BioSante Pharmaceuticals

Improving **health** *for* **life**

2007

ANNUAL REPORT
FORM 10-K

BioSante Pharmaceuticals Key Achievements 2007-08

Near-Term Product Achievements

We received notice of allowance in the United States of a patent covering the formulation used in Elestrin™, our FDA approved estradiol gel, and LibiGel®, our testosterone gel, in Phase III clinical development. The patent issued in April 2007.

We signed an amendment to our development and license agreement with a subsidiary of Teva Pharmaceutical Industries Ltd. under which Teva reinitiated the development of Bio-T-Gel™, our male testosterone therapy product, for the U.S. market.

Elestrin (estradiol gel) was launched commercially. Elestrin is our ultra-low dose transdermal estrogen therapy approved by the FDA in December 2006 for the treatment of hot flashes in menopausal women. Currently, Elestrin is marketed by our marketing licensee Nycomed.

We along with Pantarhei Bioscience B.V., a Netherlands-based pharmaceutical company, initiated a Phase II human clinical trial of a new oral contraceptive using our patented "triple-therapy" contraceptive technology, The Pill-Plus™.

We received clarity from and announced we are in agreement with the FDA on key safety requirements for the development and approval of LibiGel in the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD).

We initiated our Phase III cardiovascular events safety study of LibiGel to evaluate the cardiovascular risk of treating women with testosterone. The Phase III study seeks to show the relative safety of using low-dose testosterone versus placebo in the treatment of FSD in menopausal women.

We reached agreement with the FDA under the SPA process for our Phase III safety and efficacy clinical trials for LibiGel. The SPA agreement with the FDA confirms the FDA's position that FSD is a true diagnosable condition that women experience; that there are clinical endpoints that can be studied, measured and evaluated; and that FSD is a condition which deserves therapeutic options for treatment, and affirms that the FDA agrees that the LibiGel Phase III clinical trials' design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval.

CaP Nanotechnology Achievements

We achieved positive results of a dose ranging pre-clinical study demonstrating that our calcium phosphate (CaP) nanoparticle-based vaccine adjuvant, BioVant™, may serve as a vaccine adjuvant for the development of an effective vaccine against H5N1 avian flu, widely known as bird flu.

We signed a license agreement covering the use of CaP as a facial filler (BioLook™) in aesthetic medicine, with Medical Aesthetics Technology Corporation (MATC) with whom we have been working in the field of aesthetic medicine, and received an equity stake in MATC.

Financial Highlights

We received $10.5 million in milestone payments from Nycomed under the terms of our Elestrin™ licensing agreement.

We completed an $18.3 million private placement of our common stock and warrants to institutional and other accredited investors. A total of 3,054,999 shares of common stock were sold at a purchase price of $6.00 per share. Investors also received warrants to purchase 763,750 shares of common stock at an exercise price of $8.00 per share.

Our common stock began trading on NASDAQ under the symbol BPAX. We were formerly listed on The American Stock Exchange.

BioSante Pharmaceuticals

111 Barclay Boulevard
Lincolnshire, Illinois 60069
Tel: (847) 478-0500

Stephen M. Simes
President and CEO

To our stockholders:

For BioSante, the past year has been gratifying and exciting. I am pleased to review our accomplishments in 2007 and early 2008 because they provide many reasons for our optimism about 2008 and beyond.

LibiGel®, our transdermal testosterone gel for the treatment of female sexual dysfunction (FSD), has made significant clinical and regulatory progress. Building on the remarkable results attained in our Phase II clinical trial, we reached agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) and subsequently initiated all three of our Phase III trials. In addition to establishing the parameters of the clinical trial design and affirming that these measures will serve as the basis for regulatory approval, this SPA effectively establishes that FSD, specifically hypoactive sexual desire disorder (HSDD), is a true medical condition which deserves therapeutic remedies. Today, there are no FDA approved products for the treatment of FSD or HSDD in the U.S. Thus, if approved, LibiGel could be a significant product, capable of addressing a genuinely unserved market. We believe this market could exceed the male erectile dysfunction market which today is over $2 billion.

BioSante and our licensee, Pantarhei Bioscience B.V., a Dutch pharmaceutical company, initiated a Phase II clinical trial of a new oral contraceptive using BioSante's patented "triple-therapy" contraceptive technology. Here too, the market potential is very large with current sales of oral contraceptives estimated at $3.0 billion.

In other exciting news, BioSante and our licensee, Teva Pharmaceutical Industries Ltd., signed an amendment to our license agreement and reinitiated the development of Bio-T-Gel™, our male testosterone therapy product.

We also continued to make progress with our calcium phosphate (CaP) nanotechnology. In November, BioSante announced a license agreement with Medical Aesthetics Technology Corporation to use our CaP as a facial line filler known as BioLook™.

All of these advances have given us solid reasons to look forward to continuing to deliver good news in 2008 and beyond.

LibiGel

In September 2007, BioSante received clarity from the FDA on key FDA safety requirements for the development of LibiGel in the treatment of FSD. Then, in January 2008, BioSante reached agreement with the FDA under the SPA process for our Phase III safety and efficacy clinical trials of LibiGel. These two extremely important milestones enabled us to confidently initiate both LibiGel Phase III safety and efficacy trials and the Phase III cardiovascular safety study.

The primary endpoints in the two Phase III safety and efficacy trials are an increase in the number of satisfying sexual events and sexual desire. The secondary endpoint is a decrease in sexual distress. In Phase II, treatment with LibiGel significantly increased satisfying sexual events (238% versus baseline) in surgically menopausal women suffering from FSD.

The LibiGel Phase III cardiovascular safety study seeks to show the relative safety of using low-dose testosterone versus placebo in the treatment of FSD in menopausal women. This study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events-driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months. After 12 months BioSante intends to submit a

LibiGel NDA (New Drug Application) for review and possible approval by the FDA. We will continue to follow the women enrolled in the safety study for an additional four years after the NDA submission and possible approval of LibiGel.

Elestrin™

BioSante received approval from the FDA in December 2006 for Elestrin, an ultra-low dose transdermal estrogen therapy for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. In June 2007, we announced the commercial launch of Elestrin by BioSante's marketing licensee, Nycomed.

Bio-T-Gel

Bio-T-Gel is a once-daily transdermal testosterone gel currently in development for the treatment of male hypogonadism, or low testosterone levels. Bio-T-Gel is moving through the clinical development process by our partner, Teva Pharmaceutical Industries, Ltd.

CaP Nanotechnology

Under the option and license agreement with Medical Aesthetics Technology Corporation for the development and commercialization of products in the field of aesthetic medicine, BioSante announced in 2007 that CaP will be used as a facial line filler known as BioLook.

Currently, further pre-clinical tests are being conducted to confirm the positive results of past tests to determine whether BioSante's BioLook can extend the beneficial wrinkle-filling effects longer than those produced by leading hyaluronic acid fillers. Human clinical testing of CaP for this use is being planned and is expected to be initiated in 2008.

2007 Financial Results

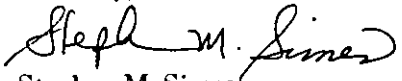
The progress BioSante is making with the products in our pipeline, combined with the granting of patents and the commercial launch of Elestrin have been instrumental in our efforts to increase stockholder value.

For the year ended December 31, 2007, BioSante's cash, cash equivalents and short-term investments were approximately $30.7 million as compared to $11.4 million a year earlier. This increase was due to the Nycomed milestone payments ($10.5 million) for Elestrin and proceeds from an $18.3 million private placement of shares of common stock and warrants to institutional and other accredited investors. BioSante's net loss was approximately $7.6 million or $(0.30) per basic and diluted share for the year ended December 31, 2007, compared to a net income of $2.8 million or $0.13 per basic and diluted share for the same period in 2006. This decrease is due to the recognition of Elestrin licensing and milestone revenue in 2006.

Finally, in November 2007, BioSante's common stock began trading on the NASDAQ Global Market under the symbol BPAX. We had the opportunity to ring the NASDAQ closing bell in January 2008 and see BioSante and LibiGel displayed on the world's largest video display, the NASDAQ billboard in Times Square.

At BioSante, we remain dedicated to expanding upon the successes we have achieved and the progress we are making. In the last year, BioSante, and especially LibiGel, generated significant attention from the media that has strengthened our position as the leading company in the development of potentially the first FDA-approved product for FSD for menopausal women. I'd like to thank our employees for their dedication and the continuing support of you, our stockholders. We hope you share our enthusiasm for our successes in the last year and our commitment to delivering even more exciting progress and stockholder value in 2008 and beyond.

Sincerely,



Stephen M. Simes
President and Chief Executive Officer

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2007

☐ **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** (Address of principal executive offices)	**60069** (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 ☐ NO ☒

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The aggregate market value of the registrant's common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sales price at which the common stock was last sold as of June 30, 2007 (the last business day of the registrant's second quarter) as reported by the American Stock Exchange on that date was $151,387,673.

As of March 10, 2008, 26,794,607 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 2008 Annual Meeting of Stockholders to be held in June 2008.

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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 heading "Item 1. Description of Business — Forward-Looking Statements." 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™, NanoVant™, BioLook™, CAP-Oral™ and BioAir™. This report also contains trademarks, trade names and service marks that are owned by other persons or entities.

PART I

Item 1. DESCRIPTION OF BUSINESS

General

We are a biopharmaceutical company that develops hormone therapy products to treat men and women. 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 hormone therapy products address a variety of hormone therapies for symptoms that affect both men and women, with an emphasis on women. Symptoms addressed by these hormone therapies in women include sexual dysfunction (hypoactive sexual desire disorder) and hot flashes. The products are gel formulations of testosterone, estradiol and various combinations of testosterone and estradiol.

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, to be absorbed into the skin without a trace of residue and to dry within one to two minutes.

The following is a list of our key hormone therapy products:

- LibiGel — once daily transdermal testosterone gel in Phase III development for treatment of female sexual dysfunction (FSD).
- Elestrin — once daily transdermal estradiol (an estrogen) gel FDA-approved for treatment of menopausal symptoms in women.
- Bio-T-Gel — once daily transdermal testosterone gel in development for 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 treatment of FSD in women using oral or transdermal contraceptives.

In order to market our hormone therapy 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 United States Food and Drug Administration (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 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 agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Effective February 21, 2008, Nycomed US Inc. completed its acquisition of Bradley. As a result, all references to Bradley have been changed to Nycomed in this report. Nycomed commercially launched Elestrin in the U.S. in June 2007.

Prior to submitting an NDA or ANDA for our other hormone therapy products, the products must undergo additional human clinical trials. LibiGel successfully has completed a Phase II clinical trial, and we began the first of two Phase III safety and efficacy clinical trials in December 2006 and a separate safety study in January 2008. We believe based on FDA discussions, meetings and agreements, 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 separate 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.

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 — 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, including hepatitis B, avian flu and biodefense vaccines for toxins such as anthrax. 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.

Business Strategy

Our goal is to develop and commercialize our hormone therapy products and develop our CaP technology into a wide range of pharmaceutical products. Key elements of our strategy to obtain this goal are to:

- ***Pursue the development of our hormone therapy products.*** We are focused on building a pipeline of hormone therapy products for various potential indications in women and men. We received approval of an NDA for Elestrin in December 2006. Our U.S. marketing licensee, Nycomed, commercially launched Elestrin in the U.S. in June 2007. LibiGel successfully has completed a Phase II clinical trial, and we began the first of two Phase III safety and efficacy clinical trials in December 2006 and a separate safety study in January 2008. We believe based on FDA discussions, meetings and agreements, 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 separate 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. In June 2007, we announced that we and a subsidiary of Teva Pharmaceutical Industries Ltd. reinitiated our collaboration on the development of Bio-T-Gel, our male testosterone gel, for the U.S. market.

- ***Continue to develop our nanoparticle-based CaP platform technology and seek collaborations for its development through government agencies and corporate partner sublicenses.*** We have entered into and are seeking opportunities to enter into additional business collaborations, joint ventures or

sublicenses with companies that have businesses or technologies complementary to our CaP technology business, such as aesthetic medicine expertise, vaccine and/or drug delivery pharmaceutical or biotechnology companies, and with various governmental entities focused on developing new vaccines and alternative drug delivery systems. We believe that this partnering strategy will enable us to capitalize on our partners' strengths in product development, manufacturing and commercialization and thereby enable the introduction into the market of products incorporating our CaP technology sooner than we otherwise would be able. In addition, these collaborations have continued to enable us to progress CaP development yet minimize our spending on the development of products incorporating our CaP technology.

