BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 27, 2007

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

FORM 10-K

(Mark one)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006

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

FOR THE TRANSITION PERIOD FROM TO .

Commission file number 001-31812

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

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
111 Barclay Boulevard **Lincolnshire, Illinois** (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 Exchange Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	**The American Stock Exchange**

Securities registered under Section 12(g) of the Exchange Act:
None

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

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

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

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

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

Large accelerated filer: o Accelerated filer: o Non-accelerated filer: x

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

The aggregate market value of the registrant s common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sales price at which the common stock was last sold as of June 30, 2006 (the last business day of the registrant s second quarter) as reported by the American Stock Exchange, was $38,084,678.

As of March 15, 2007, 22,975,040 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 2007 Annual Meeting of Stockholders to be held in June 2007.

TABLE OF CONTENTS

Item 1. DESCRIPTION OF BUSINESS
General
Business Strategy
Hormone Therapy Market
Description of Our Hormone Therapy Products
Description of Our CaP Technology and Products
Sales and Marketing
Research and Product Development
Manufacturing
Patents, Licenses and Proprietary Rights
Competition
Governmental Regulation
Employees
Forward-Looking Statements
Available Information

Item 1A. RISK FACTORS

Item 1B. UNRESOLVED STAFF COMMENTS

Item 2. PROPERTIES

Item 3. LEGAL PROCEEDINGS

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

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Item 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER REPURCHASES OF EQUITY SECURITIES
Market Price
Number of Record Holders; Dividends
Recent Sales of Unregistered Equity Securities
Issuer Purchases of Equity Securities
Stock Performance Graph

Item 6. SELECTED FINANCIAL DATA

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
General Overview
Financial Overview
Critical Accounting Policies
Results of Operations
Liquidity and Capital Resources
Recent Accounting Pronouncements

Item 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK
Item 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
Item 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE
Item 9A.	CONTROLS AND PROCEDURES Evaluation of Disclosure Controls and Procedures Change in Internal Control Over Financial Reporting
Item 9B.	OTHER INFORMATION
Item 10.	DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT
Item 11.	EXECUTIVE COMPENSATION
Item 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS Securities Authorized for Issuance Under Equity Compensation Plans
Item 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS
Item 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES
Item 15.	EXHIBITS, FINANCIAL STATEMENTS, SCHEDULES

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K

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 used in this report, including without limitation, BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-E-Gel®, Elestrin , Bio-E/P-Gel , LibiGel®, LibiGel-E/T and Bio-T-Gel . 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 licenses and 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 vaccine adjuvants or immune system boosters and drug delivery systems.

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 hot flashes and decreased sexual desire and sexual activity. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen.

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 hormone therapy gel products:

- Elestrin (formerly known as Bio-E-Gel) once daily transdermal bioidentical estrogen gel FDA-approved for the treatment of menopausal symptoms in women.

- LibiGel once daily transdermal bioidentical testosterone gel in Phase III development for treatment of female sexual dysfunction (FSD).

- Bio-E/P-Gel once daily transdermal combination gel of bioidentical estrogen and a progestogen for treatment of menopausal symptoms in women.

- LibiGel-E/T once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone for treatment of FSD in menopausal women.

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

- Triple Hormone Contraceptive the use of LibiGel in women using oral 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). We submitted an NDA for Elestrin in February 2006 and received approval of the NDA from the FDA for Elestrin in December 2006. The Elestrin FDA approval is 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 agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Prior to submitting an NDA or ANDA for our other hormone therapy products, the products must undergo additional human clinical trials. Our proposed LibiGel product has successfully completed a

Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and 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, 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. Second, 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). Third, our CaP technology is being tested in the area of aesthetic medicine.

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

- 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.

- BioCap using CaP technology in the field of aesthetic medicine.

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 the treatment of human hormone deficiencies. We submitted an NDA with the FDA for Elestrin in February 2006 and received approval of the NDA for Elestrin in December 2006. In November 2006, we entered into an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Under the terms of the agreement, we received an upfront payment and will receive FDA approval-triggered milestone payments, royalties on net sales and sales based milestone payments. Prior to submitting an NDA or ANDA for our other hormone therapy products, the products must undergo additional human clinical trials. Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006.

- ***Continue to develop our nanoparticle-based CaP platform technology and seek assistance in the 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 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 us to introduce into the market products incorporating our CaP technology sooner than we otherwise would be able. In addition, these collaborations have enabled us to minimize our spending on the development of products incorporating our CaP technology.

