BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 16, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2008

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 under 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 LLC** **(NASDAQ Global Market)**

Securities registered under Section 12(g) of the Act:

None

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

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

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

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

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

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant s common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sales price at which the common stock was last sold as of June 30, 2008 (the last business day of the registrant s second quarter) as reported by The NASDAQ Global Market on that date was $115,885,108.

As of March 13, 2009, 27,042,764 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 2009 Annual Meeting of Stockholders to be held in June 2009.

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This annual report on Form 10-K contains 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 may, will, should, expects, anticipates, contemplates, estimates, believes, plans, projected, predicts, potential or continue or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the headings Part I. Item I. Description of 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®, Elestrin , LibiGel®, Bio-E-Gel®, Bio-E/P-Gel , LibiGel-E/T , Bio-T-Gel , The Pill-Plus , BioVant , BioLook , CAP-Oral and BioAir . 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. DESCRIPTION OF BUSINESS

General

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. Our primary products are gel formulations of testosterone and estradiol. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

The following is a list of our key products:

- 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.

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

- The Pill-Plus (triple hormone 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.

In order to market our products in the United States, we are required to obtain approval of a new drug application (NDA) or an abbreviated NDA (ANDA) for each such product from the FDA. With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. (Bradley) which was subsequently purchased by Nycomed US Inc. (Nycomed) in February 2008, for the marketing of Elestrin in the United States, which agreement was subsequently terminated by the parties effective August 6, 2008. Pursuant to the termination, release and settlement agreement with Nycomed, we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited (Azur) for the marketing of Elestrin and

the sale of certain assets related to Elestrin. Azur has agreed to promote Elestrin using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement.

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. PharmaSwiss intends to submit our approved U.S. NDA to the Israeli authorities based on our results and manufacturing information. Approval of Elestrin in Israel is expected approximately one year after such submission.

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Prior to submitting an NDA or ANDA for our other products, the products must undergo additional human clinical trials. With respect to LibiGel, we believe, based on agreements with the FDA, including a Special Protocol Assessment (SPA) received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular 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, hypoactive sexual desire disorder (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. The 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.

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, we are pursuing the creation of improved versions of current vaccines and of new vaccines by the adjuvant activity of our proprietary nanoparticles that enhance 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.

- 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.

One of our strategic goals is 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 from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor in connection with our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. No timetable has been set for completion of the exploration of strategic alternatives, and there can be no assurance

that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive

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terms. We do not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

Hormone Therapy Market

Hormone therapy is used to relieve one or more symptoms caused by declining or low hormone levels. Symptoms addressed by hormone therapies include female sexual dysfunction and menopausal symptoms in women, including hot flashes, vaginal atrophy and impotence, lack of sex drive and muscle weakness in men. The primary goal of hormone therapy is to safely and effectively relieve these dysfunctions and symptoms with minimal side effects.

Testosterone Therapy for Women. Although generally characterized as a male hormone, 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 (FSD), 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.

There is no pharmaceutical product currently approved in the United States for FSD, specifically hypoactive sexual desire disorder (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.

In December 2004, the FDA s Reproductive Health Drugs Advisory Committee panel voted unanimously against recommending the approval of Procter & Gamble s Intrinsa testosterone patch for HSDD. The panel s main concern was a desire to have additional safety data available particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Despite the recommendation not to approve Intrinsa, the panel voted that Intrinsa provides a clinically meaningful benefit for women with HSDD. Procter & Gamble withdrew its NDA for Intrinsa and it is our understanding that Procter & Gamble completed two Phase III studies in over 1,000 surgically menopausal women, two additional Phase III studies in over 1,000 naturally menopausal women (i.e., with an intact uterus and ovaries) as well as additional Phase III studies in different patient populations for a total of five Phase III clinical trials with several currently not yet finished. However, to date, we are not aware of any clinical activity by Procter & Gamble to provide the required safety data. Procter & Gamble received European regulatory approval for its Intrinsa patch in July 2006 and began marketing the product in Europe during the first half of 2007. It is our understanding that Procter & Gamble has not made any final decision as to whether it will continue to pursue regulatory approval of Intrinsa in the United States.

Pursuant to our discussions, meetings and agreements with the FDA including an SPA received in January 2008 regarding LibiGel, we believe two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III safety study with a four-year follow-up post-NDA filing and potentially

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post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel.

Estrogen and Combined Estrogen Therapy for Women. 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, recent 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 $1.4 billion in 2008, of which the transdermal segment, mostly patches, is reported at about $290 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.

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.

Women who have not had a hysterectomy must take estrogen in combination with progestogen (either progestin or progesterone) as estrogen alone may increase endometrial hyperplasia and endometrial cancer risks. In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone (conjugated estrogen plus progestin) therapy. The NIH announced that it was discontinuing the arm of the study investigating the use of the estrogen/progestogen tablet combination from the WHI study because Prempro®, the combination oral estrogen/progestogen therapy product used in the study, was shown to cause an increase in the risk of invasive breast cancer after an average follow-up period of 5.2 years. 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 the orally delivered combined estrogen plus progestogen product among healthy postmenopausal women. Also in July 2002, the National Cancer Institute (NCI) published the results of an observational study in which it found 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. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies.

In March 2004, the NIH announced that the estrogen-alone arm of the 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

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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.

Recently published results suggest that age has an effect on these results and women who begin estrogen therapy in their fifties might in fact see a decrease in the risk of heart disease and breast cancer. The WHI studies were conducted using only oral conjugated estrogen.

In May 2006, data from the Nurses Health Study (NHS) were published in the *Archives of Internal Medicine* showing no increase in invasive breast cancer risk among postmenopausal hysterectomized women who used estrogen-alone therapy for less than 10 years. The NHS researchers also reported a nonsignificant decrease in breast cancer risk among current estrogen therapy users for five to 9.9 years. These data are consistent with the recent findings on estrogen therapy and breast cancer that were published from the Women s Health Initiative (WHI) Estrogen Therapy (ET) sub-study. The NHS is a large prospective cohort study of over 120,000 registered nurses in the United States. There were 11,508 women who had a hysterectomy and reported information on estrogen use at baseline in 1980. The study population was expanded every two years as NHS participants reported having a hysterectomy and becoming menopausal. By the final follow-up period (2000- 2002), there were 28,835 women being followed in the study.

In February 2007, the medical journal *Circulation* published data suggesting the risks of hormones are dramatically reduced when the drugs are absorbed through the skin in patches and gels rather than taken as pills. The study by French researchers showed that one of the most serious risks associated with hormone use blood clots could be virtually eliminated if women switch to a skin-delivery system like the patch. It is estimated that more than six million U.S. women use menopause hormones to relieve hot flashes and other symptoms. Although hormone drugs come in pills, patches, gels, a lotion and rings, the vast majority of U.S. women use the pill form.

Among the 881 women studied in the *Circulation* report, researchers found that women who took oral hormone pills were four times as likely to suffer a serious blood clot. Women who used transdermal hormone patches or gels were at no higher risk for blood clots than women who did not take hormones at all. The research, collected from a continuing study called ESTHER (which stands for Estrogen and Thromboembolism Risk), was funded primarily by French government health agencies and also received some support from drug companies that make patch treatments. The women studied were taking either estrogen only or an estrogen-and-progestin combination.

As a result of the findings from the WHI and other studies, the FDA has required that black box labeling be included on all estrogen products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention. In addition, NIH guidelines, which are supported by many physicians and the FDA, as well as the American College of Obstetricians and Gynecologists (ACOG) and the North American Menopause Society (NAMS), recommend hormone therapy for treating menopausal symptoms in the lowest dose possible for the shortest duration of time consistent with therapeutic goals.

The primary advantage of transdermal estrogen therapy products over oral products is that the estrogen avoids the first pass through the liver where it may have certain negative effects and it avoids being metabolized and losing potency, thereby allowing a lower dosage of hormone to be used. In addition, unlike the oral products containing conjugated estrogens, which were evaluated in the NIH trials, transdermal products, such as our Elestrin, use estradiol which is identical to the estrogen produced naturally by a woman s ovaries. No studies to date have evaluated the long-term effects of transdermal estrogen alone. Despite the lack of such studies, however, the FDA has approved several transdermal

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estrogen or estrogen combined with progestogen products, including transdermal patches and a spray, manufactured by Noven Pharmaceuticals, Inc., Berlex Laboratories, Inc., Mylan Laboratories, Inc., Novartis Pharma AG, Pfizer Inc., Watson Pharmaceuticals, Inc. and KV Pharmaceutical Co.; transdermal gels marketed by Ascend Therapeutics, Inc. and Upsher-Smith Laboratories, Inc. and our Elestrin transdermal gel marketed by Azur.

Testosterone Therapy for Men. 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 21 percent in 2008 to $755 million from $624 million in 2007. We have entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA agreed to develop our male testosterone gel, Bio-T-Gel, for the U.S. market.

Description of Our Products

Overview. Our primary products are gel formulations of testosterone, estradiol and a combination of estradiol and testosterone. The gels 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 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;

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

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

Our principal gel products include LibiGel, Elestrin and Bio-T-Gel. In addition to our gel products, we also have licensed The Pill-Plus, which is a triple hormone contraceptive that uses various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

LibiGel. 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 has successfully completed a Phase II clinical trial, and our three Phase III safety and efficacy clinical trials are underway and enrolling women.

With respect to LibiGel, we believe based on agreements with the FDA, including an SPA 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 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. 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.

Currently, three LibiGel Phase III trials are underway: 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 at which time we intend to submit an NDA to the FDA. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years. We expect the Phase III clinical trial program of LibiGel to require significant resources.

Elestrin. Our estrogen formulated gel 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

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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 November 2006, we entered into an exclusive sublicense agreement with Nycomed for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of $3.5 million. In addition, in 2007, Nycomed paid us an additional $10.5 million which was triggered by FDA approval of Elestrin which occurred in the fourth quarter of 2006. Nycomed also agreed to pay us additional sales-based milestone payments, plus royalties on sales of Elestrin. Nycomed commercially launched Elestrin in the U.S. in June 2007. We did not receive any meaningful royalties from Nycomed on net sales of Elestrin. Pursuant to a termination, release and settlement agreement with Nycomed, who was not interested in marketing women s products, we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin in August 2008. Nycomed provided us all information, documents and know-how that related to Elestrin, including the manufacture, use or sale of the product. In addition, Nycomed agreed not to market or sell any low-dose topical estrogen gel products for the treatment of menopausal hot flashes for a period of 12 months. The termination, release and settlement agreement also provides for a mutual release between the parties and the survival of the confidentiality, indemnification and insurance provisions of the exclusive sublicense agreement for a period of five years.

In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur for the marketing of Elestrin and the sale of certain assets related to Elestrin. Upon execution of the agreement, we received $3.325 million comprised of a $0.5 million product licensing fee and $2.825 million for transfer of the Elestrin trademark and inventories, among other items, less $462,500 we paid to Antares, our licensor. Azur has agreed to promote Elestrin using its women s health sales force that consists of approximately 50 sales people that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. The financial terms of the sublicense agreement include an upfront sublicense fee, sales-based milestone payments and royalty payments to us ranging primarily from 10 percent to 20 percent and depending primarily upon the annual sales levels of Elestrin. Azur s obligation to pay royalties will end on the later of (i) the last expiration of the patents covering Elestrin in the United States and (ii) December 31, 2023. Either party may terminate the license agreement upon the other party s material breach of the agreement after written notice specifying the alleged breach and an opportunity to cure the breach or upon the other party s insolvency or bankruptcy. Azur may terminate the sublicense agreement for any reason upon 90 days prior written notice and we may terminate the sublicense agreement if Azur discontinues distribution of the product for at least three months.

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. PharmaSwiss intends to submit our approved U.S. NDA to the Israeli authorities based on our results and manufacturing information. Approval in Israel is expected to take approximately one year after such submission.

Our Other Hormone Therapy Products. In addition to LibiGel and Elestrin, our products include Bio-T-Gel and The Pill-Plus. We have entered into several license and sublicense agreements covering these and some of our other proposed products.

Bio-T-Gel. In December 2002, we entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA agreed to develop and market our male testosterone gel, Bio-T-Gel, for the U.S.

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market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA 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. In 2005, we were notified that Teva USA had discontinued development of the product and indicated to us a desire to formally terminate the agreement. In June 2007, we signed an amendment to the agreement under which we and Teva USA reinitiated our collaboration on the development of the product. There were no changes to the master license agreement in force at that time. Teva USA withdrew its previous notice of its desire to terminate the agreement and reinitiated funding and development of the product. Teva USA also agreed to pay us certain milestone payments plus royalties on sales of the product, if and when commercialized. The product is owned by us with no royalty or milestone obligations to any other party. Teva USA is responsible under the revised agreement for continued development of the product, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product.

The Pill-Plus. The Pill-Plus is based on three issued U.S. patents claiming triple hormone 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 hormone contraception. In July 2005, we obtained 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 hormone 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 sub-licensed U.S. rights to a new triple hormone oral contraceptive 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 hormone contraceptives.

In September 2008, we announced positive results of clinical work on our Pill-Plus triple hormone therapy oral contraceptive. The Pill-Plus adds a third hormone, an androgen, to the normal two hormone (estrogen and progestogen) oral contraceptive to prevent androgen deficiency which often leads to a decrease in sexual desire, sexual activity and mood changes. We retain rights to the Pill-Plus for transdermal development and marketing. In a completed Phase II double-blind randomized clinical trial, the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. Paradoxically, many women who use oral contraceptives have reduced sexual desire, arousabilty and activity due to the estrogen and progestogen in normal oral contraceptives. The Pill-Plus is designed to improve the condition known as female sexual dysfunction in oral contraceptive users, among other potential benefits.

