.

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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. In addition, even after obtaining regulatory approval, we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or our manufacture 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 pre-clinical studies and 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. Pre-clinical studies on animals must be conducted on some of our products. We expect the number of pre-clinical studies and 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. 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.

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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 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, specifically, HSDD 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 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 these clinical trials, which can result from unforeseen issues, FDA interventions, problems with enrolling subjects and other reasons, could delay significantly commercial launch and affect our product development costs. Moreover, results from these clinical studies may not be as favorable as the results we obtained in prior, completed studies. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

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.

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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.

If clinical trials for our products are prolonged or delayed, we may be unable to commercialize our 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 trials for our products that may cause us or a regulatory authority to delay or suspend those clinical trials 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 trials for our products and negatively impact our ability to obtain regulatory approval or enter into collaborations 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 trials;
- 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 trials;
- negative or inconclusive results from clinical trials, 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 clinical trials; 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 trials are conducted all have the power to stop our clinical trials prior to completion. Our clinical trials for our products may not begin as planned, may need to be restructured, 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 trial program.

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We entered into an exclusive license agreement with Azur Pharma International II, Limited for the marketing of Elestrin in the United States. Our ability to obtain sales-based milestones of up to $140 million from Azur is dependent upon Azur s ability to market and sell Elestrin.

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. Azur launched sales and marketing activities related to Elestrin in April 2009. We recognized royalty and other revenue from sales of Elestrin of $1.1 million for the year ended December 31, 2009. In December 2009, we entered into an amendment to our original licensing agreement with Azur which permanently reduced the royalty percentage due to us related to Azur s sales of Elestrin. Upon signing the amended agreement, Azur made a $1.0 million nonrefundable payment in December 2009 in exchange for a permanent reduction in future royalty rates, and received options to make a total of $2.16 million in additional non-refundable payments (which were exercised during the first quarter of 2010) in exchange for the elimination of substantially all remaining future royalties and milestone payments due us under the terms of the original license. The $1.0 million nonrefundable payment was recorded as revenue during the fourth quarter of 2009 as we had no remaining performance obligations with respect to this amount. 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 or that Azur will remain focused on the commercialization of Elestrin, especially if Azur does not experience significant Elestrin sales. Based on sales of Elestrin to date, we believe it is unlikely that we will receive any sales-based milestone payments from Azur.

Our other products, if they receive FDA approval and are introduced commercially 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, if they receive the required FDA or other regulatory approvals, is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our products could be affected by several factors, including:

- the availability of alternative products from competitors;
- the price of our products relative to that of our competitors;
- the timing of market entry; and
- the ability to market our products effectively.

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 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 the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future 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.

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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 clinical trials or commercial sale. In order to continue to develop products, apply for regulatory approvals and commercialize our products following approval, 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 trials could be seriously delayed.

To the extent that we or our licensees seek to 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. 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 collaborators may not be able to initiate or continue clinical trials of product candidates that are under development;
- we and our collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and
- we and our collaborators may not be able to meet commercial demands for any approved products.

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 both of our two executive officers, but neither of our 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.

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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 development collaborators, 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.

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 and results of operations, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, we must comply with FDA requirements with respect to the development of our products and our clinical trials, and if any of our products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of our products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. 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.

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 GVAX cancer immunotherapies 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. 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. For example, if we were to enter into an license agreement with a third party under which we agree to license rights to our gel technology, GVAX cancer immunotherapies or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc., Johns Hopkins University and The Whitehead Institute for BioMedical Research, the University of California or Wake Forest University could either, depending upon the terms of the license agreement, cause us to breach our obligations under the license agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the license fees. Our failure to retain the right to these technologies could harm our business and future prospects. This is true in particular with respect to LibiGel, which we believe if approved by the FDA could be a very successful product.