- ***Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies***. We continually monitor opportunities to enter into business collaborations or joint ventures with entities that have businesses or technologies complementary to our business.

- ***License or otherwise acquire other drugs that will add value to our current product portfolio***. We will consider opportunities to in-license or otherwise acquire other products in the late-stage development phase. In reviewing these opportunities, we consider products that cover therapeutic areas treated by a limited number of physicians and drugs that are in or require human clinical trials that involve a limited number of subjects and not a significant amount of time and cost needed to complete them. We believe that products that are currently in or ready for human clinical trials would decrease the risks associated with product development and would likely shorten the time before the products can be introduced into the market. In addition to late-stage development products, we would also consider opportunities to in-license or otherwise acquire products that (1) have FDA approval, (2) have been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have an extensive portfolio under development.

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 menopausal symptoms in women, including hot flashes, vaginal atrophy, decreased sexual desire, sexual activity and impotence, lack of sex drive and muscle weakness in men. The primary goal of hormone therapy is to safely and effectively relieve these symptoms with minimal side effects.

Estrogen and Combined Estrogen Therapy for Women. 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 most common physical symptoms of natural or surgical menopause and the resultant estrogen deficiency are hot flashes, vaginal atrophy, decreased sexual desire, sexual activity 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 $1.3 billion in 2006, of which the transdermal segment, mostly patches, is reported at about $250 million. As the baby boomer generation ages, the number of women reaching menopause and needing estrogen or combined estrogen therapy is expected to increase.

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-only products are only recommended for use by women who do not have a uterus. 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 by healthy women. 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 hormone 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 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. 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, creams, gels 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, 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 bioidentical 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.; a transdermal lotion marketed by Esprit Pharma; a transdermal gel developed by Solvay Pharmaceuticals, Inc. and our Elestrin transdermal gel to be marketed by Bradley Pharmaceuticals, Inc.

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. Female sexual dysfunction, or FSD, is often 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 the key efficacy endpoint chosen by the FDA for pivotal clinical trials of FSD therapies. There are several testosterone therapy products for the treatment of FSD in development, including our LibiGel product, Proctor & Gamble s Intrinsa patch and products being developed by Vivus, Inc.

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 hypoactive sexual desire disorder.

Procter & Gamble has since withdrawn its NDA for Intrinsa and it is our understanding that they have 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. In October 2005, the FDA updated its guidance for development of testosterone for HSDD. The FDA acknowledges the efficacy of testosterone in the treatment of HSDD. Procter & Gamble received European regulatory approval for its Intrinsa patch in July 2006 and it is our understanding that Procter & Gamble intends to begin marketing the product in Europe 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 with the FDA, we believe two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel. We began the first of these two Phase III trials in December 2006.

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 may also 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 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 15% in 2006 to $510 million from $440 million in 2005.

Description of Our Hormone Therapy Products

Overview. Our hormone therapy products are gel formulations of bioidentical testosterone, bioidentical estradiol, a combination of bioidentical estradiol and bioidentical testosterone and a combination of bioidentical estradiol and a progestogen. Bioidentical refers to the structure of the hormone which is equivalent to the testosterone and estradiol produced by men and women. 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 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.

Elestrin. Our estrogen formulated gel product, Elestrin, is a once daily gel designed to deliver estrogen without the skin irritation associated with, and the physical presence of, transdermal patches, and to avoid the effects of oral estrogen. Elestrin contains bioidentical 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 per day is the lowest daily dose of estradiol approved by the FDA for the treatment of hot flashes.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of $2.625 million. In addition, in March 2007, Bradley paid us $5.25 million which was triggered by FDA approval of Elestrin by Bradley in the U.S. and has agreed to pay us an additional $2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares Pharma IPL AG, our licensor of the transdermal estradiol gel formulation in Elestrin, as a result of our receipt of such payments from Bradley. Bradley also has agreed to pay us additional sales-based milestone payments, plus royalties on sales of Elestrin. It is our understanding that Bradley is planning to commercially launch Elestrin in mid-2007.

LibiGel. Our LibiGel product is a once daily transdermal testosterone gel designed to treat female sexual dysfunction, specifically hypoactive sexual desire disorder, or HSDD. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes due to aging or following surgical menopause. Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006.

The Phase II LibiGel trial was a double-blind, placebo-controlled study to determine the effect of LibiGel on women s sexual activity. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel.

Our Phase II trial showed statistically significant results for the primary endpoints of the study. In the U.S.-based, double-blind, placebo-controlled study of 46 women to determine the effect of LibiGel on women s sexual activity, 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.