Other Proposed 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.

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In August 2001, we entered into a sublicense agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sublicenses our estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million, future milestone payments and escalating sales-based royalties. Solvay has been responsible for all costs of development to date. We believe that the hormone therapy 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.

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 in a project 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.

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

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- 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.

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 covering the use of our CaP as a facial filler (BioLook) in aesthetic medicine. The license was signed with Medical Aesthetics Technology Corporation (MATC) with whom we previously had been working in the field of aesthetic medicine under an option agreement. 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 this license, we have taken 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. Further pre-clinical tests currently are underway to confirm these preliminary positive results and determine whether BioLook can extend the beneficial wrinkle-filling effects longer than those produced by the leading hyaluronic acid fillers, such as Restylane currently marketed by Medicis Pharmaceutical

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Corporation, which typically last about six months after injection into the skin. Human clinical testing of BioLook for this use is being planned and is expected to be initiated by MATC in 2009.

Vaccine Adjuvant and Delivery System. We believe that our CaP nanoparticles may offer a means of preparing new improved formulations of current 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 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. Also, we believe that CaP will allow for creation of safe and effective vaccines for diseases and conditions for which new vaccine alternatives may be preferred. 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.

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.

In November 2008, we announced that we had been 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 will be 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.

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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 hormone therapy 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 and sublicense agreements, our licensee and sub-licensees have agreed to market the products covered by the agreements in certain countries. For example, under our sublicense 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. Our former sublicensee, Nycomed, commercially launched Elestrin in June 2007. As such, we recognized royalty revenue based on a percentage of Nycomed s net sales of Elestrin during the year ended December 31, 2007 and royalty and other revenue during the year ended December 31, 2008.

If and when we are ready to commercially launch a product not covered by our license or sublicense 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 $15.8 million in 2008, $4.8 million in 2007 and $3.9 million in 2006 on research and development activities. We spent an average of approximately $1.3 million per month on our research and development activities during 2008. We expect our research and development expenses to be significantly higher in 2009 compared to 2008 as a result of the increased expenses related to the conduct of our LibiGel Phase III clinical trial program. We expect our research and development expenses to remain at the average 2008 levels until late in the first half of 2009, when we expect them to increase to at least $2.0 million per month. 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. If we do not raise additional financing or secure another funding source for our clinical trial program prior to the end

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of our second quarter 2009, we will need to delay or cease new enrollment in our Phase III clinical trial program of LibiGel, however, it is our intention to continue the clinical program for those women already enrolled. The change in clinical trial enrollment may delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this change.

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. Our plan is to use third-party current Good Manufacturing Practices, or cGMP, manufacturers to manufacture our products in accordance with FDA and other appropriate regulations. Our gel hormone products for use in clinical trials are currently manufactured by an approved U.S.-based manufacturer under FDA-approved, cGMP conditions as is Elestrin for commercial supplies.

Patents, Licenses and Proprietary Rights

Our success depends and will continue to depend in part upon our ability to maintain our exclusive licenses, to maintain patent protection for our products and processes, to preserve our proprietary information 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.

We license the technology underlying certain of our products, other than Bio-T-Gel, The Pill-Plus and the CaP technology, from Antares Pharma, Inc. We entered into the license agreement with Antares in June 2000. Under the agreement, Antares granted us an exclusive license to certain products, including rights to sublicense the products, in order to develop and market the products in certain territories. We are the exclusive licensee in certain territories for an Antares issued patent for these products in the United States and have filed additional patent applications (several that include BioSante personnel as inventors) 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 licensed technology. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. We license the technology underlying our proposed triple hormone contraceptives 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 described earlier in this report, we have entered into several sublicense agreements with respect to our products. The financial terms of these agreements generally include an upfront license fee, milestone payments, 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.

CaP Technology. In June 1997, we entered into a licensing agreement with the Regents of the University of California, which has subsequently 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 expiration dates of these patents range from 2010 to 2014. In addition, we own several patents and patent applications covering the technology expiring beginning

in 2021. The University of California also has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada,

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Europe and Japan. The license agreement requires us to undertake various obligations, including the payment of 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.

As described earlier in this report, we have entered into a few 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.

Patents and Patent Applications. As described above, we have licensed a patent portfolio relating to our hormone therapy products from Antares. Antares also has a number of patent applications pending that we believe we would benefit from and would be the subject of our license agreement with Antares.

In April 2007, we announced that a new patent had issued covering the formulations used in LibiGel and Elestrin. The patent, which was issued on April 3, 2007 and covers both LibiGel and Elestrin, is expected to expire on June 25, 2022. This patent lists our Chief Executive Officer as a coinventor. In January 2009, we announced that another patent had issued covering the formulation used in Elestrin. This patent, which issued on December 30, 2008, also lists our Chief Executive Officer as a coinventor and is also expected to expire on June 25, 2022. Both patents are assigned to Antares and licensed to us.

With respect to our CaP technology, we own two United States patents and a number of non-U.S. related patents and pending patent applications. We also have patent applications pending with the U.S. Patent and Trademark Office and internationally relating to our development work with CaP, including applications as a vaccine adjuvant, as a carrier for biologically active material, as a controlled release matrix for biologically active material, and for other applications of our CaP technology. We also have certain rights to several licensed patents from the University of California, which are governed under our license agreement with the University of California.

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® and BIOAIR . In addition, we have filed trademark applications for several other marks including ELESTRIN (pursuant to our sublicense 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 , and BIOAIR . 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 conceived by these individuals during their employment by BioSante will be our property.

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Competition

There is intense competition in the biopharmaceutical industry, including in the hormone therapy market, the market for prevention and/or treatment of the same infectious diseases we target and in the acquisition 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. All of our competitors in categories (1) and (2) and some of our competitors in category (3) 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 in the field is being carried out at academic and government institutions. These institutions are becoming increasingly aware of the commercial value of their findings and are becoming more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

There are several firms currently marketing or developing products similar to ours. They include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc., Wyeth, Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc., KV Pharmaceutical Co. and Solvay Pharmaceuticals, Inc. 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, is also 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 have generally 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.

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 proposed 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 must also 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

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subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

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

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

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

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

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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.

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.

In January 2008, we announced that we successfully completed and reached agreement with the FDA under the SPA process for our Phase III safety and efficacy clinical trials for LibiGel in the treatment of FSD, specifically, HSDD in 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.

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

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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.

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 23 employees as of December 31, 2008, including 18 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, might, possibl potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate or continu terms of similar meaning. These forward-looking statements may be contained in the notes to our financial statements and elsewhere in this report, including under the heading 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 trials and other regulatory status of our proposed products, including any approval of our drugs by the FDA that are currently in clinical development;

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- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;

- the future market and market acceptance of our products;

- 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;

- our substantial and continuing losses;

- our engagement of Deutsche Bank Securities and our efforts, with the assistance of Deutsche Bank Securities, to continue to evaluate various strategic alternatives with respect to our products and our company; and

- the effect of new accounting pronouncements.

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 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 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 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. 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,

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as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also make available, free of charge and through our Internet web site, to any stockholder who requests, our corporate governance guidelines, the charters of our board committees and our Code of Conduct and Ethics. Requests for copies can be directed to Investor Relations at (847) 478-0500, extension 120.

Item 1A. RISK FACTORS

The following are significant risk factors known to us that could materially adversely affect our business, financial condition or operating results.

Risks Related to Our Business

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

We have a history of operating losses. We incurred a net loss of $17.4 million for the year ended December 31, 2008 and as of December 31, 2008, our accumulated deficit was $71.9 million. Substantially all of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions, revenue earned from subcontracts with various parties and royalty revenue. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs continue and various preclinical and clinical trials commence or continue, including in particular our Phase III clinical trial program for LibiGel. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

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

- the timing and cost of obtaining necessary regulatory approvals for our proposed products;

- the commercial success and net sales of Elestrin, on which we receive royalties and potentially may receive sales-based milestones;

- the timing and cost of obtaining third party reimbursement for our products; and

- the progress, timing and costs of our business development efforts to implement business collaborations, joint ventures, licenses and other business combinations or transactions with entities that have businesses or technologies complementary to our business.

In order to generate new and significant revenues, we successfully must develop our own proposed products and enter into collaborative agreements with others who successfully can commercialize them. Even if our proposed products and the products we may license or otherwise acquire are introduced commercially, they may never achieve market acceptance and we may not generate additional revenues or achieve profitability in future years.

We will need to raise substantial additional capital in the near future 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 our proposed products or to complete the commercialization of any of our proposed products. We expect the Phase III clinical trial

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program of LibiGel to require significant resources. Therefore, we will need to raise substantial additional capital to fund our operations. Although we believe that our cash, cash equivalents and short-term investments of $14.8 million at December 31, 2008 will be sufficient to meet our liquidity requirements through at least the next 12 months, if we do not raise additional financing or secure another funding source for our clinical trial program prior to the end of our second quarter 2009, we will need to delay or cease new enrollment in our Phase III clinical trial program of LibiGel, however, it is our intention to continue the clinical program for those women already enrolled. The change in clinical trial enrollment may delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this change.

Our future capital requirements will depend upon numerous factors, including:

- 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 products and our company;

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

- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;

- the commercial success and net sales of Elestrin;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our proposed products;

- the rate of technological advances;

- the commercial success of our proposed products;

- our general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products; and

- the activities of our competitors.

The stock market in general, and the NASDAQ Global Market and the market for life sciences companies in particular, have experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of listed companies. There have been dramatic fluctuations in the market prices of securities of biopharmaceutical companies such as ours. Broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance, and may adversely impact our ability to raise additional funds. Due to such market conditions, as well as the status of our product development programs, we cannot assure you that additional financing 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 be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, including most importantly, as mentioned above, our Phase III clinical trial program for

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LibiGel. As an alternative to raising additional financing, we may choose to sublicense 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, 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. We may be required to relinquish greater or all rights to our proposed products at an earlier stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern and cause us to significantly curtail or cease ongoing operations.

If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we incur debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting 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.

The current adverse domestic and worldwide economic conditions have adversely affected our ongoing exploration of strategic alternatives process.

General domestic and worldwide economic conditions have experienced a significant downturn due to the effects of the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions, liquidity concerns among other factors. Our company is not immune to these adverse conditions. We believe the current domestic and worldwide economic crisis has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. One of our strategic goals has been, and continues to be, to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor to assist us in our efforts to explore strategic alternatives. Strategic alternatives we may pursue could include, but are not limited to, licenses, partnering or other collaboration agreements, a sale of some or all of our assets, a merger or sale of the entire company, continued execution of our operating plan, or other strategic transaction. While no timetable has been set for the completion of our exploration of strategic alternatives process, we believe that it is likely that the process will take significantly longer than we originally anticipated. We believe this is due, in significant part, to the current challenging capital markets environment and uncertain general domestic and worldwide economic conditions, both of which have reduced companies willingness to use their cash and/or stock to acquire other companies and products, especially development stage products that involve risk. We believe based on sales data for male sexual dysfunction products as well as published papers and independent primary market research that the estimated market for an FDA approved FSD product could reach more than $2.0 billion, and that if approved by the FDA, LibiGel could become the first FDA approved treatment specifically indicated for HSDD in menopausal women. However, we expect the Phase III clinical trial program of LibiGel to require significant resources. We also understand the significant risks involved in conducting clinical trials, obtaining regulatory approvals and commercializing a product that could be the first product of its kind to reach the market. While we continue in our ongoing efforts to explore strategic alternatives, we are mindful of these risks and the general economic environment which currently exists, both of which we believe has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. Accordingly, we cannot provide any assurance as to when or if our exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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Our proposed products are in the development stages and likely will not be commercially introduced for several years, if at all.

Our proposed 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 have 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, we believe that our estrogen/progestogen combination transdermal gel product sublicensed 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. We cannot assure you that any of our proposed products will:

- be successfully developed;
- prove to be safe and effective in clinical trials;
- 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 commercially manufacture 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 is typically lengthy and expensive, and approval is never certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed 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, our management s credibility, the value of our company and our operating results and liquidity would be adversely affected. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. 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 its manufacture are subsequently discovered. The FDA may also 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 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

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licensees, clinical trials on humans on each of our proposed products. Pre-clinical studies on animals must be conducted on some of our proposed 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 patient 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 patients; and
- lack of effectiveness of the product being tested.

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

Although we successfully have completed and reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trials 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.

We anticipate that LibiGel, if approved by the FDA, could be a very successful product. However, 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 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

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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. 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 patients and other reasons, could significantly delay 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 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 exceed the benefits from the use of those products among healthy 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 healthy 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 healthy 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 was also halted. Our products differ from the products used in the WHI study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Recent reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of our products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms have declined as a result of these published studies. The release of any follow-up or other studies that show adverse

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affects from hormone therapy, including in particular, hormone therapies similar to our products, would also adversely affect our business and likely decrease our stock price.

If clinical trials for our proposed products are prolonged or delayed, we may be unable to commercialize our proposed 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 proposed products that will cause us or any 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 proposed products and negatively impact our ability to obtain regulatory approval or enter into collaborations for, or market or sell, a particular proposed 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 proposed 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.

We entered into an exclusive sublicense agreement Azur for the marketing of Elestrin in the United States as a result of which we are dependent upon Azur for the marketing and sale of our Elestrin product.