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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, Solvay Pharmaceuticals, B.V. (now owned by Abbott Laboratories), Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA. 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 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, at this time and as previously disclosed, we believe that our estrogen/progestogen combination transdermal gel product licensed to Abbott Laboratories is not in active development by Abbott, and we do not expect its active development to occur at any time in the near future. As an additional 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 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 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.

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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.

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:

result in costly litigation;

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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, 2009, the sale price of our common stock has ranged from a low of $1.03 to a high of $2.70. 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;
governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products or our competitors products;
the results of our clinical trials or those of our competitors;
announcements of technological innovations or new products by us or our competitors;
announcements by licensors or licensees of our technology;
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;

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loss of key management;

common stock sales in the public market by one or more of our larger stockholders, officers or directors; and other potentially negative 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.

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 securities 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.

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 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.

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We may issue additional equity securities which would dilute your share ownership.

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.

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 12,000 square feet of office space for approximately $23,000 per month. Our lease for this space expires in April 2012. Our CaP development operations are located within the Bucks County Biotech Park in Doylestown, Pennsylvania where we lease approximately 2,000 square feet of laboratory space for approximately $3,900 per month. This lease is renewable in one year increments each July and expires in July 2010. Management of our company considers our leased properties suitable and adequate for our current and foreseeable needs.

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Item 3. LEGAL PROCEEDINGS

We are presently involved in one legal action and 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.

On July 1, 2009, a putative shareholder class action lawsuit concerning our then proposed merger with Cell Genesys, Inc. was filed in California Superior Court in San Mateo County naming Cell Genesys, its officers and directors, and our company as defendants. On July 6, 2009, a second putative shareholder class action lawsuit naming the same parties and containing essentially identical allegations was filed in California Superior Court in San Mateo County. On July 8, 2009, a third putative shareholder class action lawsuit was filed in California Superior Court in San Mateo County, which also named the same parties and contained essentially identical allegations as the two prior lawsuits. On July 15, 2009, the Court consolidated these three lawsuits into one action and appointed interim lead counsel. On August 13, 2009, plaintiffs filed a consolidated class action complaint alleging that defendants breached their fiduciary duties and/or aided and abetted the breach of fiduciary duties owed to Cell Genesys stockholders in connection with the then proposed merger, including by failing to engage in a fair sales process, failing to obtain a fair price for the sale of Cell Genesys, and failing to provide Cell Genesys stockholders with material information regarding the merger. Plaintiffs sought an order certifying the lawsuit as a class action, injunctive relief to enjoin the merger or, in the event the then pending merger was completed, a rescission of the merger or rescissory damages. Plaintiffs further sought an accounting for all damages and an award of attorneys fees and costs.

Solely to avoid the costs, risks and uncertainties inherent in litigation, on September 18, 2009, we and Cell Genesys entered into a memorandum of understanding with plaintiffs counsel in the San Mateo County action pursuant to which we, Cell Genesys, the other named defendants and the plaintiffs agreed to settle the lawsuits subject to court approval. If the Court approves the settlement, the lawsuits will be dismissed with prejudice. Pursuant to the memorandum of understanding, Cell Genesys agreed to pay to plaintiffs counsel an amount not more than $240,000 as is approved by Court order for plaintiffs attorneys fees, costs and expenses in the San Mateo County action and to make additional disclosures in a current report on Form 8-K, without admitting in any way that the certain disclosures are material or otherwise required by law. Cell Genesys filed the Form 8-K on September 21, 2009. Pursuant to the memorandum of understanding, plaintiffs counsel conducted confirmatory discovery to confirm the fairness and adequacy of the settlement. The parties filed a stipulation of settlement with the Court and moved the Court for preliminary approval and issuance of a notice of settlement to the potential class members, after which the parties intend to seek final settlement approval and dismissal of the action with prejudice. As a result of our merger with Cell Genesys, we assumed Cell Genesys s rights and obligations relative to this lawsuit. We have recorded a liability of $240,000 for the potential settlement and believe that the resolution of this matter will not have a material impact on our financial position, cash flows or results of operations.