In December 2006, we initiated the first of two Phase III clinical trials of LibiGel. The double-blind, placebo-controlled Phase III trial will enroll approximately 360 surgically menopausal women for a six-month clinical trial, conducted under a Phase III protocol and investigational new drug application (IND) reviewed by and on file with the FDA.

Our Other Hormone Therapy Products. In addition to Elestrin and LibiGel, our hormone therapy products include Bio-E/P-Gel, LibiGel-E/T and Bio-T-Gel. In addition, we have in-licensed 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.

Women whose uteri are intact often use combined hormone therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial hyperplasia and endometrial cancer associated with estrogen-alone therapy in these women. Our Bio-E/P-Gel, which is a combined estrogen/progestogen gel product, has been licensed to Solvay Pharmaceuticals, B.V., which has been responsible for all costs of development to date.

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 Bio-T-Gel. Teva USA also is responsible under the terms of this agreement for continued development, regulatory filings and all manufacturing and marketing associated with the product. 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 commercialized product upon approval in exchange for rights to develop and market Bio-T-Gel in the United States. Teva USA has discontinued development of Bio-T-Gel and indicated to us a desire to formally terminate this agreement. Accordingly, we are in the process of exploring various alternatives with respect to our Bio-T-Gel product, including licensing the product to another third party or continuing the development of the product ourselves. We believe the decision by Teva to discontinue the development of Bio-T-Gel is based on strategic decisions by Teva.

LibiGel is a non-partnered product; and therefore, we can control better the timing and future development and commercialization of this product, subject to customary and inevitable uncertainties associated with the product development process, regulatory approvals and market acceptance of such product. Those products we have licensed to others, such as Bio-E/P-Gel and Bio-T-Gel, are reliant on our partners for timely development, obtaining required regulatory approvals, commercialization and an ongoing commitment to the products, subject to regulatory and market conditions. From time to time, based on various circumstances including market analysis or a change in the strategic plan of the partner,

a partner may elect to restructure or terminate its arrangement with us, which may result in entering into a revised agreement or a mutual termination. Any restructuring or termination of these agreements by such partners as Solvay Pharmaceuticals, B.V. or Teva Pharmaceuticals USA, Inc. could adversely affect the timing of the development and or commercialization of the products underlying the licenses if we are unable to license the proposed products to another qualified partner on substantially the same or better economic terms or continue the development and or commercialization of the proposed products ourselves.

Description of Our CaP Technology and Products

We believe our CaP technology can serve as an effective vehicle for delivering drugs and vaccines and enhancing the effects of vaccines. Our CaP nanoparticles have successfully passed the first stage of toxicity studies for administration orally, into muscles, under the skin, and into the lungs by inhalation. We have successfully 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). For comparison, a polio virus particle is about 27 nm in diameter, a herpes virus particle has a central core measuring 100 nm in diameter, contained in an envelope measuring 150-200 nm, while a tuberculosis bacterium is rod-shaped, about 1,200 nm long by 300 nm across. 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 coated 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.

A major immune response that is triggered by these combination particles is the creation of antibody molecules, which can then specifically counteract an invading virus or bacterium. Similarly, a drug will produce an effect on an organ system only if it can attach to specific receptors on the surface of target cells (e.g., tumor cells). The stabilizing and slow release capabilities of a drug carrier and delivery system based on this discovery can lead to significant advances towards finding more effective and less toxic or harmful molecules to seek out and attach to such receptors.

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, through 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:

- 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 teams in our laboratories in Smyrna, Georgia and Doylestown, Pennsylvania are currently pursuing the development of our CaP technology in these areas as well as exploring other areas, such as allergy and aesthetic medicine applications.

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 no vaccines currently exist, for example, a bird flu vaccine. 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. 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 trial was completed and there was no apparent difference in the side effects profile between CaP and placebo.

Drug Delivery Systems. The second 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. Pfizer has received FDA approval of its Exubera inhaled insulin product. 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 successfully created a formulation for the inhaled delivery of insulin, which we call BioAir. We are working with potential licensees for the further development of our BioOral and BioAir. 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.

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

- BioVant proprietary CaP adjuvant technology in development for improved versions of current vaccines and new vaccines against allergies, 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 administration (including the buccal and intranasal routes of 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.

We have completed a Phase I human clinical trial of CaP as a vaccine adjuvant and delivery system, a necessary step in the process of obtaining FDA approval to market the product. 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 February 2007, an FDA advisory committee recommended approval of 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.