- **Continue to seek and implement strategic alternatives with respect to our products, including business collaborations, joint ventures licenses and other business combinations and transactions with other pharmaceutical and biotechnology companies.** We continually evaluate various strategic alternatives with respect to our products. One of our strategic goals is to continue to seek and implement business collaborations, joint ventures, licenses and other business combinations or transactions with entities that have businesses or technologies complementary to our business. Therefore, as a matter of course from time to time, we engage in discussions with third parties regarding licensure or acquisition of products and technologies or a merger or acquisition of our company.

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, 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, 1.4 million testosterone prescriptions were written off-label for women by U.S. physicians in 2006. Female sexual dysfunction, or 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. 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 development 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 hypoactive

sexual desire disorder (HSDD). The panel's main concern was a desire to have available additional safety data 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 additional Phase III studies in over 1,000 naturally menopausal women (i.e., with an intact uterus) as well as additional Phase III studies in different patient populations for a total of five Phase III clinical trials. 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 a Special Protocol Assessment (SPA) received in January 2008 regarding LibiGel, we believe two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate 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.

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 removed surgically 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 2007, of which the transdermal segment, mostly patches, is reported at about $260 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, stomach upset, gallstones, blood clots as well as an increase in C-reactive protein, a possible marker for cardiovascular inflammation. Recent 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 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 hormone therapy 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 estrogen or estrogen combined with progestogen products, including transdermal patches, manufactured by Noven Pharmaceuticals, Inc., Berlex Laboratories, Inc., Mylan Laboratories, Inc., Novartis Pharma AG, Pfizer Inc., and Watson Pharmaceuticals, Inc.; transdermal gels marketed by Ascend Therapeutics, Inc. and Upsher-Smith Laboratories, Inc. and our Elestrin transdermal gel marketed by Nycomed.

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 22 percent in 2007 to $624 million from $510 million in 2006. 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 Hormone Therapy Products

Overview. Our hormone therapy products are gel formulations of testosterone, estradiol, 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 hormone therapy products have a number of benefits over competitive hormone therapy 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;
- 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.

LibiGel. LibiGel is a once daily transdermal testosterone gel designed to treat female sexual dysfunction, specifically hypoactive sexual desire disorder. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes due to aging or following surgical menopause. LibiGel successfully has completed a Phase II clinical trial, and we began the first of two Phase III safety and efficacy clinical trials in December 2006, a separate safety study in January 2008 and plan to begin the second safety and efficacy trial in the first half of 2008.

Our Phase II LibiGel trial was a U.S.-based, double-blind, placebo-controlled study of 46 women to determine the effect of LibiGel on women's sexual activity. Our Phase II trial showed statistically significant results for the primary endpoint of the study. In the trial, there was a 238 percent increase from baseline ($p<0.0001$) in the frequency of satisfying sexual events as measured by individual patient diaries. This increase also was significant versus placebo ($p< 0.05$). The data indicate an effective LibiGel dose for the treatment of HSDD in women, and that LibiGel was well tolerated during the course of the trial, and had a safety profile similar to that of the placebo, with no women discontinuing use due to adverse events.

We believe based on FDA discussions, meetings and agreements 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 separate 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. In January 2008, we announced that we successfully completed and reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trials for LibiGel in the treatment of FSD, specifically, HSDD. The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III 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. The SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD. These SPA trials use our validated instruments to measure the clinical endpoints.

The Phase III safety and efficacy trials of LibiGel in the treatment of female sexual dysfunction, one of which has been initiated, are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. We hope to initiate the second Phase III efficacy trial in the first half of 2008.

We initiated the Phase III cardiovascular safety study in January 2008. The 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. The safety study will track a list of cardiovascular events including cardiovascular death, myocardial infarction and stroke in women 50 years of age or older and suffering from at least one cardiovascular risk factor including hypertension or diabetes. The objective of the safety study is to show the relative safety of testosterone compared to placebo in the number of cardiovascular events. The incidence of breast cancer also will be tracked over the course of the study. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

Elestrin. Our estrogen formulated gel product, Elestrin, is a once daily 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. Elestrin 0.87 grams, that delivers 12.5 mcg of estradiol per day, is one of the lowest daily doses of estradiol approved by the FDA for the treatment of hot flashes and is 50 percent lower than the lowest dose, FDA-approved estrogen patch on the market. The Elestrin FDA approval was a non-conditional and full approval 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 Nycomed for the marketing of Elestrin in the United States. Nycomed commercially launched Elestrin in the U.S. in June 2007.

Our Other Hormone Therapy Products. In addition to LibiGel and Elestrin, our hormone therapy products include Bio-T-Gel, LibiGel-E/T and The Pill-Plus. We have entered into several license or sublicense agreements covering some of our hormone therapy products, including a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA is developing our male testosterone gel, Bio-T-Gel, for the U.S. market and an agreement with Paladin Labs Inc. covering Canadian rights to certain of our hormone therapy 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.

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.

Description of Our CaP Technology and Products

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

- 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, such as allergy applications.

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 cancer, viral and bacterial infections and autoimmune diseases, among others, including hepatitis B, avian flu and biodefense vaccines for toxins such as anthrax. 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 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 within the next six months.

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.

In January 2007, we announced positive results of a dose ranging pre-clinical study demonstrating that our CaP-based vaccine adjuvant, BioVant, may serve as a vaccine adjuvant for the development of an effective vaccine against H5N1, widely known as bird flu. Our pre-clinical study's objective was to determine the optimal formulation of BioVant with a very low dose of H5N1 antigen. At the start of the 16-week pre-clinical trial, mice received either the H5N1 antigen alone or in one of several formulations with BioVant, as well as various control groups. A booster immunization was administered after two and 10 weeks. Results showed that the administration of a BioVant/H5N1 formulation stimulated a significantly higher production of titers of H5N1-specific antibodies than H5N1 alone. Further, the anti-bird flu antibody levels continued to increase over the entire study period, suggesting good duration of immunity. We believe this dose ranging study confirms the potential of BioVant to be used as part of a dose sparing, easier to administer, non-injected vaccine.

In 2007, the FDA approved a bird flu vaccine developed by Sanofi-Aventis comprised of 90 micrograms of H5N1 antigen per dose. Our BioVant vaccine candidate uses 3 micrograms of H5N1 antigen per dose thereby providing a possible way to avoid vaccine shortages.

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 the oral insulin mouse models in fasted mice, our proposed product, which we call BioOral, has shown an 80 percent reduction of glucose levels within the first hour of treatment. These reduced glucose levels were maintained for 12 hours versus 20-25 percent glucose reduction for three hours for free insulin. In fed mouse models, our oral formulation reduced glucose levels by 50 percent for six hours versus no significant reduction with free insulin.

Furthermore, we believe we may have created successfully a formulation for the inhaled delivery of insulin, which we call BioAir. We also have conducted preclinical studies of our BioAir delivery system for inhalable insulin. The studies showed that BioAir significantly increased the systemic residence time and duration of action of the insulin, increasing the amount of insulin that became available through the bloodstream (bioavailability) 1.8 times over that of injected insulin. The results indicate that our CaP technology may extend the duration of action many times over that of injecting insulin alone, which could allow diabetics to substantially reduce the number of injections needed to control blood glucose levels.

Our research and development efforts in these areas are ongoing, testing insulin and other drugs that must now be given by injection. We also are developing a buccal formulation for protein delivery since buccal administration results in significantly higher bioavailability of proteins and may be better suited to proteins than oral delivery. The discontinuation of the marketing by Pfizer of Exubera, an inhaled insulin, points to the need for longer acting, lower dose inhaled proteins.

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.

In September 2005, we signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products. The partner company will fund its development of potential products for the treatment of conditions including rhinitis, asthma, conjunctivitis, dermatitis, and allergic gastrointestinal diseases. Under the terms of the agreement, we received a nonrefundable $250,000 upfront payment. If the option is exercised and the parties enter into an exclusive license agreement, we will receive a one-time license fee, annual maintenance payments, milestone payments upon the achievement of regulatory milestones and royalties on commercial sales of any allergy product that is developed using CaP.

In December 2005, we were awarded a subcontract by the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration. The year-to-year subcontract was awarded to us as part of the University's five year $10.0 million grant entitled "GMP Recombinant FIX for IV and Oral Hemophilia B Therapy" from the National Institutes of Health. We believe this subcontract leverages our expertise in alternative routes of drug administration, specifically buccal and pulmonary administration using our proprietary CaP BioOral and BioAir technologies.

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 Nycomed, Nycomed has agreed to use its best commercially reasonable efforts to manufacture, market, sell and distribute Elestrin for commercial sale and distribution throughout the United States. 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.

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 expect to spend a significant amount of our financial resources on product development activities, with the largest portion being spent on clinical trials of our hormone therapy products, including in particular LibiGel. We spent approximately $4.8 million in 2007 and $3.9 million in 2006 on research and development activities. We spent an average of approximately $400,000 per month on our research and development activities during 2007. We expect our research and development expenses potentially to be significantly higher in 2008 compared to 2007 as a result of the initiation of our LibiGel Phase III clinical trial program. We expect our research and development expenses to remain at the average 2007 levels until late in the first half of 2008, when we expect them to increase to at least $800,000 to $1.0 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) our development schedule, including the timing of our clinical trials; (2) resources available; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our products; and (5) competitive developments.

Manufacturing

We currently do not have any facilities suitable for manufacturing on a commercial scale basis any of our products nor do we have any experience in volume manufacturing. 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.

Hormone Therapy Products. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares granted us an exclusive license to certain proposed hormone therapy products including rights to sublicense the hormone therapy products, in order to develop and market the hormone therapy products in certain territories. We are the exclusive licensee in our territories for an Antares issued patent for these products in the United States and has filed additional patent applications (several that include BioSante personnel as inventors) for this licensed technology in the U.S. and several foreign jurisdictions. Our license agreement with Antares required us to pay a $1.0 million up-front license fee to Antares and to pay royalties to Antares based on a percentage of the net sales of any products we or our sublicensees, such as in the case of Elestrin, Nycomed, sell incorporating the licensed technology.

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. We paid Antares 25 percent of these payments as a result of our license agreement with Antares. Nycomed also has 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.

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 our 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, 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 reinitiated our 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 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 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.

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 ($1.7 million net of the related payments due to Antares and Paladin Labs Inc.), 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.

In September 2000, we sublicensed the marketing rights to our portfolio of hormone therapy 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.

In April 2002, we exclusively in-licensed from Wake Forest University Health Sciences (formerly known as 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. In July 2005, we 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 us if a product incorporating the licensed technology gets approved and subsequently marketed.

In May 2007, we announced that we sub-licensed the 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.

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 has 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, 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 and the payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which amounted to $0 and $8,236 in 2007 and 2006, respectively.

In September 2005, we signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products. The partner company will fund its 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, we received a nonrefundable $250,000 upfront payment. If the option is exercised and the parties enter into an exclusive license agreement, we will receive a one-

time license fee, annual maintenance payments, milestone payments upon the achievement of regulatory milestones and royalties on commercial sales of any allergy product that is developed using CaP.

In December 2005, we were awarded a subcontract by the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration. The year-to-year subcontract was awarded to us as part of the University's five year $10 million grant entitled "GMP Recombinant FIX for IV and Oral Hemophilia B Therapy" from the National Institutes of Health. The first year of the subcontract was valued at approximately $250,000, $75,000 for the second year and we have applied for $75,000 for the third year of the contract. We believe this subcontract leverages our expertise in alternative routes of drug administration, specifically buccal and pulmonary administration using our proprietary CaP BioOral and BioAir technologies.

In February 2006, we signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation for the use of our CaP technology in the field of aesthetic medicine. In November 2007, we signed a license agreement with MATC covering the use of our CaP as a facial filler (BioLook) in aesthetic medicine. 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 about five percent. 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.