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Item 4. RESERVED

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and the offices held, as of March 15, 2010, are as follows:

Name	Age	Title
Stephen M. Simes	58	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	49	Chief Financial Officer, Treasurer and Secretary

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 a director of our company since January 1998 and Chief Executive Officer since March 1998. From October 1994 to January 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 using the delivery of nervous system growth factors. As a result of our merger with Cell Genesys, we acquired an investment equivalent to approximately 16 percent of the total equity of Ceregene, and by virtue of such ownership, we have the right to designate one member of Ceregene s board of directors.

Phillip B. Donenberg, CPA, has served as our Chief Financial Officer, Treasurer 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.

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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 2009 and 2008.

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

2008	High	Low
First Quarter	$ 5.05	$ 2.05
Second Quarter	$ 5.85	$ 3.50
Third Quarter	$ 5.79	$ 3.26
Fourth Quarter	$ 4.85	$ 0.81

Number of Record Holders; Dividends

As of March 15, 2010, there were 847 record holders of our common stock and six record holders of our class C stock. To date, we have not declared or paid any cash dividends on our common stock and our class C stock is not eligible to receive dividends.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2009, we did not issue or sell any equity securities of ours without registration under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2009. 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,				
	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue					
Licensing revenue	$	$ 3,384	$ 199	$ 14,136	$ 45
Grant revenue	116	65	59	247	181
Royalty revenue	1,142	34	69		
Other revenue		298	166	55	32
Total revenue	1,258	3,781	493	14,438	258
Interest income	12	588	1,095	429	401
Expenses					
Research and development	13,681	15,790	4,751	3,908	6,409
General and administration	5,374	5,125	4,331	4,550	3,801
Acquired in-process research and development	9,000				
Excess consideration paid over fair value	20,192				
Licensing expense	300	836		3,500	
Depreciation and amortization	137	43	90	118	101
Total expenses	48,684	21,794	9,172	12,076	10,311
Other income Fair value adjustment	33				
Other expense Interest expense	147				
Net (loss) income	$ (47,528)	$ (17,425)	$ (7,584)	$ 2,791	$ (9,651)
Basic and diluted net (loss) income per share	$ (1.40)	$ (0.64)	$ (0.30)	$ 0.13	$ (0.50)
Weighted average number of shares outstanding	33,952	27,307	25,486	21,484	19,392

	As of December 31,				
	2009	2008	2007	2006	2005

	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 29,858	$ 14,787	$ 30,655	$ 11,450	$ 9,102
Total assets	36,437	17,679	31,241	22,371	9,575
Total current liabilities	3,930	3,853	1,516	4,300	2,666
Convertible senior notes	16,676				
Stockholders equity	15,830	13,826	29,725	18,071	6,819

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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 2009 Financial Results and Outlook for 2010. This section provides a brief summary of our financial results and financial condition for 2009 and our outlook for 2010.

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, menopause, contraception and male hypogonadism. In addition, we are evaluating and seeking opportunities for our GVAX cancer immunotherapies, 2A/Furin and other technologies we acquired in our merger with Cell Genesys, Inc. We also are developing our calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery.

Our products for female sexual health, menopause, contraception and male hypogonadism 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.

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The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

Bio-T-Gel once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.

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 one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women.

Currently, three LibiGel Phase III studies are underway and enrolling women: two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months after which time we intend to submit an NDA to the FDA. In February 2010, we announced that based upon the second review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee (DMC) unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. As of such date, there had been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. In view of DMC recommendation, we will continue the LibiGel Phase III development program as planned. We continue to target submission to the FDA of an NDA by mid-2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

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 which permanently reduced the royalty percentage due to us related to Azur s sales of Elestrin. Upon signing the amended agreement, Azur made a $1.0 million nonrefundable payment in December 2009 in exchange for a permanent reduction in future royalty rates, and received options to make a total of $2.16 million in additional non-refundable payments (which were exercised during the first quarter of 2010) in exchange for the elimination of substantially all remaining future royalties and milestone payments due us under the terms of the original license. The $1.0 million nonrefundable payment was recorded as revenue during the fourth quarter of 2009 as we had no remaining performance obligations with respect to this amount. 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.