In December 2008, we entered into an exclusive sublicense agreement with Azur for the marketing of Elestrin in the United States pursuant to which we received an upfront license payment and have the right to receive certain sales-based milestone payments, plus royalties on sales of Elestrin. As a result of this agreement, Elestrin is subject to not only general market acceptance of the product, but also the success of Azur in marketing and selling the product. Sales of Elestrin by our former sublicensee, Nycomed (which acquired Bradley in February 2008), were minimal and did not result in our receipt of any meaningful royalty revenue. We cannot assure you that Azur will be successful in marketing Elestrin or that Azur will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of our agreement, especially if Azur does not experience significant Elestrin sales. Any breach by Azur of its obligations under our agreement or a termination of the agreement could adversely affect the success of Elestrin if we are unable to sublicense the product to another party on substantially the same or better terms or continue the future commercialization of the product ourselves.

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Elestrin, which is FDA approved, and our other proposed products, if they receive FDA approval, may not achieve expected levels of market acceptance, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

The commercial success of our FDA-approved product, Elestrin, and our other proposed products, if they receive the required regulatory approvals, is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our products could be impacted 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 Elestrin to Azur. Elestrin and our proposed 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 have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

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

We have no manufacturing experience or manufacturing capabilities for the production of our proposed products for clinical trials or commercial sale. In order to continue to develop proposed products, apply for regulatory approvals and commercialize our proposed products following approval, we or our sublicensees 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, clinical trials by us could be seriously delayed.

To the extent that we or our sublicensees seek to enter into manufacturing arrangements with third parties, we and such sublicensees will depend upon these third parties to perform their 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;

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- 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 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 legally bound to remain employed for any specific term. Although we have key man life insurance on our Vice Chairman, President and Chief Executive Officer, Stephen M. Simes, we do not have key man life insurance policies covering our other executive officer or any of our other employees. If key individuals leave BioSante, we could be adversely affected 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.

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

Section 404 of the Sarbanes-Oxley Act requires our management to assess and our independent registered public accounting firm to provide an opinion on the effectiveness of our internal controls over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission provides a framework for companies to assess and improve their internal control systems. If we are unable to maintain effective internal controls, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the NASDAQ Stock Market. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting is effective. If we are unable to assert that our internal controls over financial reporting is effective (or if our independent registered public accounting firm is unable to express an opinion or issues an adverse opinion on the effectiveness of our internal controls over financial reporting), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal controls over financial reporting could have an adverse effect on our common stock price.

Risks Related to Our Industry

Because our industry is very competitive and many of our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical, chemical 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

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public and private research organizations are also 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 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 proposed products and our clinical trials, and if any of our proposed 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 the technology underlying most of our products and a portion of our CaP technology from third parties and may lose the rights to license them, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.

We license certain of the technology underlying our products from Antares Pharma, Inc., a portion of our CaP technology from the University of California and the Pill Plus from Wake Forest University. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California s license agreement within 60 days after written notice from the University of California, the other party to these agreements 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. Our failure to retain the right to license the technology underlying our proposed products or CaP technology could harm our business and future operating results. For example, if we were to enter into an sublicense agreement with a third party under which we agree to sublicense our hormone therapy technology or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc., the University of California or Wake Forest University could either, depending upon the terms of the sublicense agreement, cause us to breach our obligations under the sublicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the sublicense fees.

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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 sublicense agreements or a termination of these sublicense 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 proposed products.

We have licensed our CaP technology for use as a facial line filler to MATC and some of our hormone therapy product to third parties, including Azur, Solvay Pharmaceuticals, B.V., 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 manufacturing and marketing associated with the products. In addition, we may in the future enter into additional similar license agreements. Our products that we have licensed to others are thus 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 proposed 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 proposed products. For example, at this time, we believe that our estrogen/progestogen combination transdermal hormone therapy gel 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. As an additional example, in 2005, we were notified that Teva USA had discontinued development of our male testosterone gel, Bio-T-Gel, product and indicated to us a desire to formally terminate the agreement. 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 and Teva withdrew its previous notice of its desire to terminate the agreement and reinitiated funding and development of the product, prior to such time, no third party was developing our Bio-T-Gel. 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 adversely affect development of the products in these agreements if we are unable to sublicense the proposed products to another party on substantially the same or better terms or continue the development and future commercialization of the proposed 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. However, these legal means 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. However, our owned and licensed patents and patent applications 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.

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- 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 may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore we cannot use our technology as claimed under our patent. Competitors may also have our patents reexamined by demonstrating to the patent examiner that the invention was not original or novel or was obvious.

- We are engaged in the process of developing proposed 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 proposed 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. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

- 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 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. However, such agreements 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.

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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 can conduct only limited searches to determine whether our technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

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

Like most other stocks, the price of our common stock has decreased significantly recently and likely will continue to be 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.

During the past 12 months, the closing sale price of our common stock has ranged from a low of $0.81 to a high of $5.85. 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;

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- 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, cash equivalents and short-term investment balance, operating expenses, cash burn rate or revenues;

- 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 minimum stockholders equity requirement and certain corporate governance standards. Although Nasdaq has suspended the minimum $1.00 closing bid price rule through Friday, April 17, 2009, the rule is scheduled to be reinstated on Monday, April 20, 2009. Our common stock price has traded at or below $1.00 per share in the recent past. If our stock price trades below $1.00 as of April 20, 2009, there can be no assurance that Nasdaq will not take action to enforce its listing requirements. In addition, although we met the minimum $10 million in stockholders equity requirement as of December 31, 2008, it is likely that if we do not raise additional financing in the near future, we may not meet the $10 million minimum stockholders equity requirement when we file our first quarter 2009 quarterly report on Form 10-Q. Thus, there can be no assurance that we will continue to meet all requirements for continued listing on the Nasdaq Global Market. 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

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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.

Exercise of outstanding options and warrants will dilute stockholders and could decrease the market price of our common stock.

As of March 1, 2009, we had issued and outstanding 27,042,764 shares of common stock, 391,286 shares of our class C stock and outstanding options and warrants to purchase 5,479,063 additional shares of common stock. The existence of the outstanding options and warrants may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital.

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

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.

Risks Relating to our Committed Equity Financing Facility with Kingsbridge

The Committed Equity Financing Facility that we entered into with Kingsbridge may not be available to us if we elect to make a draw down.

In December 2008, we entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of

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two years, shares of our common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF 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 CEFF 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 CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

The CEFF that we entered into with Kingsbridge may require us to make additional blackout or other payments to Kingsbridge.

In connection with our CEFF with Kingsbridge, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement registering the resale of shares of our common stock issued or issuable to Kingsbridge and prohibit Kingsbridge from selling shares under that registration statement. Such circumstances include, for example, if we possess material nonpublic information about our company such that in our good faith judgement it would be detrimental to our company or our stockholders for resales of shares of our common stock to occur pursuant to the resale registration statement. If, however, we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the agreement, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

The CEFF that we entered into with Kingsbridge may result in dilution to our stockholders if we sell shares to Kingsbridge under the CEFF or issue shares in lieu of a blackout payment.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effective on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 14 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if we were to issue shares when our stock price is higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

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 $22,000 per month. Our lease for this space expires in April 2010 and is renewable for an additional year expiring April 2011. Our CaP development operations are located within the Bucks County Biotech Park in Doylestown, Pennsylvania

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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 2009. Management of our company considers our leased properties suitable and adequate for our current and foreseeable needs.

Item 3. LEGAL PROCEEDINGS

There are no material proceedings that we believe would have a material adverse effect on our results of operations or financial condition.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of our security holders during the fourth quarter ended December 31, 2008.

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Item 4A. **EXECUTIVE OFFICERS OF THE REGISTRANT**

Our executive officers, their ages and the offices held, as of March 15, 2009, are as follows:

Name		Age		Title
Stephen M. Simes		57		Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg		48		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 Solvay Pharmaceuticals, Inc.) a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.).

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 Solvay Pharmaceuticals, Inc.) 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 REPURCHASES OF EQUITY SECURITIES

Market Price

Our common stock is listed for trading on the NASDAQ Global Market, under the symbol BPAX. Our common stock has traded on the NASDAQ Global Market since November 5, 2007. From October 1, 2003 to November 2, 2007, our common stock traded on the American Stock Exchange under the symbol BPA .

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 on which our common stock was listed for trading on the NASDAQ Global Market.

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

2007	High	Low
Fourth Quarter (beginning November 5, 2007)	$ 5.86	$ 3.50

The following table sets forth the high and low daily sale prices for our common stock, as reported by the American Stock Exchange, for each calendar quarter on which our common stock was listed for trading on the American Stock Exchange.

2007	High	Low
First Quarter	$ 6.25	$ 2.55
Second Quarter	$ 8.00	$ 5.28
Third Quarter	$ 6.71	$ 5.00
Fourth Quarter (through November 4, 2007)	$ 6.10	$ 5.21

Number of Record Holders; Dividends

As of March 1, 2009, there were 305 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.

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Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2008, we did not issue or sell any equity securities of ours without registration under the Securities Act of 1933, as amended, other than entering into the committed equity financing facility with Kingsbridge and issuing a warrant to purchase 300,000 shares of our common stock at an exercise price of $4.00 per share to Kingsbridge in connection with such transaction. We filed a registration statement on Form S-3 with the Securities and Exchange Commission on December 18, 2008 registering the offering and resale of 5,705,840 shares of our common stock in connection with the transaction, including the 300,000 shares of common stock issuable upon exercise of the warrant we issued to Kingsbridge and the remaining shares issuable to Kingsbridge under the committed equity financing facility. This registration statement was declared effective by the SEC on December 29, 2008. In issuing such warrant and entering into such facility with Kingsbridge, we relied upon Section 4(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering or Regulation D of the Securities Act. In connection with such transaction, we made certain inquiries of Kingsbridge to establish that our sales of securities qualified for such exemption from the registration requirements. In particular, we confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) the offer of sale and sale were made by personal contact from our officers and directors or other persons closely associated with our company, (ii) Kingsbridge made representations that it was sophisticated in relation to its investment (and we have no reason to believe that such representations were incorrect), (iii) Kingsbridge gave assurance of investment intent, and (iv) offers and sales were made just to Kingsbridge.

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, 2008. 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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Stock Performance Graph

The following graph shows the five-year cumulative total stockholder return on our common stock from January 1, 2004 until December 31, 2008, with the annual cumulative total return over the same period of the Russell 3000 Index and the Biological Products Index.

The comparison assumes the investment of $100 in each of our common stock, the Russell 3000 Index and the Biological Products Index on January 1, 2004, and the reinvestment of all dividends.

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

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Item 6. SELECTED FINANCIAL DATA

The following selected financial data sets forth our results of operations and balance sheet data for the fiscal years and as of the dates indicated:

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue					
Licensing revenue	$ 3,384	$ 199	$ 14,136	$ 45	$ 10
Grant revenue	65	59	247	181	68
Royalty revenue	34	69			
Other revenue	298	166	55	32	
Total revenue	3,781	493	14,438	258	78
Interest income	588	1,095	429	401	250
Expenses					
Research and development	15,790	4,751	3,908	6,409	9,162
General and administration	5,125	4,331	4,550	3,801	3,080
Licensing expense	836		3,500		
Depreciation and amortization	43	90	118	101	102
Total expenses	21,794	9,172	12,076	10,311	12,344
Net (loss) income	$ (17,425)	$ (7,584)	$ 2,791	$ (9,651)	$ (12,016)
Basic and diluted net (loss) income per share	$ (0.64)	$ (0.30)	$ 0.13	$ (0.50)	$ (0.70)
Weighted average number of shares outstanding	27,307	25,486	21,484	19,392	17,145

	As of December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 14,787	$ 30,655	$ 11,450	$ 9,102	$ 17,269
Total assets	17,679	31,241	22,371	9,575	17,827
Stockholders equity	13,826	29,725	18,071	6,819	15,921

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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 2008 Financial Results and Outlook for 2009**. This section provides a brief summary of our financial results and financial condition for 2008 and our outlook for 2009.

- **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 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. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

Our primary products are gel formulations of testosterone and estradiol. Our key products include:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment for the treatment of female sexual dysfunction.

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.

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

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- The Pill-Plus (triple hormone 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.

With respect to LibiGel, we believe based on agreements with the FDA, including an SPA received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular 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 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.

Currently, three LibiGel Phase III trials are underway; 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 at which time we intend to submit an NDA to the FDA. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years. We expect the Phase III clinical trial program of LibiGel to require significant resources.

With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006 with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive sublicense agreement with Bradley (which was subsequently purchased by Nycomed) for the marketing of Elestrin in the United States, which agreement was subsequently terminated by the parties effective August 6, 2008. Upon execution of the sublicense agreement with Nycomed, we received an upfront payment of $3.5 million. In addition, Nycomed paid us $10.5 million in milestone payments during 2007 as a result of the FDA approval of Elestrin in the U.S., which occurred in December 2006 and royalties on sales of Elestrin commencing in June 2007, when Nycomed commercially launched Elestrin. We did not receive any meaningful royalties from Nycomed on sales of Elestrin.

In August 2008, we entered into a termination, release and settlement agreement with Nycomed, pursuant to which we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin in exchange for, among other things, a $100,000 payment to Nycomed. In December 2008, we entered into a sublicense 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, comprised of a $500,000 product sublicensing fee and approximately $2.8 million for transfer of the Elestrin trademark and inventories, among other items. Under the sublicense agreement, we are entitled to receive additional payments of up to an aggregate of $144.5 million if certain sales-based milestones are achieved. In addition, under the sublicense agreement, Azur has agreed to pay us royalties on sales of Elestrin ranging primarily from 10 percent to 20 percent depending primarily upon the annual sales levels. Azur has agreed to promote Elestrin using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement. As a result of our sublicense agreement with Azur, we were required to pay Nycomed an additional $150,000. 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.