Patents and patent applications. We have licensed a patent portfolio relating to hormone therapy from Antares Pharma, Inc. The expiration dates of these patents vary, ranging to 2022. The rights to this portfolio are governed by our license agreement with 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, will expire on June 25, 2022. This patent lists our Chief Executive Officer as an inventor of the formulation.

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, BIO-T-GEL BIOVANT and NANOVANT, covering goods that include or are closely related to hormone therapy products, vaccines and vaccine adjuvants and drug delivery platforms. In addition, we own common law rights to several trademarks, including BIOSANTE, LIBIGEL, ELESTRIN, BIO-E-GEL, BIO-T-GEL, THE PILL-PLUS, LIBIGEL-E/T, BIO-E/P-GEL, BIOLOOK, CAP-ORAL, BIOVANT, BIOAIR, NANOVANT 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.

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 hormone therapy products similar to ours. They include Upsher-Smith Laboratories, Inc., Noven Pharmaceuticals, Inc., Wyeth, Auxilium Pharmaceuticals, Inc., Ascend Therapeutics, Inc., Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc. Competitor hormone therapy products include oral tablets, transdermal patches and gels. We expect our FDA-approved product, Elestrin, and our other hormone therapy 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.

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 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 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 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, hypoactive sexual desire disorder.

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.

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

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

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 11 employees as of December 31, 2007, including seven in product development and four 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. As of February 29, 2008, we had 16 employees and we expect this number to increase to about 20 by the end of the first quarter.

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," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue" and other words and 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 caption "Management's Discussion and Analysis of Financial Condition and Results of Operation." Our forward-looking statements generally relate to:

- the timing of the commencement, enrollment and completion of our clinical trials and other regulatory status of our proposed products;
- the future market and market acceptance of our products;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of marketing capabilities and licensure or acquisition of new products;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need and ability to raise additional capital through future equity and other financings;
- our substantial and continuing losses; and
- valuation, expected returns and ability to liquidate investments in our investment portfolios based on risks affecting underlying securities or the markets in which they are bought and sold.

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

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

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

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.

We have a history of operating losses, expect continuing losses and may never again achieve profitability.

We have a history of operating losses. We incurred a net loss of $7.6 million for the year ended December 31, 2007 and as of December 31, 2007, our accumulated deficit was $54.5 million. 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 generated by our marketing licensee, Nycomed, who commercially launched Elestrin in June 2007. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs expand 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 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 program of LibiGel to require significant resources. Therefore, we may need to raise substantial additional capital to fund our operations. We believe that our cash, cash equivalents and short-term investments of $30.7 million at December 31, 2007 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 18 months, and if we are unable to liquidate our auction rate securities, through at least the next 12 months. However, we may resort to seeking additional financing prior to that time. As an alternative to raising additional financing, we may be able to license LibiGel to a third party who would finance the continued development and if approved, commercialization of LibiGel. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews of 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;
- 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.
- our ability to license LibiGel or other products for development and commercialization;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products, or restrict us from acquiring new products that we believe may be beneficial to our business.

Our proposed products are in the development stages and will likely 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, which was commercially introduced in June 2007 by our marketing licensee, Nycomed, 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 hormone therapy 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 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 FDA discussions, meetings and agreements, 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 separate 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. In January 2008, we announced that we successfully completed and reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trials for LibiGel in the treatment of FSD, specifically, hypoactive sexual desire disorder. The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III 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. The SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD. The SPA agreement, however, is not a guarantee of LibiGel approval by the FDA or approval of any permissible claims about LibiGel. In particular, it is 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 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 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 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 hormone therapy products differ from the products used in the Women's Health Initiative 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 hormone therapy 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 affects from hormone therapy, including in particular, hormone therapies similar to our products, would also adversely affect our business.

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

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States pursuant to which we received an upfront license payment, certain regulatory milestone payments 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 Bradley in marketing and selling the product. Bradley commercially launched Elestrin in June 2007. We recognized $69,353 in royalty revenue from the sales of Elestrin during the year ended December 31, 2007 which represents the gross royalty revenue received from Bradley and not our corresponding obligation to pay Antares a portion of the royalties received. We, therefore, have not received any meaningful royalty revenue from the sale of Elestrin and we do not know when if ever, Bradley's Elestrin sales will result in significant royalty revenue to us. Effective February 21, 2008, Nycomed US Inc. completed its acquisition of Bradley. As a result, all references to Bradley have been changed to Nycomed in this report. Although we have no reason to believe that the acquisition of Bradley will adversely affect its desire to continue to be our exclusive sublicensee for Elestrin or adversely affect Nycomed's future sales of Elestrin, no assurance can be provided that the acquisition will not have such an adverse effect. We cannot assure you that Nycomed will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of our agreement, especially if Nycomed's Elestrin sales do not increase significantly. Any breach by Nycomed 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.

We license the technology underlying most of our hormone therapy 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 most of the technology underlying our hormone therapy products from Antares Pharma, Inc. and a portion of our CaP technology from the University of California. 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 hormone therapy 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. or the University of California 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.

We have licensed some of our hormone therapy 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 some of our hormone therapy product to third parties, Nycomed, Solvay Pharmaceuticals, B.V., Teva Pharmaceuticals USA, Inc. and Pantarhei Bioscience B.V. All of these parties, except for Nycomed, 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 may also 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.

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 Nycomed. 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.

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 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.

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.

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.

- Competitors may interfere with our patents and patent process in a variety of ways. 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. 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.

- Enforcing patents is expensive and 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.

It also is unclear whether efforts to secure our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors resulting in a loss of protection. 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. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

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 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.

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.

Our investments in auction rate securities are subject to risks which may cause losses and adversely affect our liquidity.

At December 31, 2007, we had $15.0 million in short-term investments consisting primarily of auction rate securities. At March 14, 2008, we had approximately $14.0 million invested in auction rate securities. Liquidity for our auction rate securities historically has been provided by an auction process which has allowed us the opportunity to sell the securities at each auction date, and for those securities not sold, resets the applicable interest rate every 28 days. Although auctions have been successful for periods immediately subsequent to December 31, 2007, recently auctions for our auction rate securities have failed which therefore have eliminated our ability to sell these securities through the standard auction process. Currently there is no liquid market for these securities. There is no assurance that future auctions in our auction rate securities will succeed. An auction failure means that the parties wishing to sell their securities could not be matched with an adequate volume of buyers. In the event that there is a failed auction the indenture governing the security requires the issuer to pay interest at a contractually defined rate which may or may not correspond to market rates for other types of similar short-term instruments. Our securities for which auctions have failed will continue to accrue interest at the contractual rate and be subject to the auction process every 28 days until the auction succeeds, the issuer redeems the securities or they mature. As a result, our ability to liquidate our investment in these securities and use the cash proceeds to operate our business in the near term may be limited. Our ability to fully recover the carrying value of our investment in these securities may also be limited or non-

existent in the near term. All of our investments in auction rate securities are classified as short-term investments in our financial statements for the fiscal year ended December 31, 2007. However, these recent developments may result in the classification of some or all of these securities as long-term investments in our future financial statements.

All of the underlying assets of our auction rate securities are student loans substantially all of which are backed by the federal government under the Federal Family Education Loan Program. Substantially all of our auction rate securities are currently rated AAA, the highest rating available by a rating agency. We currently believe the market values of our auction rate securities are not significantly impaired, primarily due to government agency backing of the underlying securities and the investment-grade credit rating of each auction rate security in our portfolio. However, it could take until the final maturity or issuer refinancing of the underlying debt for us to realize the recorded value of our investments in these securities. If the issuers of our auction rate securities are unable to successfully close future auctions or redeem or refinance the securities and their credit ratings deteriorate, we may in the future be required to record an impairment charge on these investments, and may need to sell these securities on a secondary market. Although we believe we will be able to liquidate our investments in these securities without any significant loss, the timing and financial impact of such an outcome is uncertain. Based on our expected cash expenditures, our cash and cash equivalents balance and other potential sources of cash, including our anticipated ability to borrow using these securities as collateral, we do not anticipate that the potential lack of liquidity of these investments in the near term will adversely affect our ability to execute our current business plan. However, no assurance can be provided that our ability to execute our business plan will not be affected by this risk.

The price and trading volume of our common stock has been, and may continue to be, volatile.

Historically, the market price and trading volume of our common stock closing price has fluctuated over a wide range. In 2007, our common stock closed in a range from a low of $2.72 to a high of $7.68, and our daily trading volume ranged from 18,500 shares to 928,700 shares. It is likely that the price and trading volume 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 and volume fluctuations, often unrelated to the operating performance of these companies. In particular, the market price and trading volume of our common stock may fluctuate significantly due to a variety of factors, including:

- governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products or our competitors' products;
- the results of our clinical trials or those of our competitors;
- announcements of technological innovations or new products by us or our competitors;
- announcements by licensors or licensees of our technology;
- public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;
- developments or disputes concerning patents or other proprietary rights;
- our ability to obtain needed financing;

- 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;

- 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; and

- general stock, market and general economic conditions in the United States and abroad, not directly related to BioSante.

In addition, the occurrence of any of the risks described above or elsewhere 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. For example, in December 2004, primarily as a result of the unanimous vote by the FDA's Reproductive Health Drugs Advisory Committee panel against recommendation for approval of Procter & Gamble's Intrinsa testosterone patch for hypoactive sexual desire disorder, the price of our common stock decreased over 35 percent in one trading day and over 50 percent over the course of three trading days. In addition, on the day of and first two trading days after the public announcement of FDA advisory panel's recommendation, the daily trading volume of our common stock went from an average of approximately 166,000 shares per day to an average of over approximately 3 million shares per day for those same three days and then back down to an average of approximately 140,000 shares per day. Our current trading volume is approximately 110,000 shares per day.

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.

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 6,800 square feet of office space for approximately $12,000 per month. Our lease for this space expires in March 2009. Our CaP development operations are located within the Bucks County Biotech Park in Doylestown, Pennsylvania where we lease approximately 2,000 square feet of laboratory space for approximately $3,700 per month. This lease is renewable in one year increments each July and expires in July 2008. 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 affect 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, 2007.

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and the offices held, as of March 15, 2008, are as follows:

Name	Age	Title
Stephen M. Simes	56	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	47	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.

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, in dollars and cents (in lieu of fractions), 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.

NASDAQ Global Market

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

The following table sets forth, in dollars and cents (in lieu of fractions), 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.

American Stock Exchange

2006	High	Low
First Quarter	$4.69	$3.51
Second Quarter	$4.29	$1.91
Third Quarter	$2.42	$1.60
Fourth Quarter	$3.14	$1.55

2007	High	Low
First Quarter	$6.25	$2.55
Second Quarter	$8.00	$5.28
Third Quarter	$6.71	$5.00
Fourth Quarter	$6.10	$5.21

Number of Record Holders; Dividends

As of March 10, 2008, there were 317 record holders of our common stock and six record holders of our class C stock. To date, we have not declared or paid any cash dividends on our common stock and our class C stock is not eligible to receive dividends.

Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2007, we did not issue or sell any equity securities of ours without registration under the Securities Act of 1933, as amended.

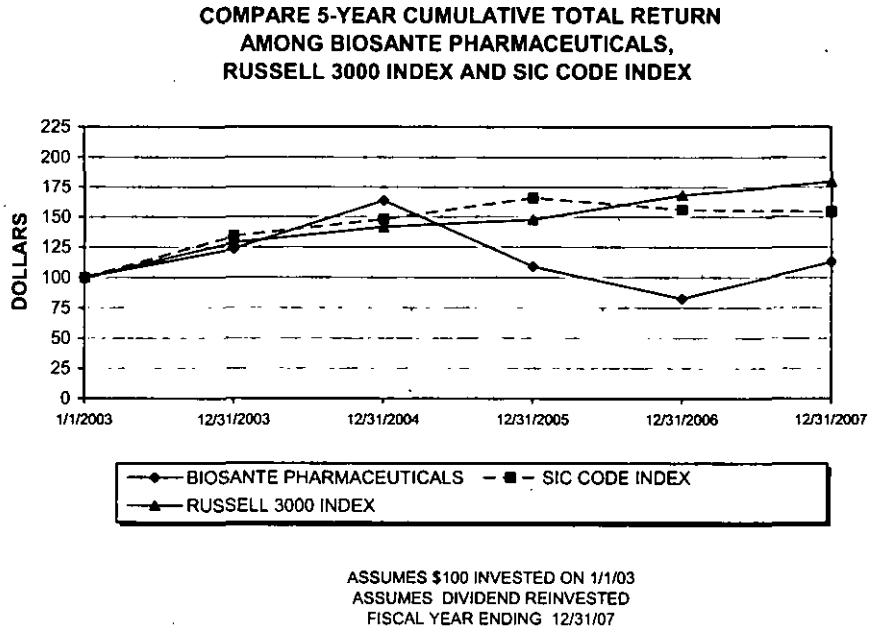
Issuer Purchases of Equity Securities

We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2007. Our Board of Directors has not authorized any repurchase plan or program for 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.