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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 licensing-related proceeds and 4.5 percent of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. 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 is subsequently marketed.

As a result of our October 2009 merger with Cell Genesys, we acquired a portfolio of products, including GVAX cancer immunotherapies. GVAX cancer immunotherapies are cancer vaccines designed to stimulate the patient s immune system to effectively fight cancer. Multiple Phase II trials of these technologies which had been ongoing at the date of the acquisition are continuing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer programs, including pancreatic cancer, leukemia and breast cancer. We license our GVAX cancer immunotherapy technology from Johns Hopkins University. Under 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 licensees sell incorporating the in-licensed technology.

Our strategy with respect to our CaP technology is to continue development of our nanoparticle technology and actively seek collaborators and licensees to fund and accelerate the development and commercialization of products incorporating the technology. In addition to continuing our own product development in the potential commercial applications of our CaP technology, we have sought and continue to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in development and marketing arrangements with respect to our CaP technology. For example, we have entered into a license agreement with Medical Aesthetics Technology Corporation (MATC) covering the use of our CaP as a facial line filler in aesthetic medicine (BioLook). Under the license agreement, MATC is responsible for continued development of BioLook, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. In exchange for the license, we received an ownership position in MATC of approximately five percent of the common stock of MATC. In addition to the ownership position, we may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology.

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.

Summary of 2009 Financial Results and Outlook for 2010

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, to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future.

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We have not introduced commercially any products. Azur, our marketing licensee for Elestrin, commercially launched Elestrin in April 2009. As a result, we received royalties on net sales of Elestrin from Azur. We recognized $1.1 million in royalty revenue from sales of Elestrin during the year ended December 31, 2009, which includes $141,665 in royalty payments pursuant to our original agreement with Azur, and $1.0 million of additional royalty income resulting from payments received as a result of the amendment of the agreement in December 2009. This royalty revenue amount represents the gross royalty revenue we received from Elestrin through December 31, 2009 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $63,749 for the year ended December 31, 2009, is recorded within general and administrative expenses in our statements of operations. In December 2009, we entered into an amendment to our original licensing agreement with Azur which permanently reduced the royalty percentage due to us related to Azur s sales of Elestrin. Upon signing the amended agreement, Azur made a $1.0 million nonrefundable payment in December 2009 in exchange for a permanent reduction in future royalty rates, and received options to make a total of $2.16 million in additional non-refundable payments (which were exercised during the first quarter of 2010) in exchange for the elimination of substantially all remaining future royalties and milestone payments due us under the terms of the original license. The $1.0 million nonrefundable payment was recorded as revenue during the fourth quarter of 2009 as we had no remaining performance obligations with respect to this amount. Upon receiving the final payment in February 2010, our future Elestrin royalty stream was reduced to zero. We expect to receive a portion of our Elestrin royalties from Azur for January 2010 and a portion of February 2010. Pursuant to a separate agreement with Antares and related to the Azur royalty stream and milestone buydown, we paid Antares an aggregate of $268,750 in February 2010.

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 complete the commercialization of any of our products for which we have not entered into marketing relationships. We believe that our cash and cash equivalents of $29.9 million at December 31, 2009 and the additional $17.5 million in net proceeds from our March 2010 registered direct offering will be sufficient to meet our liquidity requirements through at least the next 12 months.

We incurred expenses of approximately $1.1 million per month on research and development activities during the year ended December 31, 2009. Our research and development expenses decreased 13 percent to $13.7 million for the year ended December 31, 2009 compared to the year ended December 31, 2008, primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study to conserve cash. We have reinitiated screening and enrollment in our safety study, and we expect our monthly research and development expenses to increase significantly in 2010 compared to 2009. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) the amount of resources, including cash and cash equivalents, available; (2) our development schedule, including the timing of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our products; and (5) competitive developments.