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PharmaSwiss intends to submit our approved U.S. NDA (new drug application) to the Israeli authorities based on our results and manufacturing information. Approval of Elestrin in Israel is expected approximately one year after such submission.

We license the technology underlying certain of our products, other than Bio-T-Gel, The Pill-Plus and the CaP technology, 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 sub-licensees sell incorporating the licensed technology. Specifically, we are obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that we may receive. Bio-T-Gel was developed and is fully-owned by us. We license the technology underlying our proposed triple hormone contraceptives 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.

In the beginning of September 2008, we announced positive results of clinical work on our Pill-Plus triple hormone therapy oral contraceptive. The Pill-Plus adds a third hormone, an androgen, to the normal two hormone (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 FSD in oral contraceptive users, among other potential benefits.

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, 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. As another example, in November 2008, we announced that we had been awarded a $150,000 Small Business Innovation Research grant from the NIH to support our development of formulations for the pulmonary delivery of interferon alpha (IFN-α) using our CaP technology. The grant will be used to fund product development for IFN-α formulated with CaP particles for administration via inhalation.

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 from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor in connection with our ongoing process to explore strategic alternatives in order to maximize

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value to our stockholders. No timetable has been set for completion of the exploration of strategic alternatives, and there can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms. We do not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

Summary of 2008 Financial Results and Outlook for 2009

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

We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our former marketing sublicensee for Elestrin, commercially launched Elestrin in June 2007. As a result, from June 2007 until the termination of our agreement with Nycomed and reacquisition of Elestrin in August 2008, we received royalties on net sales of Elestrin. Subsequent to August 2008, we recognized other revenue resulting from sales of Elestrin less a fee paid to Nycomed for distributing, storing and processing of Elestrin sales. We recognized $142,656 in other revenue and $34,200 in royalty revenue from sales of Elestrin during the year ended December 31, 2008. This royalty revenue amount represents the gross royalty revenue we received from Nycomed through December 31, 2008 and not our corresponding obligation to pay Antares royalties. Our corresponding obligation to pay Antares a portion of the royalties received, which equaled $21,830 for the year ended December 31, 2008, is recorded within general and administrative expenses in our statements of operations. We expect to receive royalties during 2009 from Azur based on net sales of Elestrin. As with our royalties from Nycomed, we will be required to pay Antares a portion of any royalties we receive from Azur.

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 proposed 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 current or proposed products for which we have not entered into marketing relationships. Although we believe that our cash, cash equivalents and short-term investments of $14.8 million at December 31, 2008 will be sufficient to meet our liquidity requirements through at least the next 12 months, if we do not raise additional financing or secure another funding source for our clinical trial program prior to the end of our second quarter 2009, we will need to delay or cease new enrollment in our Phase III clinical trial program of LibiGel, however, it is our intention to continue the clinical program for those women already enrolled. The change in clinical trial enrollment may delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this change.

As an alternative to raising additional financing, we may choose to sublicense LibiGel or another product to a third party, 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.

We incurred expenses of approximately $1.3 million per month on research and development activities during the year ended December 31, 2008. Our research and development expenses increased 232 percent to $15.8 million for the year ended December 31, 2008 compared to the year ended December 31, 2007, primarily as a result of the conduct of the LibiGel Phase III clinical trials. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year

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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, 2008 increased $793,573, or 18 percent, compared to the year ended December 31, 2007. This increase was due primarily to 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 the year ended December 31, 2007. The primary reason for this increase was the grant of options to purchase an aggregate of 45,000 shares of our common stock to new employees in the third quarter 2008 and options and warrants to purchase an aggregate of 682,250 and 80,000 shares of our common stock, respectively, to new and certain existing employees and an investor and public relations firm in the second quarter 2008. 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.

We recognized a net loss for the year ended December 31, 2008 of approximately $17.4 million compared to a net loss of approximately $7.6 million for the year ended December 31, 2007. This increase was primarily due to the increased LibiGel clinical development expenses discussed above. We expect 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 trial program for LibiGel. The actual amount of these losses, however, may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

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

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

- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;

- the commercial success and net sales of Elestrin;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our proposed products;

- the rate of technological advances;

- ongoing determinations of the potential markets for and commercial success of our proposed products;

- the timing and cost of various cash and non-cash general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products;

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- the activities of our competitors; and

- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

In December 2008, we entered into a Committed Equity Financing Facility, or CEFF, 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. We may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase 300,000 shares of common stock at an exercise price of $4.00. The warrant will become exercisable on June 15, 2009, the six-month anniversary of the date of the Purchase Agreement (December 15, 2008), and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Other than attorneys fees, we did not make any other payments to secure the CEFF. The CEFF does not impose any material restrictions on our operating or financial activities. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, including a minimum price for our common stock of $1.15 per share. As of December 31, 2008, we had not sold any shares to Kingsbridge under the CEFF.

Critical Accounting Policies and Estimates

Our significant accounting policies are described in Note 2 to our financial statements included in Item 8 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 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 in the preceding paragraph when the milestone is achieved.

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Additionally, 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.

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.

Results of Operations

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

	Year Ended December 31,		
	2008	**2007**	**2006**
Revenue	$ 3,780,829	$ 493,054	$ 14,438,621
Expenses	21,794,471	9,172,498	12,075,691
Research and development	15,789,980	4,751,313	3,908,290
General and administrative	5,124,934	4,331,361	4,549,620
Licensing expense	836,420		3,500,000
Interest income	588,464	1,095,009	428,343
Net (loss) income	$ (17,425,178)	$ (7,584,435)	$ 2,791,273
Net (loss) income per share (basic and diluted)	$ (0.64)	$ (0.30)	$ 0.13
Weighted average number of shares outstanding	27,307,494	25,485,513	21,483,911

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 sublicense 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 trial program.

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.

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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.

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

Revenue for the year ended December 31, 2007 decreased significantly compared to revenue for 2006 primarily due to the recognition in 2006 of $14.0 million in licensing revenue as a result of the execution of our sublicense agreement with Nycomed and subsequent FDA approval of Elestrin in 2006.

Research and development expenses for the year ended December 31, 2007 increased 22 percent compared to research and development expenses for 2006 primarily as a result of increased spending in 2007 on our Phase III LibiGel clinical trial program, which commenced in December 2006.

Our general and administrative expenses for the year ended December 31, 2007 decreased five percent compared to general and administrative expenses for 2006 primarily as a result of a decrease in business development costs and a decrease in non-cash, stock-based compensation expense, partially offset by an increase in personnel-related expenses. Our non-cash, stock option-based compensation expense for the year ended December 31, 2007 decreased $365,573, or 34 percent, compared to non-cash, stock-based compensation expense for the year ended December 31, 2006 primarily as a result of $746,616 of expense that was recorded in 2006 related to the March 2006 grant of stock options to our non-employee directors, which options were immediately exercisable and as a result were fully expensed on the grant date.

Licensing expense for the year ended December 31, 2007 decreased significantly compared to licensing expense for 2006 primarily due to the recognition in 2006 of $3.5 million in licensing expense as a result of the execution of our sublicense agreement with our former Elestrin sub-licensee, subsequent FDA approval of Elestrin in 2006 and related licensing expense to our Elestrin licensor as of December 31, 2006.

Interest income for the year ended December 31, 2007 increased 156 percent compared to interest income during 2006 primarily as a result of a higher average invested cash balances and higher 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 and sublicensing 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 material 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, obtain regulatory approval of our other proposed products or complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. We expect the ongoing Phase III clinical trial program of LibiGel to require significant resources.

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To date, we have used primarily equity financings, licensing income and interest income 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, 2008, we had approximately $11.8 million of cash and cash equivalents and an additional $3.0 million of short-term investments. In January 2009, all $3.0 million of our short-term investments were converted into cash and cash equivalents as a result of the sale of our auction rate securities as described below. We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations. As of December 31, 2008, we did not have any outstanding debt or existing credit facilities under which we could borrow funds.

In December 2008, we entered into a Committed Equity Financing Facility, or CEFF, 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 CEFF, we are not obligated to utilize any of the $25.0 million available under the CEFF 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 CEFF over the two-year term 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 CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of our common stock during the applicable pricing period. In connection with the CEFF, we issued a warrant to Kingsbridge to purchase 300,000 shares of common stock at an exercise price of $4.00. The warrant will become exercisable on June 15, 2009, the six-month anniversary of the date of the purchase agreement (December 15, 2008), 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 CEFF. The CEFF does not impose any material restrictions on our operating or financial activities. During the term of the CEFF, Kingsbridge is prohibited from engaging in any short selling or derivative transactions related to our common stock. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, including a minimum price for our common stock of $1.15 per share. As of December 31, 2008, we had not sold any shares to Kingsbridge under the CEFF.

As of December 31, 2008, our cash and cash equivalents resided in a 100% FDIC insured, non-interest bearing checking account and our short-term investments consisted primarily of auction rate securities and related assets and money market fund investments. The underlying assets of the auction rate securities are portfolios of student loans backed by the federal government. As of December 31, 2008, our auction rate securities with a $3.0 million par value were held in an account with UBS Financial Services, Inc. (UBS). In August 2008, UBS and its affiliates reached agreements with the SEC, the New York Attorney General, the Massachusetts Securities Division, the Texas State Securities Board and other state regulatory agencies represented by the North American Securities Administrators Association to restore liquidity to UBS clients who held auction rate securities. Pursuant to these agreements, in October 2008, we received rights from UBS entitling us to sell to UBS or its affiliates and requiring UBS or its affiliates to purchase our $3.0 million in auction rate securities for their face (or par) value plus any accrued and unpaid interest at any time we decided during a two-year period commencing on January 2, 2009. In October 2008, we exercised our rights to require UBS to purchase our $3.0 million of auction rate securities and on January 8, 2009, pursuant to those rights, we received $3.0 million principal plus accrued and unpaid interest from UBS.

Our future capital requirements will depend upon numerous factors, including:

- 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

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

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

- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;

- the commercial success and net sales of Elestrin;

- our ability to license LibiGel or our other products for development and commercialization;

- the cost, timing and outcome of regulatory reviews of our proposed products;

- the rate of technological advances;

- the commercial success of our proposed products;

- our general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products; and

- the activities of our competitors.

Although we believe that our cash, cash equivalents and short-term investments of $14.8 million at December 31, 2008 will be sufficient to meet our liquidity requirements through at least the next 12 months, if we do not raise additional financing or secure another funding source for our clinical trial program prior to the end of our second quarter 2009, we will need to delay or cease new enrollment in our Phase III clinical trial

program of LibiGel, however, it is our intention to continue the clinical program for those women already enrolled. The change in clinical trial enrollment may delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long we need to continue this change.

Due to the current economic recession and market conditions, as well as the status of our product development programs, we cannot assure you that additional financing 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 be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, including most importantly, as mentioned above, our Phase III clinical trial program for LibiGel. As an alternative to raising additional financing, we may choose to sublicense 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, 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. We may be required to relinquish greater or all rights to our proposed products at an earlier stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern and cause us to significantly curtail or cease ongoing operations.

If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have

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rights, preferences or privileges senior to those of existing stockholders. If we incur debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting 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.

Uses of Cash and Cash Flow

Net cash used in operating activities was $15.5 million for the year ended December 31, 2008 compared to net cash provided by operating activities of $739,991 for the year ended December 31, 2007 and net cash used in operating activities of $5.0 million for the year ended December 31, 2006. Net cash used in operating activities for the year ended December 31, 2008 was primarily the result of the net loss for that period which was higher due to higher clinical trial related expenses, and to a lesser extent, an increase in prepaid expenses and other assets related to an increase in our prepaid clinical trial-related costs, partially offset by an increase in accounts payable and accrued liabilities. Net cash provided by operating activities of $739,991 for the year ended December 31, 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 during the year ended December 31, 2007.

Net cash provided by investing activities was $11.3 million for the year ended December 31, 2008 compared to net cash used in investing activities of $11.2 million for the year ended December 31, 2007 and net cash provided by investing activities of $5.0 million for the year ended December 31, 2006. 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 a bottle filling machine due to the conduct of our LibiGel clinical trial program. Net cash used in investing activities for 2007 and 2006 consisted primarily of purchases and sales, respectively, of short-term investments.

Net cash provided by financing activities was $319,377 for the year ended December 31, 2008 compared to $18.5 million for the year ended December 31, 2007 and $7.4 million for the year ended December 31, 2006. Net cash provided by investing activities for 2008 resulted from warrant exercises. Net cash provided by financing activities during 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. Net cash provided by financing activities for 2006 was primarily the result of the completion of our June 2006 private placement that resulted in net proceeds to us of approximately $7.1 million, after deduction of transaction expenses.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2008. We have, however, several potential financial commitments, including 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, 2008:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Leases	$ 384,198	$ 293,478	$ 90,720		
Obligation under License Agreement with Antares	5,393	5,393			
Commitments Under License Agreement with Wake Forest	720,000	130,000	230,000	160,000	200,000
Total Contractual Cash Obligations	$ 1,109,591	$ 428,871	$ 320,720	$ 160,000	$ 200,000

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably 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 materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurement (SFAS 157). The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS 157 was effective for us on January 1, 2008. In October 2008, the FASB issued Staff Position (FSP) No. FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active which clarifies the application of SFAS 157 in an inactive market and illustrates how an entity would determine fair value when the market for a financial asset is not active. The Staff Position is effective immediately and applies to prior periods for which financial statements have not been issued, including interim or annual periods ending on or before September 30, 2008. See Note 12, Fair Value Measurements, for disclosure of our adoption of SFAS 157.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 permits an entity to elect fair value as the initial and subsequent measurement attribute for many financial assets and liabilities. Entities electing the fair value option are required to recognize changes in fair value in earnings. SFAS 159 also requires additional disclosures to compensate for the lack of comparability that will arise from the use of the fair value option. SFAS 159 was effective for us beginning on January 1, 2008. We did not elect the fair value option for any of our existing financial assets and liabilities as of January 1, 2008, but did elect the fair value option during 2008 for the right to sell the auction rate securities to UBS at par. See Note 12, Fair Value Measurements, for additional information.