Stock Performance Graph

The following graph shows the five-year cumulative total stockholder return on our common stock from January 1, 2003 until December 31, 2007, 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, 2003, 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.

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,				
	2007	2006[1]	2005[1]	2004	2003
	(in thousands, except per share data)				
Statement of Operations Data:					
Licensing revenue	$ 199	$ 14,136	$ 45	$ 10	$ 65
Grant revenue	59	247	181	68	—
Royalty revenue	69	—	—	—	—
Other revenue	166	55	32	—	—
Total revenue	493	14,438	258	78	65
Interest income	1,095	429	401	250	87
Expenses Research and development	4,751	3,908	6,409	9,162	3,691
General and administration	4,331	4,550	3,801	3,080	2,327
Licensing expense	—	3,500	—	—	—
Depreciation and amortization	90	118	101	102	93
Total expenses	9,172	12,076	10,311	12,344	6,111
Net (loss) income	$ (7,584)	$ 2,791	$ (9,651)	$ (12,016)	$ (5,959)
Basic and diluted net (loss) income per share	$ (0.30)	$ 0.13	$ (0.50)	$ (0.70)	$ (0.54)
Weighted average number of shares outstanding	25,486	21,191	19,392	17,145	11,039

(1) The 2006 and 2005 statements of operations data have been corrected to reflect the reclassification of stock option expense. See Note 2, Summary of Significant Accounting Policies to our financial statements for the year ended December 31, 2007 included herein.

	As of December 31,				
	2007	2006	2005	2004	2003
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 30,655	$ 11,450	$ 9,102	$ 17,269	$ 9,134
Total assets	31,241	22,371	9,575	17,827	9,565
Stockholders' equity	29,725	18,071	6,819	15,921	8,684

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 captions "Forward-Looking Statements" in Item 1 and "Risk Factors" in Item 1A of this annual report on Form 10-K. The following discussion of the results of the operations and financial condition of BioSante should be read in conjunction with our financial statements and the related note hereto. The Management's Discussion and Analysis of Financial Condition and Results of Operations has been corrected to reflect the reclassification described in Note 2, Summary of Significant Accounting Policies to our financial statements for the year ended December 31, 2007 included herein.

General Overview

We are a biopharmaceutical company that develops hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

Hormone Therapy Products. Our hormone therapy products are gel formulations of testosterone, estradiol and various combinations of testosterone and estradiol. Our key hormone therapy products include LibiGel, Elestrin, Bio-T-Gel and The Pill-Plus (triple hormone contraceptives). We license the technology underlying our hormone therapy products, except Bio-T-Gel and The Pill-Plus, from Antares Pharma, Inc. Bio-T-Gel was developed and is fully-owned by us. 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 and required us to pay an up-front license fee. 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 an upfront license fee, regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and is subsequently marketed.

We have entered into several sublicense agreements covering our hormone therapy products, including 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, an agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product and an agreement with Paladin Labs Inc. covering Canadian rights to certain of our hormone therapy products. We believe that our estrogen/progestogen combination transdermal hormone therapy gel product which we have sub-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. The financial terms of these agreements generally include an upfront license fee, milestone payments and royalty payments to us if a product incorporating the licensed technology gets approved and is subsequently marketed and a portion of any payments received from subsequent successful out-licensing efforts.

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 sublicense agreement, 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. Nycomed also has agreed to pay us additional payments of up to $40.0 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. We license the transdermal estradiol gel formulation that is used in Elestrin from Antares Pharma, Inc. Under our license agreement with Antares, we are obligated to pay Antares 25 percent of all licensing-related milestones and a portion of any future associated royalties. Nycomed began its commercial launch of Elestrin in June 2007. The Elestrin FDA approval was a non-conditional and full approval with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin.

LibiGel successfully has completed a Phase II clinical trial, and we began the first of two Phase III safety and efficacy clinical trials in December 2006. We believe based on FDA discussions, meetings and agreements 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 separate 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. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional

four years. The Phase III cardiovascular 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. We initiated the safety study in January 2008. The Phase III safety and efficacy trials of LibiGel in the treatment of female sexual dysfunction, one of which was initiated in December 2006 and the other of which we intend to initiate in the first half of 2008, are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial.

In January 2008, we announced that we successfully completed and reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trials for LibiGel in the treatment of FSD, specifically, hypoactive sexual desire disorder. The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III 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. The SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD. These SPA trials use our validated instruments to measure the clinical endpoints.

In May 2007, we announced that we sub-licensed U.S. rights to a new triple hormone oral contraceptive to Pantarhei Bioscience B.V., 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.

CaP Technology and Proposed Products. 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 September 2005, we signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use our CaP in the development of a series of allergy products. Under the agreement, we received a nonrefundable $250,000 upfront payment. We are recognizing revenue from this agreement on a pro rata basis over the term of the agreement. The remainder of the upfront payment is recorded as deferred revenue. If the option is exercised and the parties enter into an exclusive license agreement, we will receive a one-time license fee, annual maintenance payments, milestone payments upon the achievement of regulatory milestones and royalties on commercial sales of any allergy product that is developed using CaP. We recorded licensing revenue of $59,091 and $136,364 in 2007 and 2006, respectively, related to this contract.

In February 2006, we signed an exclusive option and license agreement with Medical Aesthetics Technology Corporation (MATC) for the use of our CaP technology in the field of aesthetic medicine. In November 2007, we signed a license agreement with MATC covering the use of our CaP as a facial filler in aesthetic medicine. 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. We recorded licensing revenue of $140,000 related to this license and ownership position in MATC.

Under a subcontract with DynPort Vaccine Company LLC, we provided BioVant, our vaccine adjuvant, and DynPort provided recombinant antigens to be used in potential vaccines against anthrax. The objective was to assess the immunogenic potential of BioVant when used in anthrax vaccines versus the immunogenic response of anthrax vaccines that use alum as the vaccine adjuvant. We completed the subcontract and recorded approximately $300,000 in revenue over the life of the subcontract with $1,806 and $82,985 recognized in 2007 and 2006, respectively. Currently, we are seeking additional funding from government sources or potential partners for our anthrax program.

Financial Overview

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sublicensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future. However, Nycomed, our marketing sublicensee for Elestrin, launched Elestrin in June 2007. As a result, commencing in mid-2007, we began to receive royalties on net sales of Elestrin. However, such royalties were minimal during 2007.

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. In 2006, upon execution of the sublicense agreement with Nycomed, we received an upfront payment of $3.5 million. In addition, Nycomed paid us $7.0 million and $3.5 million in the first and fourth quarters 2007, respectively, both triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter 2006. Under our license agreement with Antares, we are obligated to pay Antares 25 percent of all licensing-related milestones and a portion of any future associated royalties. The aggregate $14.0 million received from Nycomed (consisting of the following amounts paid by Nycomed to us: $3.5 million in the fourth quarter 2006, $7.0 million in the first quarter 2007 and $3.5 million in the fourth quarter 2007) was recognized as revenue in 2006 since the entire $14.0 million was non-refundable, we had a contractual right to receive such payments, the contract price was fixed, the collection of the resulting receivable was reasonably assured and we had no further performance obligations under the license agreement. The corresponding obligations to Antares were represented as "Due to Licensor — Antares" on our balance sheet as of December 31, 2006 and expensed as "Licensing expense" on our statement of operations for 2006. Nycomed also has agreed to pay us additional payments of up to $40.0 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin. We are obligated to pay 25 percent of any sales-based milestone payments and a specified portion of royalties to Antares, which we will recognize as these payments are triggered, based on reported levels of future Elestrin sales.

Nycomed commercially launched Elestrin in June 2007. As such, we recognized royalty revenue of $69,353 based upon Nycomed's net sales of Elestrin during the year ended December 31, 2007. The royalty revenue presented in our statements of operations represents the gross royalty revenue to be received from Nycomed. Our corresponding obligation to pay Antares a portion of the royalties received was $31,209 for the year ended December 31, 2007. While we believe that royalty revenues from Nycomed may be significant in the long term, actual sales-based royalty revenue related to Elestrin was not significant for the year ended December 31, 2007, and we do not know when, if ever, Nycomed's Elestrin sales will result in significant royalty revenue to us.

In June 2007, we completed a private placement of 3,054,999 shares of our common stock and associated warrants to purchase 763,750 shares of our common stock at a purchase price of $6.00 per share. The

private placement resulted in net proceeds of approximately $17.3 million, after deduction of transaction expenses. Our cash, cash equivalents and short-term investments were $30.7 million as of December 31, 2007.

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 proposed products for which we have not entered into marketing relationships. Based on our current cash resources and our current commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next 18 months, and if we are unable to liquidate our auction rate securities, through at least the next 12 months (See "—Liquidity and Capital Resources" section). No assurance can be provided that we will not need or seek additional cash prior to such time. As an alternative to raising additional financing, we may license LibiGel or another product to a third party who may finance a portion or all of the continued development and if approved, commercialization of LibiGel or the other product, or we may elect to sell certain assets or rights we have under our existing license agreements.

We spent an average of approximately $400,000 per month on research and development activities in 2007. Our research and development expenses increased $843,023 or 22 percent, to $4.8 million for the year ended December 31, 2007 from $3.9 million for the year ended December 31, 2006, primarily as a result of the initiation of our Phase III clinical development program for LibiGel, which began in December 2006. We expect our monthly research and development expenses to remain at the average monthly 2007 levels until late in the first half of 2008, when we expect such monthly expenses to increase to at least $800,000 to $1.0 million per month. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) our development schedule, including the timing of our clinical trials; (2) resources available; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our proposed products; and (5) competitive developments.

Our general and administrative expenses for the year ended December 31, 2007 decreased $218,259 or five percent, compared to general and administrative expenses for the year ended December 31, 2006. This decrease was due primarily to a decrease in business development costs and a decrease in non-cash, stock-based compensation expense partially offset by an increase in other personnel-related costs. Our non-cash, stock-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. The primary reason for this decrease was $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. Our general and administrative expenses may fluctuate from year-to-year depending upon the amount of non-cash, stock-based compensation expense, legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

We recognized a net loss for the year ended December 31, 2007 of $7.6 million. We recognized net income of $2.8 million for the year ended December 31, 2006 primarily due to the recognition of $14.0 million in licensing revenue as a result of the execution of our sublicense agreement with Nycomed and the subsequent FDA approval of Elestrin in the fourth quarter of 2006. Although we expect to continue to receive royalty income and possibly sales-based milestone payments from Nycomed, 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 preclinical and clinical trials commence or continue, including

in particular the Phase III clinical trial program for LibiGel and other trials and studies associated with 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 and cost 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 sales-based milestones;
- the timing and cost of various cash and non-cash general and administrative items;
- 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.

Pursuant to an amendment executed in August 2006 to our license agreement with The Regents of the University of California, we are no longer obligated to pay the University of California future specified minimum annual royalties. Under the terms of the original agreement, $75,000 would have been due on February 28, 2007 for which we had accrued $37,500 at the time of the amendment. We paid the University of California $100,000 in connection with the amendment.

Critical Accounting Policies

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 the 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 SEC has defined a company's critical accounting policies as those that are most important to the portrayal of its financial condition and results of operations, and which the company is required 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 following critical accounting policies. 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 may also 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.

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 twelve months. We will recognize in future periods deferred revenue 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.