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.

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, which we call BioVant, for use in other companies vaccines, have to date included meeting with target companies and, in some cases, agreeing that the target company will test our CaP adjuvant or delivery system in their animal models. Thereafter, the target company may send to us its vaccine antigen or DNA that we will then formulate with our nanoparticles and return for use in the target company s animal models. Once this is completed, if the results are positive, we would seek to negotiate an out-license agreement with the target company.

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. Under the terms of the option and license agreement, MATC will use our 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. Within the first 18 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

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 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. Our subcontract is for the first year of the grant, and we have applied to renew the subcontract for a second year. Revenue related to the first year of the subcontract of $162,707 was recognized in 2006, and the

second year of the subcontract is valued at $75,000. 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 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. 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.

In January 2004, we announced the signing of a subcontract with DynPort Vaccine Company LLC for the development of anthrax vaccines for delivery via alternative routes of administration, including nasal, oral and needle-free transcutaneous routes. Under the subcontract, we provide BioVant and DynPort provides recombinant antigens to be used in potential vaccines against anthrax. The objective is 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. The subcontract is in support of the U.S. Department of Defense Joint Vaccine Acquisition Program. We have successfully completed this contract and are currently seeking partners or licensors to continue with this vaccine development process.

In September 2003, we announced that we were awarded a $100,000 Small Business Innovation Research (SBIR) grant from the National Institutes of Health to support our development of formulations for the oral delivery of insulin using our CaP technology. We have completed the work outlined under this grant and are currently investigating our options with respect to a Phase II SBIR grant.

It is important to point out that vaccine development is an expensive and long-term process. We have used our strategy of utilizing 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 long-term and expensive development work.

Sales and Marketing

We currently have no sales and marketing personnel to sell on a commercial basis any of our products. Under our sublicense agreements, our sub-licensees have agreed to market the products covered by the agreements in certain countries. For example, under our sublicense agreement with Bradley Pharmaceuticals, Inc., Bradley 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. If and when we are ready to commercially launch a product not covered by our 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. In addition, we retain co-promotion rights for Bio-E/P-Gel, the product covered under the Solvay Pharmaceuticals, Inc. sublicense agreement.

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. We spent

approximately $3,856,000 in 2006 and $6,311,000 in 2005 on research and development activities. To date, we have no revenues from the commercial sale of our products. As a result, these research and development costs were financed by us. We spent an average of approximately $300,000 to $350,000 per month on our research and development activities during 2006. Additionally, we recognized a license expense fee to Antares Pharma IPL AG, our Elestrin formulation licensor, in the amount of $3,500,000, as a result of the execution of the Elestrin sublicense agreement with Bradley in November 2006 and subsequent FDA approval of Elestrin in December 2006, which also resulted in our recognition of $14 million in licensing revenue during 2006. We expect our research and development expenses to potentially be significantly higher in 2007 compared to 2006 as a result of the commencement of our LibiGel Phase III clinical trial program, which we initiated in December 2006. We expect our research and development expenses to remain at the average 2006 levels until late in the second quarter of 2007, when we expect them to increase to approximately $600,000 to $800,000 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) resources available; (2) our development schedule, including the timing of our clinical trials; (3) whether we or our sublicensees are funding the development of our proposed products; (4) results of studies, clinical trials and regulatory decisions 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 a U.S.-based cGMP approved manufacturer 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 IPL AG 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. Antares has an 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, including those licensed to us. Our license agreement with Antares required us to pay a $1,000,000 up-front license fee to Antares and to pay royalties to Antares based on a percentage of the net sales of any products our sublicensees, such as in the case of Elestrin, Bradley Pharmaceuticals, Inc., sell incorporating the licensed technology.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of $2.625 million. In addition, in March 2007, Bradley paid us $5.25 million which was triggered by FDA approval of Elestrin by Bradley in the U.S. and has agreed to pay us an additional $2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. Bradley also has agreed to pay us additional sales-based milestone

payments, plus royalties on sales of Elestrin. It is our understanding that Bradley is planning to commercially launch Elestrin in mid-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 proposed Bio-T-Gel product 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 commercialized product upon approval in exchange for rights to develop and market a hormone therapy product. Teva USA is also responsible under the terms of this agreement for continued development, regulatory filings and all manufacturing and marketing associated with the product. 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 commercialized product upon approval in exchange for rights to develop and market Bio-T-Gel in the United States. Teva USA has discontinued development of Bio-T-Gel and indicated to us a desire to formally terminate this agreement. Accordingly, we are in the process of exploring various alternatives with respect to our Bio-T-Gel product, including licensing the product to another third party or continuing the development of the product ourselves. We believe the decision by Teva to discontinue the development of Bio-T-Gel is based on strategic decisions by Teva.