In December 2007, the FASB ratified Emerging Issues Task Force Issue (EITF) Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 provides guidance on how to determine whether an arrangement constitutes a collaborative arrangements, how costs incurred and revenue generated on sales to third parties should be reported by participants in a collaborative arrangement, how payments made between participants in a collaborative arrangement should be categorized, and what participants should disclose in the notes to the financial statements about a

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collaborative arrangement. EITF 07-1 is effective for the fiscal year beginning January 1, 2009. EITF 07-1 requires that the impact of adopting the issue for all arrangements existing as of the effective date be presented as a change in accounting principle through retrospective application to all prior periods presented. The adoption of EITF 07-1 did not have an impact on our results of operations or financial condition.

In June 2007, the FASB ratified Emerging Issues Task Force Issue No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 was effective for us prospectively for new contractual arrangements entered into beginning on January 1, 2008. The adoption of EITF 07-3 did not have an impact on our results of operations or financial condition.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to interest rate risk on the investments of our excess cash and short-term investments, although due to the nature of our short-term investments, we have concluded that such risk is not material. The primary objective of our investment activities is to preserve principal while at the same time maximize yields without significantly increasing risk. To achieve this objective, we typically in the past have sought to invest in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically seek to invest our excess funding in cash and cash equivalents and high-quality, short-term securities with maturities of less than one year.

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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, 2008. 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, 2008.

The effectiveness of the Company s internal control over financial reporting as of December 31, 2008 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report herein.

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

/s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

March 16, 2009

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

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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, 2008 and 2007, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such financial statements present fairly, in all material respects, the financial position of BioSante Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2009 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Deloitte & Touche LLP

Chicago, Illinois

March 16, 2009

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

BioSante Pharmaceuticals, Inc.

Lincolnshire, Illinois

We have audited the internal control over financial reporting of BioSante Pharmaceuticals, Inc. (the Company) as of December 31, 2008, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

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

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

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the financial statements as of and for the year ended December 31, 2008 of the Company and our report dated March 16, 2009 expressed an unqualified opinion on those financial statements.

/s/ DELOITTE & TOUCHE LLP

Deloitte & Touche LLP

Chicago, Illinois

March 16, 2009

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BIOSANTE PHARMACEUTICALS, INC.

Balance Sheets

December 31, 2008 and 2007

	December 31, 2008	December 31, 2007
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 11,760,920	$ 15,648,948
Short-term investments	3,026,334	15,005,976
Accounts receivable	229,775	14,566
Prepaid expenses and other assets	1,070,051	337,420
	16,087,080	31,006,910
PROPERTY AND EQUIPMENT, NET (Note 4)	814,894	54,896
OTHER ASSETS		
Investment in MATC (Note 3)	140,000	140,000
Deposits	637,397	39,536
	$ 17,679,371	$ 31,241,342
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 10)	$ 3,182,089	$ 710,575
Due to licensor - Antares (Note 3)	5,393	1,063
Accrued compensation	290,583	717,409
Other accrued expenses	374,887	77,712
Deferred revenue		9,091
	3,852,952	1,515,850
STOCKHOLDERS EQUITY (Note 6)		
Capital stock		
Issued and Outstanding		
2008 - 391,286; 2007 - 391,286 Class C special stock	391	391
2008 - 27,042,764; 2007 - 26,794,607 Common stock	85,732,688	84,206,583
	85,733,079	84,206,974
Accumulated Deficit	(71,906,660)	(54,481,482)
	13,826,419	29,725,492
	$ 17,679,371	$ 31,241,342

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Statements of Operations

Years ended December 31, 2008, 2007 and 2006

	Year Ended December 31,		
	2008	2007	2006
REVENUE			
Licensing revenue	$ 3,384,091	$ 199,091	$ 14,136,364
Grant revenue	65,051	59,060	247,257
Royalty revenue	34,200	69,353	
Other revenue	297,487	165,550	55,000
	3,780,829	493,054	14,438,621
EXPENSES			
Research and development	15,789,980	4,751,313	3,908,290
General and administration	5,124,934	4,331,361	4,549,620
Licensing expense	836,420		3,500,000
Depreciation and amortization	43,137	89,824	117,781
	21,794,471	9,172,498	12,075,691
OTHER - Interest income	588,464	1,095,009	428,343
NET (LOSS) INCOME	$ (17,425,178)	$ (7,584,435)	$ 2,791,273
(Loss) Income per common share (Note 2):			
Basic	$ (0.64)	$ (0.30)	$ 0.13
Diluted	$ (0.64)	$ (0.30)	$ 0.13
Weighted average number of common and common equivalent shares outstanding:			
Basic	27,307,494	25,485,513	21,190,946
Diluted	27,307,494	25,485,513	21,483,911

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Statements of Stockholders Equity

Years ended December 31, 2008, 2007 and 2006

	Class C Special Shares		Common Stock		Deferred Unearned	Accumulated	
	Shares	Amount	Shares	Amount	Compensation	Deficit	Total
Balance, December 31, 2005	**391,286**	**$ 398**	**19,007,800**	**$ 56,653,219**	**$ (146,459)**	**$ (49,688,320)**	**$ 6,818,838**
Option exercises - various			152,894	243,675			243,675
Stock option compensation - executive officers				(40,684)	146,459		105,775
Private placement of common shares, net			3,812,978	7,134,363			7,134,363
Stock option expense				971,057			971,057
Share redesignation		(7)		7			
Shares issued in license agreement			1,368	6,250			6,250
Net income						2,791,273	2,791,273
Balance, December 31, 2006	**391,286**	**$ 391**	**22,975,040**	**$ 64,967,887**	**$**	**$ (46,897,047)**	**$ 18,071,231**
Issuance of common shares							
Option exercises - various			53,081	192,371			192,371
Warrant exercises - various			711,487	1,019,225			1,019,225
Stock option expense				711,259			711,259
Private placement of common shares, net			3,054,999	17,282,935			17,282,935
Stock warrant expense				32,906			32,906
Net loss						(7,584,435)	(7,584,435)
Balance, December 31, 2007	**391,286**	**$ 391**	**26,794,607**	**$ 84,206,583**	**$**	**$ (54,481,482)**	**$ 29,725,492**
Issuance of common shares							
Warrant exercises - various			248,157	379,720			379,720
Stock option expense				1,102,444			1,102,444
Stock warrant expense				104,284			104,284
Credit equity financing facility				(60,343)			(60,343)
Net loss						(17,425,178)	(17,425,178)
Balance, December 31, 2008	**391,286**	**$ 391**	**27,042,764**	**$ 85,732,688**	**$**	**$ (71,906,660)**	**$ 13,826,419**

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

Statements of Cash Flows

Years ended December 31, 2008, 2007 and 2006

	December 31,		
	2008	2007	2006
CASH FLOWS (USED IN) PROVIDED BY OPERATING ACTIVITIES			
Net (loss) income	$ (17,425,178)	$ (7,584,435)	$ 2,791,273
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities			
Depreciation and amortization	43,137	89,824	117,781
Employee and director stock-based compensation	1,102,444	711,259	1,076,832
Stock warrant expense - noncash	104,284	32,906	
Loss on disposal of equipment		21,748	
MATC license revenue - noncash		(140,000)	
Changes in assets and liabilities affecting cash flows from operations			
Prepaid expenses and other assets	(1,330,492)	(103,514)	(15,985)
Accounts receivable	(215,209)	10,495,963	(10,510,529)
Accounts payable and accrued liabilities	2,189,843	449,856	(745,332)
Provision for contingencies		(550,588)	(199,412)
Due to licensor - Antares	4,330	(2,623,937)	2,625,000
Deferred revenue	(9,091)	(59,091)	(136,363)
Net cash (used in) provided by operating activities	(15,535,932)	739,991	(4,996,735)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES			
Redemption of short term investments	11,979,642	981	13,004,723
Purchase of short term investments		(11,210,979)	(8,009,812)
Purchase of capital assets	(651,116)	(29,428)	(39,255)
Net cash provided by (used in) investing activities	11,328,526	(11,239,426)	4,955,656
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Proceeds from sale or conversion of shares, net	319,377	18,494,531	7,384,288
Net cash provided by financing activities	319,377	18,494,531	7,384,288
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(3,888,029)	7,995,096	7,343,209
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	15,648,948	7,653,852	310,643
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 11,760,919	$ 15,648,948	$ 7,653,852
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Other information:			
Purchase of capital assets on account, non-cash investing activity	$ 152,019	$	$
Investment in MATC - noncash	$	$ 140,000	$

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2008

1. ORGANIZATION

BioSante Pharmaceuticals, Inc. (the Company) is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. The Company also is engaged in the development of its proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery. The Company s primary products are gel formulations of testosterone and estradiol. The Company s key products include: LibiGel, a once daily transdermal testosterone gel in Phase III development under a Special Protocol Assessment for the treatment of female sexual dysfunction; Elestrin, a once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause and marketed in the U.S.; Bio-T-Gel, a once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men; and the Pill-Plus (triple hormone contraceptive), a 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.

Substantially all of the Company s revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. To date, the Company has used primarily equity financing, licensing income, royalty income and interest income to fund its ongoing business operations and short-term liquidity needs, and the Company expects to continue this practice for the foreseeable future.

The Company s business operations to date have consisted mostly of licensing and research and development activities and the Company expects this to continue for the immediate future. The Company has not commercially introduced any products and does not expect to do so in the foreseeable future. If and when the Company s proposed products for which it has not entered into marketing relationships receive U.S. Food and Drug Administration (FDA) approval, the Company may begin to incur other expenses, including sales and marketing related expenses if it chooses to market the products itself. The Company currently does not have sufficient resources on a long-term basis to complete the FDA approval process or commercialization of any of its current or proposed products for which the Company has not entered into marketing relationships.

Although the Company believes that its cash, cash equivalents and short-term investments of $14.8 million at December 31, 2008 will be sufficient to meet its liquidity requirements through at least the next 12 months, if the Company does not raise additional financing or secure another funding source for our clinical trial program prior to the end of our second quarter 2009, the Company will need to delay or cease new enrollment in our Phase III clinical trial program of LibiGel, however, it is the Company s intention to continue the clinical program for those women already enrolled. The change in clinical trial enrollment may delay the eventual submission of the LibiGel NDA beyond the end of 2010 depending on how long the Company needs to continue this change.

Due to the current economic recession and market conditions, as well as the status of product development programs, there is uncertainty regarding whether additional financing will be available to the Company on favorable terms, or at all. If adequate funds are not available or are not available on acceptable terms when needed, the Company may be required to delay, scale back or eliminate some or all of its programs designed to obtain regulatory approval of its

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BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2008

proposed products, including most importantly, the Phase III clinical trial program for LibiGel. As an alternative to raising additional financing, the Company may choose to sublicense 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, sell certain assets or rights under the Company s existing license agreements or enter into other business collaborations or combinations, including the possible sale of the Company. The Company may be required to relinquish greater or all rights to its proposed products at an earlier stage of development or on less favorable terms than it otherwise would choose. Failure to obtain adequate financing also may adversely affect the Company s ability to operate as a going concern and cause the Company to significantly curtail or cease ongoing operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

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

Cash and Cash Equivalents

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

Short-term Investments

Short-term investments are classified as available for sale under the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Accordingly, the short-term investments are reported at fair value, with any related unrealized gains and losses included

as a separate component of stockholders equity, net of applicable taxes. Realized gains and losses and interest and dividends are included in interest income. Realized gains and losses are recorded based upon the specific identification method.

As of December 31, 2008 and December 31, 2007, the Company had $3.0 million and $15.0 million of short-term investments, respectively. The investment balance consisted of auction rate securities and related investments of $3.0 million and money market fund investments of approximately $26,000 as of December 31, 2008, and of auction rate securities investments of $14.5 million and money market fund investments of approximately $500,000 as of December

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BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2008

31, 2007. There were no gains or losses recorded in accumulated other comprehensive income as of December 31, 2008 or December 31, 2007, and there were no realized gains or losses included in earnings as the result of sale of available for sale securities for the years ended December 31, 2008, December 31, 2007 or December 31, 2006.

In April 2008, JPMorgan Chase Bank, NA commenced a tender offer to purchase certain outstanding student loan asset-backed auction rate notes. The Company owned $2.0 million in principal amount of such notes and tendered all of such notes to JPMorgan and received the entire $2.0 million principal plus accrued and unpaid interest in May 2008.

In October 2008, the Company received its entire investment of $9.0 million principal plus accrued and unpaid interest related to other student loan asset-backed auction rate notes from an affiliate of Bank of America Securities LLC (BofA) as a result of BofA and its affiliates reaching agreements with the Securities and Exchange Commission, the Secretary of the Commonwealth of Massachusetts and other regulators to restore liquidity to BofA clients who had previously held auction rate securities.

As of December 31, 2008, the Company s remaining auction rate securities with a $3.0 million par value were held in an account with UBS Financial Services, Inc. (UBS). In August 2008, UBS and its affiliates reached agreements with the SEC, the New York Attorney General, the Massachusetts Securities Division, the Texas State Securities Board and other state regulatory agencies represented by the North American Securities Administrators Association to restore liquidity to UBS clients who held auction rate securities. Pursuant to these agreements, in October 2008, the Company received rights from UBS entitling the Company to sell to UBS or its affiliates and requiring UBS or its affiliates to purchase the Company s $3.0 million in remaining auction rate securities for their face (or par) value plus any accrued and unpaid interest. On January 8, 2009, pursuant to those rights, the Company received $3.0 million principal plus accrued and unpaid interest from UBS.