Results of Operations

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

	Year Ended December 31,		
	2007	2006	2005
Revenue	$ 493,054	$ 14,438,621	$ 258,351
Expenses	9,172,498	12,075,691	10,310,573
Research and development	4,751,313	3,908,290	6,409,080
General and administrative	4,331,361	4,549,620	3,800,555
Licensing expense	—	3,500,000	—
Interest income	1,095,009	428,343	401,186
Net (loss) income	$ (7,584,435)	$ 2,791,273	$ (9,651,036)
Net (loss) income per share (basic and diluted)	$ (0.30)	$ 0.13	$ (0.50)
Weighted average number of shares outstanding	25,485,513	21,190,946	19,392,116

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 2006 recognition 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 on our Phase III LibiGel clinical trial program, which commenced in December 2006. We expect our research and development expenses to increase in 2008 compared to 2007 as a result of our Phase III LibiGel clinical trial program, which will include two Phase III safety and efficacy trials, one of which was initiated in December 2006 and the other of which we expect to initiate in the first half of 2008, and a

safety study which was initiated in January 2008. Specifically, we expect our research and development expenses to be at least $800,000 to $1.0 million per month during 2008 starting late in the first half of 2008.

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-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 2006 recognition of $3.5 million in licensing expense as a result of the execution of our sublicense agreement with Nycomed, 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.

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Revenue for the year ended December 31, 2006 increased significantly compared to revenue for 2005 primarily due to the recognition 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, 2006 decreased 39 percent compared to research and development expenses for 2005 primarily as a result of lower spending on the Elestrin NDA and only one month of Phase III LibiGel clinical trial expenses.

Our general and administrative expenses for the year ended December 31, 2006 increased 20 percent compared to general and administrative expenses for 2005 primarily due to an increase in non-cash, stock-based compensation due to the immediately exercisable option grants to our non-employee directors in March 2006.

Licensing expense for the year ended December 31, 2006 increased significantly compared to licensing expense for 2005 primarily due to the recognition of $3.5 million in licensing expense as a result of the execution of our sublicense agreement with Nycomed, 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, 2006 increased seven percent compared to interest income during 2005 primarily as a result of higher average interest rates on our invested funds.

Liquidity and Capital Resources

Working Capital

All of our revenue to date has been derived from upfront, milestone and royalty payments earned on licensing and sub-licensing transactions and from subcontracts. We have not commercially introduced any products and do not expect to do so in the foreseeable future, although our marketing sublicensee for our Elestrin product, Nycomed, commercially launched Elestrin in June 2007, as a result of which we received royalty income commencing in mid-2007.

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 to obtain regulatory approval of our other proposed products or to complete the commercialization of any of our proposed products that are not licensed to others for development and marketing. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we may need to raise substantial additional capital to fund our operations or alternatively, we may choose to sublicense LibiGel or another product for development and commercialization, enter into other business collaborations or combinations or sell certain assets or rights we have under our existing license agreements.

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. In addition, during the year ended December 31, 2007, we received $1.2 million in cash proceeds from stock option and warrant exercises.

Our cash, cash equivalents and short-term investments available to fund our operations were $30.7 million and $11.4 million at December 31, 2007 and December 31, 2006, respectively. The increase in our cash and short-term investment balances was primarily due to our receipt during 2007 of milestone payments in the amount of $10.5 million as a result of the execution of our sublicense agreement with Nycomed and subsequent FDA approval of Elestrin and the completion in June 2007 of a private placement of 3,054,999 shares of our common stock and associated warrants to purchase 763,750 shares of our common stock resulting in net proceeds to us of approximately $17.3 million, after deduction of transaction expenses. These payments were offset partially by our use of cash to fund operations, including licensing expenses to our licensor, Antares. We do not have any outstanding debt.

As of December 31, 2007, we had $15.6 million of cash and cash equivalents and an additional $15.0 million of short-term investments. Our cash and cash equivalents are invested in highly-rated, investment grade financial instruments consisting primarily of commercial paper. Our short-term investments consist primarily of money market investments and investment-grade auction rate securities, the underlying assets of which are portfolios of student loans backed by the federal government. Although such securities typically have been very liquid, such liquidity recently has been reduced as a result of recent events in the credit markets, including the market for these auction rate securities. Although we expect the markets for auction rate securities to recover in the near term and believe we will be able to liquidate our investments in our auction rate securities without any significant loss, the timing of such an outcome is uncertain. Currently there is no liquid market for these securities. Based on our expected cash expenditures, our cash and cash equivalents balance and other potential sources of cash, including our anticipated ability to borrow using these securities as collateral, we do not anticipate that the potential lack of liquidity of these investments in the near term will adversely affect our ability to execute our current business plan. However, no assurance can be provided that it will not do so.

Our securities for which auctions have failed will continue to accrue interest at the contractual rate and will be subject to auctions every 28 days until the auction process succeeds, the issuers redeem the securities or the underlying debt instruments mature. If we determine that an issuer of the securities is unable to successfully close future auctions or redeem or refinance the obligations, we might be required to reclassify the investments from a current asset to a non-current asset. If an issuer's financial stability or credit rating deteriorates or adverse developments occur in the bond insurance market, we might be required to adjust the carrying value of our action rate securities through a future impairment charge. We continue to monitor the market for auction rate securities and to consider its impact (if any) on the fair market value of our investments. We currently believe the market values of our auction rate securities are not significantly impaired, primarily due to government agency backing of the underlying securities and the investment-grade credit rating of each auction rate security in our portfolio.

We believe that our cash, cash equivalents and short-term investments as of December 31, 2007 will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 18 months, and if we are unable to liquidate our auction rate securities, through at least the next 12 months. However, we may seek to obtain additional financing prior to that time. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews of 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;
- 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.
- our ability to license LibiGel or other products for development and commercialization;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our proposed products;
- our general and administrative expenses;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

If we raise additional funds through the issuance of equity securities, our stockholders may experience dilution, which could be significant. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our stockholders. If financing is not

available when required or is not available on acceptable terms, or additional sublicense agreements are not signed, we may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the development of our proposed products and commercial introduction of our products.

Uses of Cash and Cash Flow

Cash provided by operating activities was $739,991 for year ended December 31, 2007 versus cash used in operating activities of $5.0 million for the year ended December 31, 2006. Cash provided by operating activities was primarily the result of 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. Cash used in operating activities for the year ended December 31, 2006 was primarily the result of the recognition of the $10.5 million Nycomed receivable, 25 percent of which was due to our licensor partially offset by the net income for that period. Net cash used in investing activities was $11.2 million for the year ended December 31, 2007 versus cash provided by investing activities of $5.0 million for the year ended December 31, 2006. Net purchases of short-term investments of $11.2 million and net redemptions of short-term investments of $5.0 million were the primary reasons for the net cash used in and the net cash provided by investing activities in 2007 and 2006, respectively. Net cash provided by financing activities for the year ended December 31, 2007 was $18.5 million and resulted primarily from the completion of a private placement in June 2007 that resulted in net proceeds to us of approximately $17.3 million, after deduction of transaction expenses, and warrant and stock option exercises, which resulted in net proceeds to us of $1.2 million. Net cash provided by financing activities for the year ended December 31, 2006 was $7.4 million and was primarily the result of the completion of our June 2006 private placement that resulted in net proceeds to us of approximately $7.2 million, after deduction of transaction expenses. In exchange for a license with MATC, we received an ownership position in MATC of approximately five percent of the common stock of MATC. We recorded non-cash licensing revenue of $140,000 related to this license and have recorded our investment in MATC using the cost method.

We used cash in operating activities of $5.0 million for the year ended December 31, 2006 versus cash used in operating activities of $8.3 million for the year ended December 31, 2005. The decrease in cash used in operating activities reflects the net income we recognized in 2006 versus a net loss in 2005, partially offset by an increase in accounts receivable attributed to the sublicense payments we expected to and did receive from Nycomed during the first and fourth quarters of 2007, which were recorded as revenue in 2006. Net cash provided by investing activities was $5.0 million for the year ended December 31, 2006 versus cash provided by investing activities of $7.2 million for the year ended December 31, 2005. Redemption of short-term investments provided $13.0 million in cash during 2006, and we used $8.0 million to purchase short-term investments and $39,255 to purchase computer equipment during 2006. Redemption of short-term investments provided $7.7 million in cash during 2005, while $392,375 was used to purchase short-term investments and $67,416 to purchase additional computers and office equipment during 2005. Net cash provided by financing activities during the year ended December 31, 2006 was $7.4 million, approximately $7.2 million of which resulted from our July 2006 private placement, after deduction of transaction expenses and $243,675 of which resulted from stock option exercises. Net cash provided by financing activities during the year ended December 31, 2005 was $197,768 and was primarily the result of option and warrant exercises.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2007. We have, however, several potential financial commitments, including product development milestone and royalty payments to the licensor of certain of our hormone therapy products, payments under our license agreement with Wake Forest University Health Sciences, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2007:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating Leases	$ 205,437	$ 169,206	$ 36,231	—	—
Obligation under License Agreement with Antares	1,063	1,063	—	—	—
Commitments Under License Agreement with Wake Forest	720,000	70,000	210,000	160,000	280,000
Total Contractual Cash Obligations	$ 926,500	$ 240,269	$ 246,231	$ 160,000	$ 280,000

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 July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("FIN 48"), which provides guidance for the accounting for uncertainty in tax positions. 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. We adopted the provisions of FIN 48 on January 1, 2007. The adoption of FIN 48 did not have an impact on our results of operations or financial condition.

In September 2006, the 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 would be separately disclosed by level within the fair value hierarchy. SFAS 157 will be effective for us January 1, 2008. The adoption of SFAS 157 is not expected to have an impact on our results of operations or financial condition.

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 will be effective for us beginning January 1, 2008. The adjustment to reflect the difference between the fair value and the carrying amount would be accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. We do not expect to elect the fair value option for any of its existing financial assets and liabilities, and therefore the adoption of SFAS 159 is not expected to have an impact on our current results of operations or financial condition. The future impact, if any on our results of operations or financial condition of electing the fair value option for future financial assets and liabilities, is not known.

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. We have not yet determined the impact, if any, that the adoption of EITF 07-1 will have 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 is effective for us prospectively for new contractual arrangements entered into beginning January 1, 2008. We have not yet determined the impact, if any, that the adoption of EITF 07-3 will have on our results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) "Business Combinations" ("SFAS 141(R)"). SFAS 141(R) retains the fundamental requirements of the original pronouncement requiring that the purchase method be used for all business combinations. SFAS 141(R) defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date that the acquirer achieves control and requires the acquirer to recognize the assets acquired, liabilities assumed and any noncontrolling interest at their fair values as of the acquisition date. SFAS 141(R) also requires that acquisition-related costs be recognized separately from the acquisition. SFAS 141(R) will be effective for us for the fiscal year beginning January 1, 2009. The adoption of SFAS 141(R) is not expected to have an impact on our results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financials Statements" ("SFAS 160"). This standard outlines the accounting and reporting for ownership interest in a subsidiary held by parties other than the parent. SFAS 160 will be effective for us beginning January 1, 2009. SFAS 160 is to be applied prospectively, except for the presentation and disclosure requirements. The adoption of SFAS 160 is not expected to have an impact on our results of operations or financial condition.

In December 2007, the U.S. Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 110 ("SAB 110") to amend the SEC's views discussed in Staff Accounting Bulletin 107 ("SAB 107") and extend the use of the simplified method in developing an estimate of expected life of share options in accordance with SFAS No. 123(R). SAB 110 is effective for us beginning January 1, 2008. We expect to use the simplified method until we have the historical data necessary to provide a reasonable estimate of the expected life of our options in accordance with SAB 110.

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 have invested in highly liquid and high quality debt securities. To minimize the exposure due to adverse shifts in interest rates, we typically have invested in short-term securities with maturities of less than one year.