Our general and administrative expenses for the year ended December 31, 2009 increased 5 percent compared to the year ended December 31, 2008. This increase was due primarily to a 9 percent or $111,878 increase in our non-cash, stock option and warrant expense for the year ended December 31, 2009, compared to the year ended December 31, 2008. The primary reason for this increase was the grant of options and warrants to purchase an aggregate of 1,170,929 and 180,000 shares of our common stock, respectively, to new and certain existing employees in 2009 and an investor and public relations firm in the third quarter 2009. 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, legal, public and investor relations, business development, accounting and corporate governance and other fees and expenses incurred.

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We recognized a net loss for the year ended December 31, 2009 of approximately $47.5 million compared to a net loss of approximately $17.4 million for the year ended December 31, 2008. This increase was primarily due to the impact of transaction costs incurred in connection with the merger with Cell Genesys, and associated expenses related to our acquisition of in-process research and development and the excess of the purchase price over the fair value of the assets and liabilities acquired. We expect to continue to incur substantial and continuing losses for the foreseeable future. This is true especially as our own product development programs expand and various clinical trials continue, including in particular the Phase III clinical study program for LibiGel.

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.

Revenue Recognition

We have entered and may enter into various licensing agreements that generate license revenue or other upfront fees and which also may involve subsequent milestone payments earned upon our completion of development milestones or upon the occurrence of certain regulatory actions, such as the filing of a regulatory application or the receipt of a regulatory approval. We recognize non-refundable license fees as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and we have no further performance obligations under the license agreement. Non-refundable license fees that meet these criteria and are due to us 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. We recognize revenues from milestone payments that meet the criteria above when the milestone is achieved. We record royalty revenue based upon sales of products under a license when such royalties are earned, which is generally in the quarter when the related products are sold.

Deferred revenue arises from payments received in advance of the culmination of the earnings process. We classify as a current liability any deferred revenue that is expected to be recognized within the next 12 months. If applicable, we will recognize deferred revenue in future periods when the applicable revenue recognition criteria have been met.

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Research and Development Costs

Research and development costs are charged to expense as incurred. Government grants are recorded as an offset to the related research and development costs when we have complied with the conditions attached to the grant and there is reasonable assurance that the funds will be received. Non-refundable advance payments for goods and services to be used in future research and development activities are recorded as assets and the payments are expensed when the research and development activities are performed.

During 2009, 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.

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, we recognized as an expense approximately $20.2 million representing the excess of the consideration and costs of the transaction over the fair value of assets and liabilities received.

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 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.

Results of Operations

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

	Year Ended December 31,		
	2009	**2008**	**2007**
Revenue	$ 1,258,054	$ 3,780,829	$ 493,054
Expenses	48,683,608	21,794,471	9,172,498
Research and development	13,680,573	15,789,980	4,751,313
General and administrative	5,373,945	5,124,934	4,331,361
Acquired in-process research and development	9,000,000		
Excess consideration paid over fair value	20,192,194		
Licensing expense	299,616	836,420	
Interest income	11,648	588,464	1,095,009
Other income Fair value adjustment	33,163		
Other expense Interest expense	147,025		

Net loss	$ (47,527,768)	$ (17,425,178)	$ (7,584,435)
Net loss per share (basic and diluted)	$ (1.40)	$ (0.64)	$ (0.30)
Weighted average number of shares outstanding	33,951,652	27,307,494	25,485,513

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

Revenue for the year ended December 31, 2009 decreased 67 percent compared to revenue for 2008 primarily as a result of our receipt of $3.3 million from the Azur license of Elestrin in 2008 compared to our receipt of approximately $1.1 million from Azur in 2009 which was primarily for a $1.0 million nonrefundable payment received in exchange for a permanent reduction in future royalty rates.