Property and Equipment

Property and equipment that is currently being used in the Company s operations is stated at cost less accumulated depreciation and amortization. Depreciation is computed primarily by accelerated methods over estimated useful lives of seven years.

Long-Lived Assets

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

Research and Development

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

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BIOSANTE PHARMACEUTICALS, INC.
Notes to the Financial Statements
December 31, 2008

Legal Costs

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

Basic and Diluted Net (Loss) Income Per Share

The basic and diluted net (loss) income per share is computed based on the weighted average number of the aggregate of common stock and Class C shares outstanding, all being considered as equivalent of one another. Basic (loss) income per share is computed by dividing (loss) income available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted (loss) income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The computation of diluted (loss) income per share does not include the Company s stock options or warrants when there is an antidilutive effect on income (loss) per share. Certain options and warrants had a dilutive effect under the treasury stock method as the average market price of the common stock during the period exceeded the exercise price of the options or warrants. 292,965 shares were added to the basic weighted average number of shares outstanding to determine the fully diluted weighted average number of shares outstanding for the year ended December 31, 2006.

Stock-based Compensation

The Company adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payment (SFAS No. 123(R)) under the modified prospective method on January 1, 2006. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS No. 123(R) for all share-based payments granted after that date, and based on the requirements of Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Compensation (SFAS No. 123) for all unvested awards granted prior to the effective date of SFAS No. 123(R). SFAS No. 123(R) eliminates the intrinsic value measurement method of accounting in APB Opinion 25 and generally requires measuring the cost of the employee services received in exchange for an award of equity instruments based on the fair value of the award on the date of the grant. The standard requires grant date fair value to be estimated using either an option-pricing model which is consistent with the terms of the award or a market observed price, if such a price exists. Such costs must be recognized over the period during which an employee is required to provide service in exchange for the award.

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue. Warrants of this nature to purchase an aggregate of 80,000 and 180,000 shares of the Company s common stock were issued in 2008 and 2007, respectively.

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Revenue Recognition

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

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

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

Deferred revenue arises from payments received in advance of the culmination of the earnings process. Deferred revenue is recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

Income Taxes

Deferred tax assets or liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates. A valuation allowance is provided against net deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is more likely than not. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2008 and 2007.

Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurement (SFAS 157). The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements are separately disclosed by level within the fair value hierarchy. SFAS 157 was effective for the Company on January 1, 2008. In October 2008, the FASB issued Staff Position (FSP) No. FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not

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Active which clarifies the application of SFAS 157 in an inactive market and illustrates how an entity would determine fair value when the market for a financial asset is not active. The Staff Position is effective immediately and applies to prior periods for which financial statements have not been issued, including interim or annual periods ending on or before September 30, 2008. See Note 12, Fair Value Measurements, for disclosure of the Company s adoption of SFAS 157.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 permits an entity to elect fair value as the initial and subsequent measurement attribute for many financial assets and liabilities. Entities electing the fair value option are required to recognize changes in fair value in earnings. SFAS 159 also requires additional disclosures to compensate for the lack of comparability that will arise from the use of the fair value option. SFAS 159 was effective for the Company beginning on January 1, 2008. We did not elect the fair value option for any of the Company s existing financial assets and liabilities as of January 1, 2008, but did elect the fair value option during 2008 for the right to sell the auction rate securities to UBS at par. See Note 12, Fair Value Measurements, for additional information.

In December 2007, the FASB ratified Emerging Issues Task Force Issue (EITF) Issue No. 07-1, Accounting for Collaborative Arrangements (EITF 07-1). EITF 07-1 provides guidance on how to determine whether an arrangement constitutes a collaborative arrangements, how costs incurred and revenue generated on sales to third parties should be reported by participants in a collaborative arrangement, how payments made between participants in a collaborative arrangement should be categorized, and what participants should disclose in the notes to the financial statements about a collaborative arrangement. EITF 07-1 is effective for the fiscal year beginning January 1, 2009. EITF 07-1 requires that the impact of adopting the issue for all arrangements existing as of the effective date be presented as a change in accounting principle through retrospective application to all prior periods presented. The adoption of EITF 07-1 did not have an impact on the Company s results of operations or financial condition.

In June 2007, the FASB ratified EITF No. 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 requires non-refundable advance payments for goods and services to be used in future research and development (R&D) activities to be recorded as assets and the payments to be expensed when the R&D activities are performed. EITF 07-3 was effective for the Company prospectively for new contractual arrangements entered into beginning January 1, 2008. The adoption of EITF 07-3 did not have an impact on the Company s results of operations or financial condition.

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3. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which subsequently has been amended, pursuant to which the University has granted the Company an exclusive license to seven United States patents owned by the University, including rights to sublicense such patents. The University of California has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan. The Company is obligated to pay royalties to the University if and when a product is developed using these patents.

On June 13, 2000, the Company entered into a license agreement with Antares Pharma, Inc. (Antares), covering four hormone products to treat men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, the Company also is obligated to make milestone payments upon the occurrence of certain future events.

As allowed by the licensing agreement with Antares, on September 1, 2000, the Company entered into a sub-license agreement with Paladin Labs Inc. (Paladin) to market the products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in the Company, milestone payments and pay royalties on sales of the products in Canada. The milestone payments, to date, have been made in the form of a series of equity investments by Paladin in the Company s common stock at a 10 percent premium to the market price of the Company s common stock at the date of the equity investment.

On August 7, 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay sub-licensed the Company s estrogen/progestogen combination transdermal hormone gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. Solvay has been responsible for all costs of development of the product to date. The Company believes that the hormone therapy product licensed to Solvay is not in active development by Solvay and the Company does not expect its active development to occur at any time in the near future.

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

In May 2007, the Company announced that it sub-licensed U.S. rights to a triple hormone oral contraceptive to Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company. Pantarhei is responsible under the agreement for all expenses to develop and market

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

In December 2002, the Company entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., pursuant to which Teva USA agreed to develop the Company s male testosterone gel, 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 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. In 2005, the Company was notified that Teva USA had discontinued development of the product and indicated to the Company a desire to formally terminate the agreement. In June 2007, the Company signed an amendment to the agreement under which the Company and Teva reinitiated its collaboration on the development of the product. There were no changes to the master license agreement in force at that time. Teva withdrew its previous notice of its desire to terminate the agreement and reinitiated funding and development of the product. Teva also agreed to pay the Company certain milestone payments plus royalties on sales of the product, if and when commercialized. Teva is responsible under the revised agreement for continued development of the product, including required clinical trials, regulatory filings and all manufacturing and marketing associated with the product. The product is owned by the Company with no royalty or milestone obligations to any other party.

In September 2005, the Company signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use the Company s calcium phosphate nanotechnology (CaP) in the development of a series of allergy products. The partner company will fund the development of potential products for the treatment of conditions including rhinitis, asthma, conjunctivitis, dermatitis and allergic gastrointestinal diseases. Under the terms of the agreement, in September 2005, the Company received a nonrefundable $250,000 upfront payment. The Company recognized revenue from the agreement on a pro rata basis over the term of the agreement as the Company had not yet completed all of its required performance under the terms of the agreement. The remainder of the upfront payment was recorded as deferred revenue. The initial term of the agreement was 22 months, ending in June 2007. In April 2007, the term was extended through March 31, 2008. In February 2008, the term was extended to July 2008. In July 2008, the term was extended to January 2009. This program is no longer under active development by the optionee.

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In November 2006, the Company entered into an exclusive sublicense agreement for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of $3.5 million. In addition, during 2007, Nycomed paid the Company $10.5 million triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter of 2006. Under the Company s license agreement with Antares, the Company is required to pay Antares certain development and regulatory milestone payments and royalties based on net sales of any products the Company or its sub-licensees sell incorporating the licensed technology. Specifically, the Company paid Antares 25 percent of all licensing-related proceeds and a portion of any associated royalties that the Company received, which the Company recognized as these payments were earned, based upon reported levels of Elestrin sales. The aggregate $14.0 million received from Nycomed was recognized as revenue in 2006 since the entire $14.0 million was non-refundable, the Company had a contractual right to receive such payments, the contract price was fixed, the collection of the resulting receivable was reasonably assured and the Company had no further performance obligations under the license agreement.

On August 6, 2008, the Company and Nycomed entered into a termination, release and settlement agreement pursuant to which the exclusive sublicense agreement dated November 7, 2006 between the Company and Nycomed was terminated and BioSante reacquired the rights to Elestrin effective immediately. As a result, the Company paid Nycomed $100,000 and an additional $150,000 as a result of the December 2008 Elestrin sublicense to Azur Pharma International II Limited (Azur) as described below. Nycomed has agreed on behalf of itself and its affiliates not to market or sell any low-dose topical estrogen gel products for the treatment of menopausal hot flashes for a period of 12 months. The agreement also provides for a mutual release between the parties and the survival of the confidentiality, indemnification and insurance provisions of the exclusive sublicense agreement for a period of five years.

In December 2008, the Company signed an exclusive agreement with Azur for the marketing of Elestrin in the United States. Upon execution of the agreement, BioSante received $3.325 million comprised of a $500,000 product licensing fee and $2.825 million for transfer of the Elestrin trademark and inventories, among other items. The Company paid Antares $462,500 as a result of signing the Azur agreement. The Company also is entitled to receive additional payments of up to an aggregate of $144.5 million if certain sales-based milestones are achieved. In addition, Azur has agreed to pay to BioSante royalties on sales of Elestrin ranging from 10 percent to 20 percent depending on the annual sales level. Azur has agreed to market Elestrin using its women s health and urology sales force of approximately 50 sales people that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement.

In December 2008, the Company signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. PharmaSwiss will submit BioSante s approved U.S. NDA (new drug application) to the Israeli authorities based on BioSante results and manufacturing information. Approval in Israel is expected to take approximately one year from the date of such submission.

In February 2006, the Company signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation (MATC) for the use of the Company s CaP technology in the field of aesthetic medicine. Under the terms of the option and license agreement, MATC will

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use the Company s CaP technology to develop products for commercialization in the field of aesthetic medicine, specifically, the improvement and/or maintenance of the external appearance of the head, face, neck and body. In November 2007, the Company signed a license agreement with MATC covering the use of CaP as a facial filler (BioLook) in aesthetic medicine. This license agreement is a result of MATC s exercise of the previously granted option under the original license agreement. Under the 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 this license, the Company has taken an ownership position in MATC of approximately five percent of the common shares of MATC. In addition to the ownership position, the Company may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology. The Company recorded an investment asset and licensing revenue of $140,000 in 2007 related to this license and ownership position in MATC. The MATC investment is recorded using the cost method.

4. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2008 and 2007 consist of the following:

	2008	2007
Computer equipment	**$ 375,311**	$ 129,753
Office equipment	**131,239**	126,044
Laboratory and equipment	**518,034**	36,019
	1,024,584	291,816
Accumulated depreciation and amortization	**(209,690)**	(236,920)
	$ 814,894	$ 54,896

As of December 31, 2008, $243,556 of computer equipment and $486,084 of laboratory and equipment is related to construction in progress that has not been placed into service. During 2007, the Company recognized a loss on the disposal of equipment of $21,748 as result of the closure of its Smyrna, Georgia laboratory facility.

5. INCOME TAXES

The Company adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 , or FIN 48, on January 1, 2007. FIN 48 requires companies to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions. The adoption of FIN 48 did not have an impact on the Company s financial position upon adoption. The Company determined there are no uncertain tax positions existing as of December 31, 2008 or December 31, 2007.

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The Company has analyzed its filing positions in all significant federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The only periods subject to examination by the major tax jurisdictions where the Company does business are the 2005 through 2008 tax years.

The components of the Company s net deferred tax asset at December 31, 2008 and 2007 were as follows:

	2008	2007
Net operating loss carryforwards	**$ 23,609,594**	$ 17,588,392
Tax basis in intangible assets	**403,498**	538,819
Research & development credits	**3,415,143**	2,569,848
Stock option expense	**1,462,065**	1,017,790
Other	**56,063**	103,235
	28,946,363	21,818,084
Valuation allowance	**(28,946,363)**	(21,818,084)
	$	$

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2008, the Company had approximately $62,542,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2018-2028. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, generate deferred tax benefits, which have been recorded as deferred tax assets and are entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, the amount management believes is more likely than not to be realized. Additionally, the Company has provided a full valuation allowance against $3,415,143 of research and development credits, which are available to reduce future income taxes, if any, through the year 2028.