At December 31, 2007, we held investments in $14.5 million of investment-grade auction rate securities, the underlying assets of which are student loans backed by the federal government. Although such securities typically have been very liquid, such liquidity recently has been impacted as a result of recent events in the credit markets, including the markets for these securities, and currently there is no liquid market for these securities. Although we believe we will be able to liquidate our investments in our auction rate securities in the near term without any significant loss, the timing of such an outcome is uncertain. Therefore, we are exposed to market risk related to our investments in auction rate securities. For further details, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

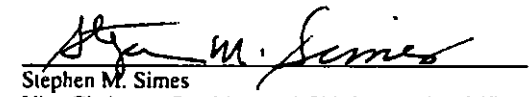
As management of BioSante Pharmaceuticals, Inc., we are responsible for establishing and maintaining an adequate system of internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, for BioSante Pharmaceuticals, Inc. This 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, 2007. 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, 2007.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2007 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report herein.



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

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

March 17, 2008

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

Deloitte

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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, 2007 and 2006, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. 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, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, 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, 2007, 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 17, 2008, expressed an unqualified opinion on the Company's internal control over financial reporting.

Deloitte & Touche LLP

March 17, 2008

Deloitte

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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, 2007, 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, 2007, 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, 2007 of the Company and our report dated March 17, 2008, expressed an unqualified opinion on those financial statements.

Deloitte & Touche LLP

March 17, 2008

BIOSANTE PHARMACEUTICALS, INC.
Balance Sheets
December 31, 2007 and 2006

	December 31, 2007	December 31, 2006
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 15,648,948	$ 7,653,852
Short-term investments	15,005,976	3,795,977
Accounts receivable	14,566	10,510,529
Prepaid expenses and other assets	337,420	248,116
	31,006,910	22,208,474
PROPERTY AND EQUIPMENT, NET (Note 4)	54,896	137,040
OTHER ASSETS		
Investment in MATC (Note 3)	140,000	-
Deposits	39,536	25,326
	$ 31,241,342	$ 22,370,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 10)	$ 710,575	$ 621,818
Due to licensor - Antares (Note 3)	1,063	2,625,000
Provision for contingencies (Note 11)	-	550,588
Accrued compensation	717,409	368,522
Other accrued expenses	77,712	65,500
Deferred revenue	9,091	68,182
	1,515,850	4,299,609
STOCKHOLDERS' EQUITY (Note 6)		
Capital stock		
Issued and Outstanding		
2007 - 391,286; 2006 - 391,286 Class C special stock	391	391
2007 - 26,794,607; 2006 - 22,975,040 Common stock	84,206,583	64,967,887
	84,206,974	64,968,278
Accumulated Deficit	(54,481,482)	(46,897,047)
	29,725,492	18,071,231
	$ 31,241,342	$ 22,370,840

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
Statements of Operations
Years ended December 31, 2007, 2006 and 2005

	Year Ended December 31,		
	2007	2006	2005
REVENUE			
Licensing revenue	$ 199,091	$ 14,136,364	$ 45,455
Grant revenue	59,060	247,257	180,896
Royalty Revenue	69,353	-	-
Other revenue	165,550	55,000	32,000
	493,054	14,438,621	258,351
EXPENSES			
Research and development	4,751,313	3,908,290	6,409,080
General and administration	4,331,361	4,549,620	3,800,555
Licensing expense	-	3,500,000	-
Depreciation and amortization	89,824	117,781	100,938
	9,172,498	12,075,691	10,310,573
OTHER - Interest income	1,095,009	428,343	401,186
NET (LOSS) INCOME	$ (7,584,435)	$ 2,791,273	$ (9,651,036)
(Loss) Income per common share (Note 2):			
Basic	$ (0.30)	$ 0.13	$ (0.50)
Diluted	$ (0.30)	$ 0.13	$ (0.50)
Weighted average number of common and common equivalent shares outstanding:			
Basic	25,485,513	21,190,946	19,392,116
Diluted	25,485,513	21,483,911	19,392,116

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
Statements of Stockholders' Equity
Years ended December 31, 2007, 2006 and 2005

	Class C Special Shares		Common Stock		Deferred Unearned	Accumulated	
	Shares	Amount	Shares	Amount	Compensation	Deficit	Total
Balance, December 31, 2004	**391,286**	**398**	**18,955,181**	**56,455,451**	**(497,959)**	**(40,037,284)**	**15,920,606**
Issuance of common shares							
Option exercises - various	-	-	14,270	41,518	-	-	41,518
Warrant exercises - various	-	-	37,825	156,250	-	-	156,250
Stock option compensation - executive officers	-	-	-	-	351,500	-	351,500
Share redesignation	-	-	524	-	-	-	-
Net loss	-	-	-	-	-	(9,651,036)	(9,651,036)
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 (FAS 123R)	-	-	-	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 (FAS 123R)	-	-	-	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**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
Statements of Cash Flows
Years ended December 31, 2007, 2006 and 2005

	December 31, 2007	2006	2005
CASH FLOWS PROVIDED BY (USED IN) OPERATING ACTIVITIES			
Net (loss) income	$ (7,584,435)	$ 2,791,273	$ (9,651,036)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities			
Depreciation and amortization	89,824	117,781	100,938
Employee and director stock-based compensation	711,259	1,076,832	351,500
Stock warrant expense - noncash	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	(103,514)	(15,985)	52,128
Accounts receivable	10,495,963	(10,510,529)	-
Accounts payable and accrued liabilities	449,856	(745,332)	(101,834)
Provision for contingencies	(550,588)	(199,412)	750,000
Due to licensor - Antares	(2,623,937)	2,625,000	(3,750)
Deferred revenue	(59,091)	(136,363)	204,545
Net cash provided by (used in) operating activities	739,992	(4,996,735)	(8,297,509)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES			
Redemption of short term investments	981	13,004,723	7,700,150
Purchase of short term investments	(11,210,979)	(8,009,812)	(392,375)
Purchase of capital assets	(29,428)	(39,255)	(67,416)
Net cash (used in) provided by investing activities	(11,239,426)	4,955,656	7,240,359
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Proceeds from sale or conversion of shares	18,494,531	7,384,288	197,768
Net cash provided by financing activities	18,494,531	7,384,288	197,768
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,995,097	7,343,209	(859,382)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,653,852	310,643	1,170,025
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 15,648,949	$ 7,653,852	$ 310,643
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			
Investment in MATC - noncash	$ 140,000	$ -	$ -

See accompanying notes to the financial statements.

1. ORGANIZATION

BioSante Pharmaceuticals, Inc. (the "Company") was established to develop prescription pharmaceutical products, vaccines, vaccine adjuvants and drug delivery systems using its nanoparticle technology ("CaP") licensed from the University of California. The research and development on the CaP technology is conducted in the Company's Doylestown, Pennsylvania laboratory facility. In addition to its nanoparticle technology, the Company also has been developing its pipeline of hormone therapy products to treat men and women, many of which products were licensed from Antares Pharma, Inc. The Company's business office is located in Lincolnshire, Illinois. The Company had been considered a development stage enterprise through the third quarter and into the fourth quarter of 2006. With the recognition of significant licensing revenues as a result of the Company's first FDA approved product during the fourth quarter of 2006, the Company is no longer a development stage company.

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, which consist primarily of auction rate securities, 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The fair value of investments is determined based on quoted market prices at the reporting date for those instruments. As of December 31, 2007, and December 31, 2006, the Company had $15.0 million and $3.8 million of short-term investments, respectively. The investment balance consisted of auction rate securities investments of $14.5 million and money market fund investments of approximately $500,000 as of December 31, 2007, and of auction rate securities investments of $3.5 million and money market fund investments of approximately $300,000 as of December 31, 2006. There were no gains or losses recorded in accumulated other comprehensive income as of December 31, 2007 or December 31, 2006, 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, 2007, December 31, 2006 or December 31, 2005.

As of December 31, 2007, the Company's investments had maturity dates ranging from May 1, 2030 to May 1, 2046. Despite the long-term contractual maturities of the underlying debt of the auction rate securities held at December 31, 2007, all of these securities were classified as short-term investments as it was the Company's intention to liquidate these securities within one year.

Liquidity for our auction rate securities typically has been provided by an auction process which has allowed us the opportunity to sell the securities at each auction date, and for those securities not sold, resets the applicable interest rate every 28 days. Although auctions have been successful for periods immediately subsequent to December 31, 2007, recently auctions for our auction rate securities have failed which therefore have eliminated our ability to sell these securities through the standard auction process. Currently there is no liquid market for these securities. There is no assurance that future auctions in our auction rate securities will succeed. An auction failure means that the parties wishing to sell their securities could not be matched with an adequate volume of buyers. In the event that there is a failed auction the indenture governing the security requires the issuer to pay interest at a contractually defined rate which may or may not correspond to market rates for other types of similar short-term instruments. Our securities for which auctions have failed will continue to accrue interest at the contractual rate and be subject to the auction process every 28 days until the auction succeeds, the issuer redeems the securities or they mature. As a result, our ability to liquidate our investment in these securities and use the cash proceeds to operate our business in the near term may be limited. Our ability to fully recover the carrying value of our investment in these securities may also be limited or non-existent in the near term. However, these recent developments may result in the classification of some or all of these securities as long-term investments in our future financial statements.

All of the underlying assets of our auction rate securities are student loans substantially all of which are backed by the federal government under the Federal Family Education Loan Program. Substantially all of our auction rate securities are currently rated AAA, the highest rating available by a rating agency. However, it could take until the final maturity or issuer refinancing of the underlying debt for us to realize the recorded value of our investments in these securities. If the issuers of our auction rate securities are unable to successfully close future auctions or redeem or refinance the securities and their credit ratings deteriorate, we may in the future be required to record an impairment charge on these investments, and may need to sell these securities on a secondary market. Although we believe we will be able to liquidate our investments in these securities without any significant loss, the timing and financial impact of such an outcome is uncertain.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation of computer, office and laboratory equipment is computed primarily by accelerated methods over estimated useful lives of seven years. Leasehold improvements are amortized on a straight-line basis over the terms of the leases, plus reasonably assured optional renewals.

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.

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) per income 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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. The standard also requires estimating the number of instruments that will ultimately be issued, rather than accounting for forfeitures as they occur.

The following table presents the pro forma impact of applying SFAS 123(R) in prior years.

	2005
Net (loss)/income	
As reported	$ (9,651,036)
Stock-based compensation included in net (loss)/income as reported	351,500
Total stock-based employee compensation determined under fair value based method for all awards	(784,329)
Pro forma net (loss)/income	$ (10,083,865)
Basic and diluted net (loss)/income per share	
As reported	$ (0.50)
Pro forma	$ (0.52)

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 180,000 shares of the Company's common stock were issued in 2007.

Correction of Prior Period Presentation

Subsequent to the issuance of the financial statements for the year ended December 31, 2006, an error was identified in the presentation of expenses related to stock-based compensation, which had been presented as a separate line item on the face of the income statement, in order to include such amounts in the relevant income statement captions to which the stock compensation expense related. As a result, prior period income statement reclassifications have been made to correct the presentation as follows:

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

For the year ended December 31, 2006:

Account Description	As Previously Reported	Impact of Reclassification	As Corrected
Research and development expense	3,855,660	52,630	3,908,290
General and administrative expense	3,525,418	1,024,202	4,549,620
Stock compensation expense	1,076,832	(1,076,832)	—

For the year ended December 31, 2005:

Account Description	As Previously Reported	Impact of Reclassification	As Corrected
Research and development expense	6,311,440	97,640	6,409,080
General and administrative expense	3,546,695	253,860	3,800,555
Stock compensation expense	351,500	(351,500)	—

These reclassifications had no impact on net (loss) income or (loss) income per share for either year or for any period.

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 expected to be recognized within the next twelve months is classified as a current liability. Deferred revenue will be recognized as revenue in future periods when the applicable revenue recognition criteria have been met.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Income Taxes

Deferred tax assets or liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates. A valuation allowance is provided against deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is more likely than not. The Company has provided a full valuation allowance against its net deferred tax assets as of December 31, 2007 and 2006.

Recent Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("FIN 48"), which provides guidance for the accounting for uncertainty in tax positions. 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. We adopted the provisions of FIN 48 on January 1, 2007. The adoption of FIN 48 did not have an impact on our results of operations or financial condition.

In September 2006, the 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 would be separately disclosed by level within the fair value hierarchy. SFAS 157 will be effective for us January 1, 2008. The adoption of SFAS 157 is not expected to have an impact on our results of operations or financial condition.