Research and development expenses for the year ended December 31, 2009 decreased 13 percent compared to research and development expenses for 2008 primarily as a result of our decision in April 2009 to delay screening new subjects for our LibiGel Phase III safety study to conserve cash. Screening has been re-initiated.

Our general and administrative expenses for the year ended December 31, 2009 increased 5 percent compared to general and administrative expenses for 2008 due primarily to a 9 percent or $111,878 increase in our non-cash, stock option and warrant expense for the year ended December 31, 2009, compared to the year ended December 31, 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 the year ended December 31, 2009 compared to 2008.

We recognized $299,616 in licensing expense for the year ended December 31, 2009 compared to $836,420 in licensing expense for 2008 due to expenses associated with both the Nycomed termination agreement and Azur licensing agreement.

Interest income for the year ended December 31, 2009 decreased 98 percent compared to interest income for 2008 primarily as a result of our decision to keep cash and cash equivalents in a 100% FDIC-insured non-interest bearing checking account for the majority of 2009, in order to ensure maximum safety of principal.

We recognized total additional expenses of $29.2 million 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.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Revenue for the year ended December 31, 2008 increased 667 percent compared to revenue for 2007 primarily as a result of our license of Elestrin to Azur and an increase in royalty and other revenue from Elestrin sales.

Research and development expenses for the year ended December 31, 2008 increased 232 percent compared to research and development expenses for 2007 primarily as a result of increased spending on our Phase III LibiGel clinical study program.

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Our general and administrative expenses for the year ended December 31, 2008 increased 18 percent compared to general and administrative expenses for 2007 primarily as a result of an increase in investor and public relations expenses and business development and other personnel-related costs. Our non-cash, stock option and warrant expense for the year ended December 31, 2008 increased $462,563, or 62 percent, compared to non-cash, stock option and warrant expense for the year ended December 31, 2007 due to an increase in the number of stock options granted and the number of stock options and warrants outstanding during the year ended December 31, 2008 compared to 2007.

We recognized $836,420 in licensing expense for the year ended December 31, 2008 compared to no licensing expense for 2007 due to expenses associated with both the Nycomed termination agreement and Azur licensing agreement.

Interest income for the year ended December 31, 2008 decreased 46 percent compared to interest income during 2007 primarily as a result of a lower average invested cash balances and lower average interest rates on our invested funds.

Liquidity and Capital Resources

Working Capital

Substantially all of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing transactions and from subcontracts. 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 other 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 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 Phase III clinical study program of LibiGel to continue to require significant resources.

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, and we expect to continue this practice for the foreseeable future. As of December 31, 2009, we had $29.9 million of cash and cash equivalents compared to $14.7 million as of December 31, 2008. Subsequent to December 31, 2009, we completed a registered direct offering of 10.4 million shares of our common stock and warrants to purchase an aggregate of 5.2 million shares of our common stock at a purchase price of $1.73 per share. The offering resulted in net proceeds of approximately $17.5 million, after deduction of placement agent fees and offering expenses.

We completed our merger with Cell Genesys in October 2009. One of the primary benefits of our merger with Cell Genesys was the cash acquired in the merger which we have used to continue our Phase III clinical studies for LibiGel. As of the completion of the merger, Cell Genesys had approximately $23.3 million in net cash and cash equivalents after deducting merger-related and other expenses. As of such date, Cell Genesys also had, and we assumed by virtue of the merger, $1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and $20.8 million in principal amount of 3.125% convertible senior notes due in May 2013. For a more complete description of these notes, see Convertible Senior Notes Due November 2011 and May 2013.

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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 clinical study 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 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 Phase III clinical study program for LibiGel;
- 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, including our efforts to obtain value for any acquired GVAX cancer immunotherapies and other technologies as a result of our merger with Cell Genesys and our efforts to continue to evaluate various strategic alternatives available with respect to our products and our company.

We expect that our current cash resources will provide us sufficient capital to maintain our projected business operations through at least the next 12 months, including continued Phase III clinical development of LibiGel. Although we believe we have sufficient cash resources for the next 12 months, our estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier.