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

	2008	2007	2006
Tax at U.S. federal statutory rate	**$ (6,030,952)**	$ (2,616,630)	$ 962,989
State taxes, net of federal benefit	**(568,133)**	(246,494)	90,716
Research and development credits	**(526,196)**	(162,675)	(135,632)
Other, net	**(2,998)**	(132,577)	32,522
Change in valuation allowance	**7,128,279**	3,158,376	(950,595)
	$	$	$

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6. STOCKHOLDERS EQUITY

In December 2008, the Company entered into a Committed Equity Financing Facility arrangement, or CEFF, with Kingsbridge Capital Limited (Kingsbridge) in which Kingsbridge has committed to purchase, subject to certain conditions and at the Company s sole discretion, up to the lesser of $25.0 million or 5,405,840 shares of the Company s common stock through the end of December 2010. Under the terms of the CEFF, the Company is not obligated to utilize any of the $25.0 million available under the CEFF and there are no minimum commitments or minimum use penalties. The Company has access, at its discretion, to the funds through the sale of newly-issued shares of the Company s common stock. The funds that can be raised under the CEFF over the two-year term will depend on the then-current price for the Company s common stock and the number of shares actually sold, which may not exceed an aggregate of 5,405,840 shares. The Company may access capital under the CEFF by providing Kingsbridge with common stock at discounts ranging from eight to 14 percent, depending on the average market price of the Company s common stock during the applicable pricing period. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, including a minimum price for the Company s common stock of $1.15 per share. In connection with the CEFF, the Company issued a warrant to Kingsbridge to purchase 300,000 shares of the Company s common stock at an exercise price of $4.00. The warrant will become exercisable on June 15, 2009, the six-month anniversary of the date of the Purchase Agreement (December 15, 2008), and will remain exercisable, subject to certain exceptions, for a period of five years thereafter. Pursuant to the CEFF, the Company filed a registration statement with respect to the resale of shares issued pursuant to the CEFF and underlying the warrant. As of December 31, 2008, the Company had not sold any shares to Kingsbridge under the CEFF.

On June 13, 2007, the Company closed a private placement of 3,054,999 shares of its common stock and associated warrants to purchase 763,750 shares of its common stock, at a purchase price of $6.00 per share to certain institutional and other accredited investors for gross proceeds of approximately $18.3 million. The private placement resulted in net proceeds to the Company of approximately $17.3 million, after deduction of transaction expenses. The warrants are exercisable for a period of three years, beginning December 14, 2007, at an exercise price of $8.00 per share. The number of shares issuable upon exercise of the warrants and the exercise price of the warrants are adjustable in the event of stock splits, combinations and reclassifications, but not in the event of the issuance of additional securities.

a) *Authorized*

Preference shares

Ten million preference shares, $0.0001 par value per share, issuable in series subject to limitation, rights and privileges as determined by the directors. No preference shares have been issued as of December 31, 2008.

Special Shares

4,687,684 Class C special shares, $0.0001 par value per share, convertible to common stock, to be held a minimum of one year from date issue, on the basis of one Class C special share and U.S. $2.50. These shares are not entitled to a dividend and carry one vote per share. There were 391,286 shares of Class C special shares issued and outstanding as of December 31, 2008 and 2007.

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Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share. There were 27,042,764 and 26,794,607 shares of common stock issued and outstanding as of December 31, 2008 and 2007, respectively. The Company has presented the par values of its common stock and the related additional paid in capital on a combined basis for all periods presented.

b) *Warrants*

In summary, the Company currently has the following warrants outstanding:

Amount	Exercise Price		Expiration
534,996	$	7.00	August 10, 2009
853,292	$	2.75	October 21, 2011
763,750	$	8.00	December 14, 2010
180,000	$	8.00	July 18, 2010
80,000	$	4.78	May 14, 2011
300,000	$	4.00	June 14, 2013

Pursuant to the Company s private placement financing in May 2004, warrants to purchase an aggregate of 534,996 shares of common stock were issued at an exercise price of $7.00 per share with a term of five years. These warrants remained outstanding and were all exercisable as of December 31, 2008.

Pursuant to the Company s private placement financing in July 2006, warrants to purchase an aggregate of 1,334,542 shares of common stock were issued at an exercise price of $2.75 per share with a term of four years and nine months, beginning January 22, 2007. Warrants to purchase an aggregate of 853,292 shares of common stock remained outstanding as of December 31, 2008.

In July 2007, the Company issued warrants to purchase 180,000 shares of common stock to an investor relations firm in return for various investor relations services. The warrants are exercisable at an exercise price equal to $8.00 per share with 50 percent of the warrants becoming exercisable on July 19, 2008 and the remainder becoming exercisable on July 19, 2009. The warrants are exercisable through and including July 18, 2010. The Company uses the Black-Sholes pricing model to value these warrants and remeasures the award each quarter until the measurement date is established. In the year ended December 31, 2008 and 2007, the Company recorded $43,988 and $32,906, respectively, in non-cash general and administrative expense pertaining to these consultant warrants.

In May 2008, the Company issued warrants to purchase an aggregate of 80,000 shares of common stock to two individuals, the sole principal and a key executive officer, of an investor and public relations firm in return for various investor and public relations services. These warrants are exercisable at an exercise price equal to $4.78 per share with 1/12 of the warrants becoming exercisable on June 15, 2008 and the remainder becoming exercisable on a monthly basis thereafter through May 15, 2009 so long as the

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investor and public relations firm continues to provide services to the Company. The warrants are exercisable through and including May 14, 2011. The Company uses the Black-Scholes pricing model to value this warrant consideration and remeasures the award each quarter until the measurement date is established. In the year ended December 31, 2008, the Company recorded $60,296 in non-cash general and administrative expense pertaining to these warrants.

During 2008, warrants to purchase an aggregate of 176,614 shares of common stock were exercised for total cash proceeds of $379,720. Warrants to purchase an aggregate of 71,543 shares of common stock were exercised on a cashless basis, for which 74,957 additional warrants were cancelled by the Company in payment of the exercise price for the exercised warrants. Warrants to purchase an aggregate of 500 shares of common stock expired without being exercised. All of the exercised warrants were granted pursuant to the Company s private placement financing in August 2003.

During 2007, warrants to purchase 371,500 shares of common stock were exercised for total cash proceeds of $1,019,225. Warrants to purchase an aggregate of 339,987 shares of common stock also were exercised on a cashless basis, for which 163,321 additional warrants were cancelled by the Company in payment of the exercise price for the exercised warrants, thus reducing the number of shares outstanding on a fully diluted basis.

During 2006, there were no warrants exercised, and warrants to purchase 367,187 shares of common stock were cancelled upon their expiration.

c) Options

During 2008, no options were exercised.

During 2007, options to purchase an aggregate of 49,201 shares of common stock were exercised for total cash proceeds of $192,371. In addition, options to purchase an aggregate of 11,333 shares of common stock were exercised on a cashless basis resulting in the issuance of 3,880 shares of common and the withholding and subsequent cancellation of 7,453 shares of common stock to pay the exercise price of such options, thus reducing the number of shares outstanding on a fully diluted basis.

7. STOCK-BASED COMPENSATION

As of December 31, 2008, the Company has two stockholder-approved equity-based compensation plans under which stock options have been granted the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (1998 Plan) and the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (2008 Plan) (collectively, the Plans). The 2008 Plan replaced the 1998 Plan, which was terminated with respect to future grants upon the effectiveness of the 2008 Plan. As of December 31, 2008, there were 2,000,000 shares of the Company s common stock authorized for issuance under the 2008 Plan, subject to adjustment as provided in the 2008 Plan. Of the 2,000,000 authorized shares, none had been issued and 53,000 shares were subject to outstanding stock options as of December 31, 2008. Outstanding employee stock options generally vest over a period of three years and have 10-year contractual

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terms. Certain of the Company s employee stock options have performance condition-based vesting provisions which result in expense when such performance conditions are probable of being achieved. The non-cash, stock-based compensation cost that was incurred by the Company in connection with the 1998 and 2008 Plans was $1,102,444, $711,259 and $1,076,832 for the years ended December 31, 2008, 2007 and 2006, respectively. No income tax benefit was recognized in the Company s statements of operations for stock-based compensation arrangements due to the Company s net loss position.

The weighted average fair value of the options at the date of grant for options granted during 2008, 2007 and 2006 was $2.41, $2.37 and $3.11, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2008	2007	2006
Expected option life (years)	**6.00**	9.83	10
Risk free interest rate	**3.45** %	4.74 %	4.10 %
Expected stock price volatility	**67.63** %	69.31 %	73.94 %
Dividend yield			

The Company uses a volatility rate calculation based on the closing price for its common stock at the end of each calendar month as reported by the NASDAQ Global Market (or The American Stock Exchange prior to November 5, 2007). Since the Company has a limited history with option exercises, the expected life was set to the entire life of the option grant through the fourth quarter 2007. Beginning with options granted during the fourth quarter 2007, the Company began estimating the expected life of its options in a manner consistent with Staff Accounting Bulletin

(SAB) 107, and SAB 110 beginning January 1, 2008, which allows companies to use a simplified method to estimate the life of options meeting certain criteria. The Company believes that the use of the simplified method provides a reasonable term for purposes of determining compensation costs for these grants, and expects to use the simplified method to estimate the expected life of future options for eligible grants. The discount rate used is the yield on a United States Treasury note as of the grant date with a maturity equal to the estimated life of the option. The Company has not in the past issued a cash dividend, nor does it have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

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

	2008	2007	2006

Research and development	**$ 356,287**	$ 202,335	$ 52,630
General and administrative	**746,157**	508,924	1,024,202
Total stock-based compensation expense	**$ 1,102,444**	$ 711,259	$ 1,076,832

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BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2008

A summary of activity under the Plans during the year ended December 31, 2008 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2007	1,427,191	$ 3.50
Granted	682,250	3.74
Exercised	(0)	
Forfeited or expired	(71,250)	2.73
Outstanding December 31, 2008	2,038,191	$ 3.66
(weighted average contractual term)	*8.0 years*	
Vested or expected to vest at December 31, 2008	1,921,525	$ 3.56
(weighted average contractual term)	*7.1 years*	
Exercisable at December 31, 2008	1,033,026	$ 3.48
(weighted average contractual term)	*5.8 years*	

There was no aggregate intrinsic value of the Company s outstanding or exercisable options as of December 31, 2008.

A summary of the Plans non-vested options at December 31, 2008 and activity under the Plans during the year ended December 31, 2008 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2007	656,333	$ 3.62
Granted	682,250	3.74
Vested	(252,168)	3.67
Forfeited	(71,250)	2.73
Non-Vested at December 31, 2008	1,015,165	$ 3.74

As of December 31, 2008, there was $1,409,577 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plans. The cost is expected to be recognized over a weighted-average period of 1.80 years.

No stock options were exercised during 2008. Cash received from option exercises under the Plans for the years ended December 31, 2007 and 2006 was $192,371 and $243,675, respectively. The intrinsic value of options exercised during the years ended December 31, 2007 and 2006 was $136,020 and $218,613, respectively. The Company did not receive a tax benefit related to the exercise of these options because of its net operating loss position. The total fair value of shares vested during the years ended December 31, 2008, 2007 and 2006 was $659,898, $326,254 and $1,076,832, respectively.

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Notes to the Financial Statements

December 31, 2008

Options and warrants to purchase an aggregate of 4,750,229 and 4,082,843 shares, respectively, were excluded from the earnings per share calculation for the years ended December 31, 2008 and December 31, 2007, respectively, since including these options and warrants would have had an anti-dilutive effect under the treasury stock method due to the Company s net loss position. Options and warrants to purchase an aggregate of 1,261,475 shares were excluded from the earnings per share calculation for the year ended December 31, 2006, since including these options and warrants would have had an anti-dilutive effect under the treasury stock method, as the average market price of the common stock during the period was less than the exercise price of the options or warrants.

8. RETIREMENT PLAN

The Company offers a discretionary 401(k) Plan (the 401(k) Plan) to all of its employees. Under the 401(k) Plan, employees may defer income on a tax-exempt basis, subject to IRS limitation. Under the 401(k) Plan, the Company can make discretionary matching contributions. Company contributions expensed in 2008, 2007 and 2006 totaled $108,019, $59,683 and $45,327, respectively.

9. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space which expires in 2010 and its laboratory facility which expires in 2009. The future minimum lease payments during 2009 and 2010 are $293,478 and $90,720, respectively.

Rent expense amounted to $277,370, $259,971 and $236,824 for the years ended December 31, 2008, 2007 and 2006, respectively.

10. RELATED PARTY TRANSACTIONS

Included in current liabilities on the balance sheet are $15,638 and $28,841, which represent amounts due to current directors and officers of the Company for reimbursement of business expenses and payment for director meeting fees as of December 31, 2008 and 2007, respectively.

11. COMMITMENTS

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. requires the Company to fund the development of the licensed products, make milestone payments and pay royalties on the sales of products related to this license. In 2006, the Company paid $875,000 to Antares and recorded a liability of $2.625 million due to Antares to be paid upon the Company s receipt of payments from Nycomed related to the Elestrin FDA approval milestone. In 2007, the Company paid $2.625 million to Antares thereby reducing the liability to zero and paid or accrued $31,209 to Antares as a result of royalties received by the Company. In 2008, the Company paid $462,500 to Antares as a result of the Azur sublicense of Elestrin and paid or accrued $21,830 to Antares as a result of royalties received by the Company.

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BIOSANTE PHARMACEUTICALS, INC.

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December 31, 2008

Wake Forest License

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

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

Year	Minimum Amount Due
2009	60,000
2010	70,000
2011	80,000
2012	80,000
2013	80,000
2014	80,000
2015	80,000
Thereafter	120,000

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

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

Aesthetic License

In February 2006, the Company signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation for the use of the Company s CaP technology in the field of aesthetic medicine. Under the terms of the option and license agreement, MATC will use the Company s CaP technology to develop products for commercialization in the field of aesthetic medicine, specifically, the improvement and/or maintenance of the external appearance of the head, face, neck and body. In November 2007, the Company exercised its options under the license and signed a license agreement with MATC covering the use of the Company s CaP as a facial filler (BioLook) in aesthetic medicine. Under the 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, the Company has taken an ownership position in MATC of about five percent of the common shares

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BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2008

of MATC. In addition to the ownership position, the Company may receive certain milestone payments and royalties as well as share in certain payments if MATC sublicenses the technology. The Company recorded an investment asset and licensing revenue of $140,000 related to this license and ownership position in MATC. The MATC investment is recorded using the cost-method.