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 will be effective for us beginning January 1, 2008. The adjustment to reflect the difference between the fair value and the carrying amount would be accounted for as a cumulative-effect adjustment to retained earnings as of the date of initial adoption. We do not expect to elect the fair value option for any of its existing financial assets and liabilities, and therefore the adoption of SFAS 159 is not expected to have an impact on our current results of operations or financial condition. The future impact, if any on our results of operations or financial condition of electing the fair value option for future financial assets and liabilities, is not known.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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. We have not yet determined the impact, if any, that the adoption of EITF 07-1 will have 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 is effective for us prospectively for new contractual arrangements entered into beginning January 1, 2008. We have not yet determined the impact, if any, that the adoption of EITF 07-3 will have on our results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007) "Business Combinations" ("SFAS 141(R)"). SFAS 141(R) retains the fundamental requirements of the original pronouncement requiring that the purchase method be used for all business combinations. SFAS 141(R) defines the acquirer as the entity that obtains control of one or more businesses in the business combination, establishes the acquisition date as the date that the acquirer achieves control and requires the acquirer to recognize the assets acquired, liabilities assumed and any noncontrolling interest at their fair values as of the acquisition date. SFAS 141(R) also requires that acquisition-related costs be recognized separately from the acquisition. SFAS 141(R) will be effective for us for the fiscal year beginning January 1, 2009. The adoption of SFAS 141(R) is not expected to have an impact on our results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financials Statements" ("SFAS 160"). This standard outlines the accounting and reporting for ownership interest in a subsidiary held by parties other than the parent. SFAS 160 will be effective for the Company beginning January 1, 2009. SFAS 160 is to be applied prospectively, except for the presentation and disclosure requirements. The adoption of SFAS 160 is not expected to have an impact on our results of operations or financial condition.

In December 2007, the U.S. Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 110 ("SAB 110") to amend the SEC's views discussed in Staff Accounting Bulletin 107 ("SAB 107") and extend the use of the simplified method in developing an estimate of expected life of share options in accordance with SFAS No. 123(R). SAB 110 is effective for us beginning January 1, 2008. We expect to use the simplified method until we have the historical data necessary to provide a reasonable estimate of expected life of the options in accordance with SAB 110.

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 hormone therapy 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. These equity investments resulted in the Company issuing a total of 1,368 shares of its common stock to Paladin at a 10 percent premium to the Company's market price in 2006. The dollar value of the premium, $6,250, was recorded as equity in the statements of stockholders' equity for 2006. No shares were issued to Paladin in 2007.

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-licenses 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. We believe 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.

3. LICENSE AGREEMENTS (continued)

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 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. The product is owned by the Company with no royalty or milestone obligations to any other party. 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.

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 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 is recognizing revenue from the agreement on a pro rata basis over the term of the agreement as the Company has not yet completed all of its required performance under the terms of the agreement. The remainder of the upfront payment is 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. If the option is exercised and the parties enter into an exclusive license agreement, the Company will receive a one-time license fee, annual maintenance payments, milestone payments upon the achievement of regulatory milestones and royalties on commercial sales of any allergy product that is developed using CaP.

3. LICENSE AGREEMENTS (continued)

In November 2006, the Company entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. ("Bradley") for the marketing of Elestrin, the Company's estradiol gel, in the United States. Effective February 21, 2008, Nycomed US Inc. ("Nycomed") completed its acquisition of Bradley. As a result, all references to Bradley have been changed to Nycomed in these financial statement and the notes hereto. Upon execution of the sublicense agreement, the Company received an upfront payment of $3.5 million. In addition, Nycomed paid the Company $7.0 million and $3.5 million in the first and fourth quarters of 2007, respectively, both triggered by the FDA approval of Elestrin in the U.S., which occurred in the fourth quarter of 2006. The Company licenses the transdermal estradiol gel formulation that is used in Elestrin from Antares

Pharma IPL AG ("Antares"). Under its license agreement with Antares, the Company is obligated to pay Antares 25 percent of all licensing-related proceeds and a portion of any future associated royalties that the Company may receive. As a result, the Company was required to pay Antares $2.625 million and $875,000 during the years ended December 31, 2007 and December 31, 2006, respectively. The aggregate $14.0 million received from Nycomed (consisting of the following amounts paid by Nycomed to the Company: $3.5 million in the fourth quarter of 2006, $7.0 million in the first quarter of 2007 and $3.5 million in the fourth quarter of 2007) 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. Nycomed also has agreed to pay the Company additional payments of up to $40 million in the event certain sales-based milestones are achieved, plus royalties on sales of Elestrin which totaled $69,353 for the year ended December 31, 2007. The Company is obligated to pay 25 percent of any sales-based milestone payments and a specified portion of royalties to Antares, which the Company will recognize as these payments are triggered, based on reported levels of Elestrin sales. Nycomed began its commercial launch of Elestrin in June 2007.

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 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 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, 2007 and 2006 consist of the following:

	2007	2006
Computer equipment	$ 129,753	$ 101,083
Office equipment	126,044	155,191
Laboratory equipment	36,019	129,433
Leasehold improvements — Laboratory	0	520,339
	291,816	906,046
Accumulated depreciation and amortization	(236,920)	(769,006)
	$ 54,896	$ 137,040

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. The closure of the Smyrna facility caused the decrease in the laboratory equipment and laboratory leasehold improvements balances.

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 January 1, 2007 or December 31, 2007.

The Company has analyzed its filing positions in all significant federal and state jurisdictions were 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 2004 through 2007 tax years.

The components of the Company's net deferred tax asset at December 31, 2007 and 2006 were as follows:

	2007	2006
Net operating loss carryforwards	$ 17,588,392	$ 14,669,434
Tax basis in intangible assets	538,819	674,141
Research & development credits	2,569,848	2,308,522
Stock option expense	1,017,790	749,290
Other	103,235	258,321
	21,818,084	18,659,708
Valuation allowance	(21,818,084)	(18,659,708)
	$ —	$ —

5. INCOME TAXES (continued)

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2007, the Company had approximately $46,591,767 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 2018-2027. 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 $2,569,848 of research and development credits, which are available to reduce future income taxes, if any, through the year 2027.

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:

	2007	2006	2005
Tax at U.S. federal statutory rate	**$ (2,616,630)**	$ 962,989	$ (3,329,607)
State taxes, net of federal benefit	**(246,494)**	90,716	(313,659)
Research and development credits	**(162,675)**	(135,632)	(255,723)
Change in valuation allowance	**3,158,376**	(950,595)	3,702,476
Other, net	**(132,577)**	32,522	196,513
	$ —	$ —	$ —

6. STOCKHOLDERS' EQUITY

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.

On July 21, 2006, the Company closed a private placement of 3,812,978 shares of its common stock and associated warrants to purchase 1,334,542 shares of its common stock at a purchase price of $2.00 per unit to certain institutional and other accredited investors for gross proceeds of approximately $7.6 million. The private placement resulted in net proceeds to the Company of approximately $7.2 million, after deduction of transaction expenses. The warrants are exercisable for a period of four years and nine months, beginning January 22, 2007, at an exercise price of $2.75 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.

6. STOCKHOLDERS' EQUITY (continued)

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, 2007.

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, 2007 and 2006.

Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share. There were 26,794,607 and 22,975,040 shares of common stock issued and outstanding as of December 31, 2007 and 2006, respectively. The Company has presented the par values of it's 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
323,614	$ 2.15	August 8, 2008
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

Pursuant to the Company's private placement financing in August 2003, warrants to purchase an aggregate of 2,767,366 shares of common stock were issued at an exercise price of $2.15 per share with a term of five years. Warrants to purchase an aggregate of 323,614 shares of common stock remained outstanding and were exercisable as of December 31, 2007.

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, 2007.

6. **STOCKHOLDERS' EQUITY (continued)**

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, 2007.

During 2005, warrants to purchase 31,250 shares of common stock were exercised for a total cash proceeds of $156,250. Warrants to purchase an aggregate of 6,575 shares of common stock were exercised on a cashless basis, for which 4,925 additional warrants were cancelled by the Company in payment of the exercise price for the exercised warrants, thus reducing the number of shares 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.

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.

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, 2007, the Company recorded $32,906 in non-cash general and administrative expense pertaining to these consultant warrants..

c) Options

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.

In 2006, options to purchase an aggregate of 91,849 shares of common stock were exercised for total cash proceeds of $243,675, and options to purchase an aggregate of 177,385 shares of common stock were exercised on a cashless basis resulting in the issuance of 61,045 shares of common stock and the withholding and subsequent cancellation of 116,340 shares of common stock to pay the exercise price of such options.

7. STOCK-BASED COMPENSATION

As of December 31, 2007, the Company maintained one stock-based compensation plan, the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan, which is described below. The non-cash, stock-based compensation cost that has been incurred by the Company in connection with this plan was $711,259 and $1,076,832 for the year ended December 31, 2007 and 2006, respectively. No income tax benefit has been recognized in the Company's statement of operations for the stock-based compensation arrangements due to the Company's net loss position.

The BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (the "Plan") permits the grant of stock options and stock awards to its employees, directors and consultants. As of December 31, 2007, 3,000,000 shares of the Company's common stock were reserved for issuance under the Plan, subject to adjustment as provided in the plan. As of December 31, 2007, 1,209,336 of the 3,000,000 shares remained available for issuance. The Company believes that equity-based incentives, such as stock options and stock awards, align the interest of its employees and directors with those of its stockholders. Options are generally granted with an exercise price equal to the market price of the Company's common stock on the date of the grant; outstanding employee stock options generally vest ratably over a period of time and have 10-year contractual terms. During 2006, stock options were granted to directors which were exercisable immediately. As a result, stock-based compensation expense was recognized on the grant date in an amount equal to the fair value of the related options. No stock awards have been granted under the Plan. The Compensation Committee of the Board of Directors of the Company may at its sole discretion modify or accelerate the vesting of any stock option or stock award at any time but may not reprice any outstanding options without obtaining stockholder approval.

The weighted average fair value of the options at the date of grant for options granted during 2007, 2006 and 2005 was $2.37, $3.11 and $3.79, 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:

	2007	2006	2005
Expected option life (years)	**9.83**	10	10
Risk free interest rate	**4.74%**	4.10%	3.96%
Expected stock price volatility	**69.31%**	73.94%	73.91%
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 of 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 SAB 107, 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

7. STOCK-BASED COMPENSATION (continued)

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 Company expects all outstanding unvested stock options to vest according to their normal vesting schedule. A summary of activity under the Plan during the year ended December 31, 2007 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2006	1,011,479	$ 3.61
Granted	590,000	3.61
Exercised	(53,081)	4.21
Forfeited or expired	(121,207)	4.53
Outstanding December 31, 2007	1,427,191	$ 3.50
(weighted average contractual term)	*7.4 years*	
Exercisable at December 31, 2007	770,858	$ 3.40
(weighted average contractual term)	*6.1 years*	

The aggregate intrinsic values of the Company's outstanding and exercisable options as of December 31, 2007 were $801,868 and $403,744, respectively.

A summary of the Plan's non-vested options at December 31, 2007 and activity under the Plan during the year ended December 31, 2007 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2006	207,833	$ 3.65
Granted	590,000	3.61
Vested	(102,167)	4.03
Forfeited	(39,333)	4.20
Non-Vested at December 31, 2007	656,333	$ 3.62

As of December 31, 2007, there was $1,229,080 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted under the Plan. The cost is expected to be recognized over a weighted-average period of 2.30 years.

Cash received from option exercises under the Plan for the years ended December 31, 2007, 2006 and 2005 was $192,371, $243,675 and $41,518, respectively. The intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was $136,020, $218,613 and $17,480, 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, 2007, 2006 and 2005 was $326,254, $1,076,832 and $784,329, respectively.

7. STOCK-BASED COMPENSATION (continued)

4,082,843 and 3,044,885 options and warrants were excluded from the earnings per share calculation for the years ended December 31, 2007 and December 31, 2005, 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. 1,261,475 options and warrants 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 Plan) to all of its employees. Under the Plan, employees may defer income on a tax-exempt basis, subject to IRS limitation. Under the Plan, the Company can make discretionary matching contributions. Company contributions expensed in 2007, 2006 and 2005 totaled $59,683, $45,327 and $71,188, respectively.

9. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space which expires in 2009 and its laboratory facility which expires in 2008. The future minimum lease payments during 2008 and 2009 are $169,206 and $36,231, respectively.

Rent expense amounted to $259,971, $236,824 and $219,516 for the years ended December 31, 2007, 2006 and 2005, respectively.

10. RELATED PARTY TRANSACTIONS

Included in current liabilities on the balance sheet are $28,841 and $25,353, 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, 2007 and 2006, respectively.

11. COMMITMENTS AND CONTINGENCIES

The Company may incur contingent liabilities which may arise during the normal course of business. Management believes the ultimate outcome of such matters will not have a material adverse impact on the financial position or results of operations of the Company.

University of California License

In August 2006, the Company entered into a Fourth Amendment to Exclusive License Agreement for patents related to the Company's CaP technology with The Regents of the University of California. Under the terms of the amendment, the Company amended certain terms of the agreement, including the elimination of future specified minimum annual royalties which equal in excess of $3 million owed to the University of California in exchange for an immediate payment of $100,000. Under the terms of the original agreement, $75,000 would have been due on February 28, 2007 for which the Company had accrued $37,500 at the time of the amendment. No future minimum royalty payments are required under the amended contract.

11. COMMITMENTS AND CONTINGENCIES (continued)

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 $2,625,000 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 $2,625,000 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.

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
2008	60,000
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.

11. COMMITMENTS AND CONTINGENCIES (continued)

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 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.

Contingencies

In May 2006, the Company, certain officers, one of its directors and a former officer entered into a Settlement Agreement related to a personnel matter, under which the Company agreed to pay the former officer post-termination payments in the aggregate amount of $780,000 in equal installments in accordance with the Company's regular payroll cycle through December 31, 2007, plus $110,000 of legal fees incurred by the former officer. As required by the agreement, the payments were secured by an irrevocable letter of credit, which was supported by the Company's short-term investment account. The outstanding balances under the letter of credit and corresponding accrued liability were $0 and $550,588 as of December 31, 2007 and December 31, 2006, respectively.

In July 2006, the Company reached an agreement with its employment practices liability insurance carrier pursuant to which in August 2006, the carrier paid the Company $500,000 in settlement of the Company's claim against the carrier for coverage in this matter. The costs of the Settlement Agreement and corresponding insurance payment receipt have been included in general and administrative expenses in the statements of operations.

12. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2007 and 2006 is as follows:

	2007			
	First(1)	Second(1)	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)

	2006			
	First(1)	Second(1)	Third(1)	Fourth
Revenue	$ 84,679	$ 175,251	$ 140,324	$ 14,038,367
Research and development expenses	1,002,539	1,098,250	766,592	1,040,909
General and administrative expenses	1,520,344	1,228,741	210,552	1,589,983
Licensing expense	—	—	—	3,500,000
Operating (loss) income	(3,324,674)	(2,295,058)	(867,545)	8,850,207
Net (loss) income	(3,228,495)	(2,224,900)	(745,061)	8,989,729
(Loss) income per share:				
Basic and diluted	$ (0.17)	$ (0.11)	$ (0.03)	$ 0.44

(1) Certain 2007 and 2006 quarterly financial data have been corrected to reflect the reclassification of stock option expense. See Note 2, Summary of Significant Accounting Policies to the financial statements included herein.

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 and principal financial officers, 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 caption "Management's Report on Internal Control over Financial Reporting."

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, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Indemnification Agreements

On March 11, 2008, our Board of Directors approved a form of indemnification agreement to be entered into with each of our current directors and executive officers (each, the "Indemnitee"). The indemnification agreements provide, among other things, subject to the procedures set forth in the indemnification agreements: (i) that we will indemnify the Indemnitee to the fullest extent permitted by our Amended and Restated Certificate of Incorporation, Bylaws and the Delaware General Corporation Law in the event the Indemnitee was or is a party to or involved with an action, suit or proceeding by reason of the fact that the Indemnitee is or was serving as one of our officers or directors; (ii) that we will advance expenses incurred by the Indemnitee in any such proceeding, including attorneys' fees, to the Indemnitee in advance of the final disposition of the proceeding; (iii) that the rights of the Indemnitees under the indemnification agreements are in addition to any other rights the Indemnitees may have under our Amended and Restated Certificate of Incorporation, Bylaws, the Delaware General Corporation Law or otherwise; and (iv) for certain exclusions from our obligations under the agreements.

Pursuant to the indemnification agreements, we have agreed to refrain from amending our Amended and Restated Certificate of Incorporation or Bylaws to diminish the Indemnitees' rights to indemnification under the indemnification agreements. We have also agreed to maintain directors' and officers' liability insurance coverage for our directors and officers, so long as such insurance is available on a commercially reasonable basis.

The summary of the indemnification agreements described above is qualified in its entirety by reference to the form of indemnification agreement attached hereto as Exhibit 10.30 and incorporated herein by reference.

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 disclose any amendments to and any waivers from a provision of our Code of Conduct and Ethics on a Form 8-K filed with the SEC.

Changes to Nomination Procedures

During the fourth quarter of 2007, 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.

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

Our only equity compensation plan under which shares of BioSante common stock may be issued is the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan. Except otherwise stated below, options granted in the future under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock 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. We expect to submit to our stockholders at our next annual meeting of stockholders a proposal to approve a new stock incentive plan, which would replace the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan pursuant to which we could issue up to 2 million shares of our common stock. The following table summarizes outstanding stock options under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of December 31, 2007.

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	1,427,191	$ 3.50	1,209,336
Equity compensation plans not approved by security holders	0	N/A	0
Total	1,427,191	$ 3.50	1,209,336

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 "Proposal Three – Ratification of Selection of Independent Registered Public Accounting Firm – 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.

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 87-92. 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. Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended (incorporated by reference to Exhibit 10.1 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-31812)).

B. Employment Agreement, dated June 11, 1998, between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg, as amended (incorporated by reference to Exhibit 10.17 to BioSante's Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 000-28637)).

C. 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)).

D. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's executive officers (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)).

E. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's executive officers (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)).

F. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's directors (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)).

G. Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's directors and executive officers (filed herewith).

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

I. Description of Executive Officer Compensation Arrangements (filed herewith).

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 17, 2008

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 Stephen M. Simes	Vice Chairman, President and Chief Executive Officer	March 17, 2008
/S/ LOUIS W. SULLIVAN, M.D. Louis W. Sullivan, M.D.	Chairman of the Board	March 11, 2008
/S/ FRED HOLUBOW Fred Holubow	Director	March 11, 2008
/S/ PETER KJAER Peter Kjaer	Director	March 11, 2008
/S/ ROSS MANGANO Ross Mangano	Director	March 11, 2008
/S/ EDWARD C. ROSENOW, III Edward C. Rosenow, III	Director	March 11, 2008

BIOSANTE PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2007

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 in connection with the August 2003 Private Placement	Incorporated by reference to Exhibit 10.2 contained in BioSante's Form 8-K as filed with the Securities and Exchange Commission on August 6, 2003 (File No. 0-28637)
4.2	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)
4.3	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)
4.4	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)
10.1	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Incorporated by reference to Exhibit 10.1 to BioSante's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-31812)

Exhibit No.	Exhibit	Method of Filing
10.2	Employment Agreement, dated June 11, 1998, between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg, as amended	Incorporated by reference to Exhibit 10.17 to BioSante's Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 000-28637)
10.3	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)
10.4	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's executive officers	Incorporated by reference to Exhibit 10.5 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.5	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's executive officers	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)
10.6	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's directors	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)
10.7	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)
10.8	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)
10.9	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 1, 2005 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14	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)
10.15	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)
10.16	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)

Exhibit No.	Exhibit	Method of Filing
10.17	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)
10.18	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)
10.23	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, 2001 (File No. 0-28637)
10.24	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)

Exhibit No.	Exhibit	Method of Filing
10.25	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)
10.26	Common Stock and Warrant Purchase Agreement dated August 4, 2003 between BioSante Pharmaceuticals, Inc. and the purchasers listed on schedule 1 thereto	Incorporated by reference to Exhibit 10.1 contained in BioSante's Form 8-K, filed on August 6, 2003 (File No. 0-28637)
10.27	Investor Rights Agreement dated August 4, 2003 between BioSante Pharmaceuticals, Inc. and the purchasers listed on Schedule 1 attached to the Common Stock and Warrant Purchase Agreement	Incorporated by reference to Exhibit 10.3 contained in BioSante's Form 8-Kas filed with the Securities and Exchange Commission on August 6, 2003 (File No. 0-28637)
10.28	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)
10.29	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)
10.30	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its directors and executive officers	Filed herewith
10.31	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.32	Description of Executive Officer Compensation Arrangements	Filed herewith
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

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.

BOARD OF DIRECTORS

Louis W. Sullivan, M.D.
Chairman of the Board of Directors
BioSante Pharmaceuticals, Inc.
President Emeritus
Morehouse School of Medicine

Stephen M. Simes
Vice Chairman, President and Chief
Executive Officer
BioSante Pharmaceuticals, Inc.

Fred Holubow
Vice President
Pegasus Associates, an operating division of
William Harris Investors

Peter Kjaer
President and Chief Executive Officer
Jet-Asia Ltd.

Ross Mangano
President and Director
Oliver Estate, Inc.

Edward C. Rosenow III, M.D.
Master Fellow
American College of Physicians and the American
College of Chest Physicians

OFFICERS

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

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

CORPORATE INFORMATION

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E-Mail: info@biosantepharma.com

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Doylestown, Pennsylvania

Transfer Agent and Registrar
Computershare Investor Services, LLC
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Chicago, Illinois 60602
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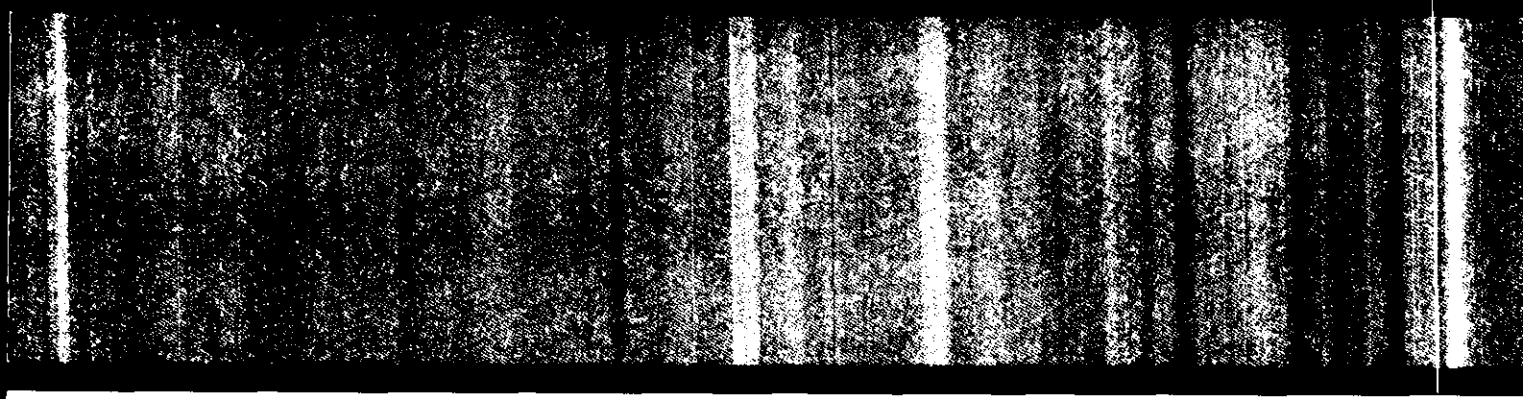
Legal Counsel
Oppenheimer Wolff & Donnelly LLP
Minneapolis, Minnesota

Independent Registered Public Accounting Firm
Deloitte & Touche L.L.P.
Chicago, Illinois

Stockholder Services
For a change of name, address, or to replace a lost stock certificate, contact BioSante's transfer agent.

Annual Meeting
BioSante's Annual Meeting of Stockholders will be held at 10:00 a.m., Central Time, on June 12, 2008.



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