As of December 31, 2009, 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 clinical study program, 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 sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights 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 2008, we entered into a committed equity financing facility with Kingsbridge Capital Limited in which Kingsbridge has committed to purchase, subject to certain conditions and at our sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of our common stock through the end of December 2010. Under the terms of the facility, 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 over the two-year term set to expire in December 2010, 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,

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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. In connection with the committed equity financing facility, we issued a warrant to Kingsbridge to purchase 300,000 shares of our common stock at an exercise price of $4.00. The warrant became exercisable on June 15, 2009 and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys fees and other direct costs related to the registration of these shares, we did not make any other payments to secure the facility. The facility does not impose any material 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, 2009, we had not sold any shares to Kingsbridge under the committed equity financing facility. As of the date of this report, we did not have an effective registration statement registering the resale of shares of our common stock issue or issuable to Kingsbridge under the 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% of the principal amount of the convertible notes, plus accrued and unpaid interest (and additional amounts, if any) to, but not including, the repurchase date and are subject to redemption for cash by us at any time in the case of the convertible notes due in 2011 and at any time on or after May 1, 2011, in the case of the convertible notes due in 2013, in whole or in part, at a redemption price equal to 100% of the principal amount of such notes if the closing price of our common stock has exceeded 150% of the conversion price then in effect with respect to such notes for at least 20 trading days in any period of 30 consecutive trading days ending on the trading day prior to the mailing of the notice of redemption. The indentures governing the convertible notes, as supplemented by the supplemental indentures, do not contain any financial covenants and do not restrict us from paying dividends, incurring additional debt or issuing or repurchasing our other securities. In addition, the indentures, as supplemented by the supplemental indentures, do not protect the note holders in the event of a highly leveraged transaction or a fundamental change of our company except in certain circumstances specified in the indentures.

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Uses of Cash and Cash Flow

Net cash used in operating activities was $18.4 million for the year ended December 31, 2009 compared to net cash used in operating activities of $15.5 million for the year ended December 31, 2008 and net cash provided by operating activities of $739,991 for the year ended December 31, 2007. 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 provided by operating activities of $739,991 for 2007 was due primarily to the receipt of approximately $10.5 million from Nycomed, 25 percent of which was due to our licensor, partially offset by our net loss of $7.6 million for 2007.

Net cash provided by investing activities was $2.9 million for the year ended December 31, 2009 compared to net cash provided by investing activities of $11.3 million for the year ended December 31, 2008 and net cash used in investing activities of $11.2 million for the year ended December 31, 2007. Net cash provided by investing activities for 2009 was primarily due to the redemption of short-term investments. Net cash provided by investing activities for 2008 was due to the redemption of approximately $11.0 million in short-term investments, partially offset by purchases of capital assets associated with clinical trial software and manufacturing equipment due to the conduct of our LibiGel clinical trial program. Net cash used in investing activities for 2007 consisted primarily of purchases and sales, respectively, of short-term investments.

Net cash provided by financing activities was $33.7 million for the year ended December 31, 2009 compared to $319,377 for the year ended December 31, 2008 and $18.5 million for the year ended December 31, 2007. Net cash provided by investing 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 investing activities for 2008 resulted from warrant exercises. Net cash provided by financing activities for 2007 resulted primarily from the completion of a private placement resulting in net proceeds to us of approximately $17.3 million, after deduction of transaction expenses, and to a lesser extent, warrant and stock option exercises.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2009. We have, however, several financial commitments, including our convertible senior notes, product development milestone payments to the licensors of certain of our products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments.