12. FAIR VALUE MEASUREMENTS

The Company has adopted the fair value methods required under SFAS No. 157 to value its financial assets and liabilities. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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

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

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

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

Financial assets recorded at fair value as of December 31, 2008 are classified in the table below in one of the three categories described above:

Description	December 31, 2008 Balance	Quoted Prices in Active	Significant Other	Significant Unobservable Inputs

			Markets for Identical Assets (Level 1)	Observable Inputs (Level 2)	(Level 3)
Available for Sale Securities	$	2,534,820			$ 2,534,820
Put Asset on Available for Sale Securities		465,180			465,180
Total	$	3,000,000			$ 3,000,000

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BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2008

The Company s auction rate securities investments and related put asset were classified as based on Level 3 inputs, due to the lack of currently observable market quotes, generally those obtained or corroborated through the auction process. The Company determines the fair value using unobservable inputs based on expected cash flows and collateral values, including assessments of counterparty credit quality, default risk underlying the security, overall capital market liquidity, and expectations of early redemption of the securities. Factors that may impact the Company s valuation include changes to credit ratings of the securities as well as to the underlying assets supporting those securities, rates of default of the underlying assets, underlying collateral value, counterparty risk and ongoing strength and quality of market credit and liquidity.

At January 1, 2008, the value of the Company s auction rate securities were based on observable prices in active markets and as such would have been considered based on Level 1 inputs. At December 31, 2008, due to the failure of auctions during 2008, the Company s remaining auction rate securities were valued based on Level 3 inputs. As a result of these declines in fair value of the Company s auction rate securities, which the Company attributed to liquidity issues affecting the credit markets associated with the securities rather than counterparty credit issues, the Company recorded an other-than-temporary impairment loss of $465,180 on its remaining auction rate securities investment, which was offset by a $465,180 gain on the right to sell the auction rate securities back to UBS at par value, both of which are recorded in other income.

The Company made an election to record the asset related to its right to sell its remaining auction rate securities to UBS at fair value with gains and losses related to this instrument recorded in earning immediately pursuant to SFAS 159, Fair Value Option, so the right to sell the auction rate securities back to UBS would offset the change in value of the underlying auction rate securities investments during the period. As a result, a gain of $232,480 related to the change in value of the put/right from October 14, 2008 (the date that the company entered into the settlement agreement) to December 31, 2008 has been recorded in other income. If the company had not elected to record this instrument at fair value, its carrying value would have been $232,700 at December 31, 2008.

The table below presents a reconciliation of the level 3 fair value measurements, which are based on significant unobservable inputs, at December 31, 2008. Both of the assets are recorded in investments. The remaining investment balance of $26,334 is invested in a money market fund.

	Fair Value Measurements Using Significant Unobservable Inputs	Fair Value Measurements Using Significant Unobservable Inputs
	Auction Rate Securities	Put Asset Related to Auction Rate Securities
January 1, 2008	$	$
Transfers into Level 3	14,000,000	232,700
Purchases, redemptions, issuances or settlements	(11,000,000)	
Total gains or losses (realized/unrealized) included in net loss	(465,180)	232,480
December 31, 2008	$ 2,534,820	$ 465,180

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BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2008

On January 8, 2009, pursuant to its rights to sell the auction rate securities to UBS at par value, the Company received $3.0 million principal plus accrued and unpaid interest from UBS. No realized gains or losses were included in the Company s statement of operations for the year ended December 31, 2008.

13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2008 and 2007 is as follows:

	2008			
	First	**Second**	**Third**	**Fourth**
Revenue	$ 62,997	$ 25,869	$ 82,212	$ 3,609,751
Research and development expenses	2,677,946	3,934,118	5,322,472	3,855,444
General and administrative expenses	1,325,493	1,593,156	1,438,816	767,469
Licensing expense				836,420
Operating loss	(3,950,215)	(5,513,714)	(6,690,835)	(1,858,878)
Net loss	(3,626,638)	(6,048,067)	(6,585,084)	(1,165,389)
Loss per share:				
Basic and diluted	$ (0.13)	$ (0.22)	$ (0.24)	$ (0.05)

	2007			
	First	**Second**	**Third**	**Fourth**
Revenue	$ 50,608	$ 69,446	$ 43,793	$ 329,307
Research and development expenses	987,470	1,405,647	1,145,764	1,212,432
General and administrative expenses	918,769	1,265,796	1,027,194	1,119,602
Licensing expense				
Operating loss	(1,888,547)	(2,630,797)	(2,147,158)	(2,012,942)
Net loss	(1,817,018)	(2,400,309)	(1,693,044)	(1,674,064)
Loss per share:				
Basic and diluted	$ (0.08)	$ (0.10)	$ (0.06)	$ (0.06)

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Management s Report on Internal Control Over Financial Reporting

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

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

Change in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. **OTHER INFORMATION**

Not applicable.

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PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors

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

Executive Officers

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

Code of Conduct and Ethics

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

Changes to Nomination Procedures

During the fourth quarter of 2008, we made no material changes to the procedures by which stockholders may recommend nominees to the Board of Directors, as described in our most recent proxy statement.

Audit Committee Matters

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

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Item 11. EXECUTIVE COMPENSATION

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

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

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes outstanding stock options under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan and the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of December 31, 2008. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan are within the discretion of the Compensation Committee of our Board of Directors and our Board of Directors therefore cannot be ascertained at this time.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	2,038,191(1)	$ 3.61	1,947,000(2)
Equity compensation plans not approved by security holders	0	N/A	0
Total	2,038,191	$ 3.61	1,947,000

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

(2) As of December 31, 2008, these shares remain available for future issuance under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. No shares remain available for grant under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan since such plan expired with respect to future grants in 2008.

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

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

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

The exhibits to this report are listed on the Exhibit Index on pages 93-99. A copy of any of the exhibits listed will be furnished at a reasonable cost, upon receipt from any person of a written request for any such exhibit. Such request should be sent to BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069, Attn: Stockholder Information.

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

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

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

C. BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 contained in BioSante s 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)).

D. Form of Incentive Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 contained in BioSante s 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)).

E. Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 contained in BioSante s 8-K as filed with the Securities and Exchange Commission on June 13, 2008 (File No. 001-31812)).

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

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

H. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated

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1998 Stock Plan (incorporated by reference to Exhibit 10.5 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 000-28637)).

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

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

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

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

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SIGNATURES

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

Dated: March 16, 2009

BIOSANTE PHARMACEUTICALS, INC.

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

By /s/ PHILLIP B. DONENBERG
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

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

Name and Signature	Title	Date
/S/ STEPHEN M. SIMES	Vice Chairman, President and	March 16, 2009
Stephen M. Simes	Chief Executive Officer	
/S/ LOUIS W. SULLIVAN, M.D.	Chairman of the Board	March 12, 2009
Louis W. Sullivan, M.D.		
/S/ FRED HOLUBOW	Director	March 13, 2009
Fred Holubow		
/S/ PETER KJAER	Director	March 16, 2009
Peter Kjaer		
/S/ ROSS MANGANO	Director	March 16, 2009
Ross Mangano		
/S/ EDWARD C. ROSENOW, III	Director	March 13, 2009
Edward C. Rosenow, III		

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BIOSANTE PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2008

Exhibit No.	Exhibit	Method of Filing
3.1	Amended and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 contained in BioSante s Registration Statement on Form SB-2, as amended, (Reg. No. 333-64218)
3.2	Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.2 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218)
4.1	Form of Warrant issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the May 2004 Subscription Agreements and the placement agents	Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 14, 2004 (File No. 001-31812)
4.2	Form of Warrant dated as of July 21, 2006 issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the Subscription Agreements dated July 7, 2006	Incorporated by reference to Exhibit 10.2 contained in BioSante s Form 8-K as filed with the Securities and Exchange Commission on July 24, 2006 (File No. 001-31812)
4.3	Form of Warrant dated as of June 13, 2007 issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the Subscription Agreements dated May 25, 2007	Incorporated by reference to Exhibit 10.2 contained in BioSante s Form 8-K as filed with the Securities and Exchange Commission on June 14, 2007 (File No. 001-31812)
4.4	Warrant dated December 15, 2008 issued by BioSante Pharmaceuticals, Inc. to Kingsbridge Capital Limited	Incorporated by reference to Exhibit 4.1 contained in BioSante s Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.1	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)

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Exhibit No.	Exhibit	Method of Filing
10.2	Amended and Restated Employment Letter Agreement dated July 16, 2008 between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the SEC on July 18, 2008 (File No. 001-31812)
10.3	BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.4	Form of Incentive Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.2 to BioSante s Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.5	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Executive Officers Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.3 to BioSante s Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.6	Form of Non-Statutory Stock Option Agreement between BioSante Pharmaceuticals, Inc. and its Directors Under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan	Incorporated by reference to Exhibit 10.4 to BioSante s Current Report on Form 8-K as filed with the SEC on June 13, 2008 (File No. 001-31812)
10.7	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 contained in BioSante s 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.8	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.5 contained in BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.9	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s Executive Officers Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.30 contained in BioSante s 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)

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Exhibit No.	Exhibit	Method of Filing
10.10	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s DirectorsUnder the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.31 contained in BioSante s 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.11	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its Directors and Executive Officers	Incorporated by reference to Exhibit 10.30 contained in BioSante s 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
10.12	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.13	Office Lease, dated December 19, 2003, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.29 contained in BioSante s 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.14	First Amendment to Lease, dated February 26, 2004, between BioSante and LaSalle National Bank Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to exhibit 10.1 contained in BioSante s 10-QSB for the fiscal quarter ended March 31, 2004 (File No. 001-31812)
10.15	Second Amendment to Lease dated as of January 4, 2005, by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 6, 2005 (File No. 001-31812)
10.16	Third Amendment to Lease dated as of January 27, 2006 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 27, 2006 (File No. 001-31812)

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Exhibit No.		Exhibit		Method of Filing
10.17		Fourth Amendment to Lease dated as of March 7, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago		Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 7, 2007 (File No. 001-31812)
10.18		Fifth Amendment to Lease dated as of November 2, 2007 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago.		Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 6, 2007 (File No. 001-31812)
10.19		Sixth Amendment to Lease dated as of April 18, 2008 by and between BioSante Pharmaceuticals, Inc. and LaSalle Bank National Association, as successor trustee to American National Bank and Trust Company of Chicago		Incorporated by reference to Exhibit 10.1 to BioSante s Current Report on Form 8-K as filed with the SEC on April 21, 2008 (File No. 001-31812)
10.20		License Agreement, dated June 18, 1997, between BioSante Pharmaceuticals, Inc. and The Regents of the University of California (1)		Incorporated by reference to Exhibit 10.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.21		Amendment to License Agreement, dated October 26, 1999, between BioSante Pharmaceuticals, Inc. and the Regents of the University of California (1)		Incorporated by reference to Exhibit 10.2 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.22		Amendment No. 2 to the License Agreement, dated May 7, 2001, between BioSante Pharmaceuticals, Inc. and The Regents of the University of California (1)		Incorporated by reference to Exhibit 10.23 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.23		Third Amendment to the License Agreement dated June 30, 2004, between BioSante and The Regents of the University of California (1)		Incorporated by reference to exhibit 10.3 contained in BioSante s 10-QSB for the fiscal quarter ended June 30, 2004 (File No. 001-31812)

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Exhibit No.		Exhibit		Method of Filing
10.24		Fourth Amendment to Exclusive License Agreement for Selected Applications of Coated Nanocrystalline Particles between The Regents of the University of California and BioSante Pharmaceuticals, Inc. dated as of August 11, 2006 (1)		Incorporated by reference to exhibit 10.1 contained in BioSante s 10-Q for the fiscal quarter ended September 30, 2006 (File No. 001-31812)
10.25		License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma, Inc.) and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.1 contained in BioSante s Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 11, 2000 (File No. 0-28637)
10.26		Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.18 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.27		Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.28		Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.20 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.29		Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.20 to BioSante s Registration Statement on Form SB-2, as amended (File No. 333-87542)
10.30		Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.25 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 0-28637)
10.31		Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.27 contained in BioSante s 10-K for the fiscal year ended December 31, 2006 (File No. 001-31812)

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Exhibit No.		Exhibit		Method of Filing
10.32		Exclusive Sublicense Agreement dated as of November 7, 2006 between BioSante and Bradley Pharmaceuticals, Inc. (1)		Incorporated by reference to Exhibit 10.28 contained in BioSante s 10-K for the fiscal year ended December 31, 2006 (File No. 001-31812)
10.33		Termination, Release and Settlement Agreement dated as of August 6, 2008 between BioSante Pharmaceuticals, Inc. and Nycomed US Inc. (1)		Incorporated by reference to Exhibit 10.6 to BioSante s Quarterly Report on Form 10-Q as filed with the SEC on August 11, 2008 (File No. 001-31812)
10.34		Form of Subscription Agreement dated as of July 7, 2006 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement		Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 10, 2006 (File No. 001-31812)
10.35		Form of Subscription Agreement dated as of May 25, 2007 by and between BioSante Pharmaceuticals, Inc. and each of the subscribers party to the Subscription Agreement		Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 25, 2007 (File No. 001-31812)
10.36		Common Stock Purchase Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited		Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
10.37		Registration Rights Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited		Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 18, 2008 (File No. 001-31812)
14.1		Code of Conduct and Ethics		Incorporated by reference to Exhibit 14.1 contained in BioSante s 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
23.1		Consent of Deloitte & Touche LLP		Filed herewith

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Exhibit No.		Exhibit		Method of Filing
31.1		Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14		Furnished herewith
31.2		Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14		Furnished herewith
32.1		Certification of Chief Executive Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		Filed herewith
32.2		Certification of Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		Filed herewith

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