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The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2009:

	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	$
Interest payment obligations related to Convertible Senior Notes	2,235,491	688,000	1,331,011	216,480	
Operating Leases	667,618	299,618	368,000		
Settlement of shareholder lawsuit	240,000	240,000			
Obligation under License Agreement with Antares	18,033	18,033			
Commitments Under License Agreements with Johns Hopkins University	550,000	95,000	235,000	80,000	140,000
Commitments Under License Agreement with Massachusetts Institute of Technology	250,000	50,000	150,000	50,000	
Commitments Under License Agreement with University of California	360,000	20,000	60,000	40,000	240,000
Commitments Under License Agreement with Wake Forest	720,000	200,000	160,000	160,000	200,000
Total Contractual Cash Obligations	$ 27,057,142	$ 1,610,651	$ 3,538,011	$ 21,328,480	$ 580,000

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

Effective July 1, 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162 (SFAS No. 168). SFAS No. 168 reduces the U.S. GAAP hierarchy to two levels, one that is authoritative and one that is not. We began to use the new guidance and reflect the new accounting guidance references when referring to GAAP for the quarterly period ended September 30, 2009, and all subsequent periods. As the guidance was not intended to change or alter existing GAAP, adoption of this pronouncement did not have an effect on our consolidated financial statements.

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In October 2009, the FASB codified and issued Accounting Standards Updated (ASU) No. 2009-13, Revenue Recognition (Topic 605), Multiple-Deliverable Revenue Arrangements (ASU No. 2009-13). ASU No. 2009-13 amends the guidance that in the absence of vendor-specific objective and third-party evidence for deliverables in multiple-deliverable arrangements, companies will be required to develop a best estimate of the selling price to separate deliverables and allocate arrangements consideration using the relative selling price method. ASU No. 2009-13 expands the disclosure requirements for multiple-deliverable revenue arrangements. The guidance will be effective for financial statements issued for fiscal years beginning after June 15, 2010. Early adoption is permitted. Adoption of ASU No. 2009-13 is not expected to have a material impact on our financial position or operations.

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, 2009. 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, 2009.

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

March 29, 2010

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 accompanying balance sheets of BioSante Pharmaceuticals, Inc. (the Company) as of December 31, 2009 and 2008, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009. 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP
Deloitte & Touche LLP
Chicago, Illinois
March 29, 2010

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BIOSANTE PHARMACEUTICALS, INC.
Balance Sheets
December 31, 2009 and 2008

	December 31, 2009	December 31, 2008
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 29,858,465**	**$ 11,760,920**
Short-term investments		**3,026,334**
Accounts receivable	**64,645**	**229,775**
Prepaid expenses and other assets	**1,487,160**	**1,070,051**
	31,410,270	**16,087,080**
PROPERTY AND EQUIPMENT, NET	**747,979**	**814,894**
OTHER ASSETS		
Investments	**3,626,000**	**140,000**
Deposits	**652,679**	**637,397**
	$ 36,436,928	**$ 17,679,371**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 2,440,096**	**$ 3,182,089**
Due to licensor Antares	**18,033**	**5,393**
Accrued compensation	**529,066**	**290,583**
Other accrued expenses	**942,922**	**374,887**
	3,930,117	**3,852,952**
Convertible senior notes due 2011 and 2013	**16,676,417**	
TOTAL LIABILITIES	**20,606,534**	**3,852,952**
STOCKHOLDERS EQUITY		
Capital stock		
Issued and outstanding		
2009 391,286; 2008 391,286 Class C special stock	**391**	**391**
2009 53,262,568; 2008 27,042,764 Common stock	**135,264,431**	**85,732,688**
	135,264,822	**85,733,079**

Accumulated deficit	**(119,434,428)**	**(71,906,660)**
	15,830,394	**13,826,419**
	$ 36,436,928	**$ 17,679,371**

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Statements of Operations
Years ended December 31, 2009, 2008 and 2007

	Year Ended December 31,		
	2009	**2008**	**2007**
REVENUE			
Licensing revenue	**$**	**$ 3,384,091**	**$ 199,091**
Grant revenue	**116,389**	**65,051**	**59,060**
Royalty revenue	**1,141,665**	**34,200**	**69,353**
Other revenue		**297,487**	**165,550**