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. As described further below, the Canadian rights to this product had previously been sublicensed to Paladin as part of that sublicense arrangement and were repurchased by us prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of our common stock with a market value of $125,000 at the date of the transaction.

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. The financial terms of the license include an upfront payment by us in exchange for exclusive rights to the license, and regulatory milestone payments, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed. 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.

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. The University of California has also 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 $8,236 in 2006.

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 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. Our subcontract is for the first year of the grant, and we have applied to renew the subcontract for a second year. The first year of the subcontract was valued at approximately $250,000 and we have applied for $75,000 for the second year. 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. Under the terms of the option and license agreement, MATC will use our 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. MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine prior to mid July 2007 upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

Patents and patent applications. We have licensed a patent portfolio relating to hormone therapy from Antares Pharma IPL AG. The expiration dates of these patents vary, ranging to 2017. The rights to this portfolio are governed by our license agreement with Antares, and 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.

In February 2007, we announced that a notice of allowance from the United States Patent and Trademark Office had been received covering the formulation used in Elestrin. The notice of allowance is the official communication issued by the U.S. Patent and Trademark Office reporting that the application has successfully completed examination and that a patent will be issued after the applicant pays the necessary fee. This new patent is calculated to expire in June 2022. This patent lists our personnel as inventors of the formulation.

In addition, we own two United States patents related to our CaP technology and we have filed for patent protection for a number of foreign counterparts. We have filed a number of additional patent applications with the U.S. Patent and Trademark Office relating to our development work with CaP, including such applications as a vaccine adjuvant, as a carrier for biologically active material and as part of a controlled release matrix for biologically active material. In addition, we have other patent applications pending in the U.S. and internationally for CaP technology. With respect to CaP we have also licensed patents from the University of California and our rights to use those patents are governed by the applicable license agreement.

Trademarks and trademark applications/registrations. We have filed trademark applications in the U.S. and certain foreign jurisdictions for the mark BIOSANTE, as well as for other trademarks covering goods that include vaccines and vaccine adjuvants, drug delivery platforms and/or hormone therapy products. In addition to the BIOSANTE mark, trademark protection is claimed, through common law rights and/or the registration process, for the following marks: BIO-E-GEL, ELESTRIN, BIO-T-GEL, BIO-E/P-GEL, CAP-ORAL, BIOVANT, BIOAIR, NANOVANT, LIBIGEL and LIBIGEL-E/T. For those trademarks for which registration has been sought, registrations have issued for some of these 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 products in the late-stage development phase or already on the market. 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 The Procter & Gamble Company, Vivus, Inc., Noven Pharmaceuticals, Inc., Wyeth, Auxilium Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc. Competitor hormone therapy products include oral tablets, transdermal patches and gels. We expect

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. A competitive or comparable company to us includes Corixa Corporation (now owned by GlaxoSmithKline plc), generally regarded as a leader in vaccine adjuvant development.

Governmental Regulation

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:

- preclinical laboratory and animal tests;
- the submission to the FDA of an investigational new drug application, commonly known as an IND application;
- clinical and other studies to assess safety and parameters of use;
- adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug product;
- the submission to the FDA of a new drug application, commonly known as an NDA, or an abbreviated NDA, commonly known as an ANDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the product.

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.

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 this 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.

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 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. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

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.

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 eight full-time employees as of December 31, 2006, including five in product development and three 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. For example, we engaged Michael C. Snabes, M.D., Ph.D. as an independent consultant to work with our product development team in last year s completion of our Elestrin NDA activities, as well as work on LibiGel development. Dr. Snabes is a board certified reproductive endocrinologist, as well as holding a Ph.D. in physiology and reproductive endocrinology. Most recently, Dr. Snabes was an Associate Professor in the Section of Reproductive Endocrinology and Infertility in the Department of Obstetrics and Gynecology at The University of Chicago Pritzker School of Medicine.

Forward-Looking Statements

This annual report on Form 10-K contains or incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, might, possibl potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate or continu terms of similar meaning. These forward-looking statements may be contained in the notes to our financial statements and elsewhere in this report, including under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations. Our forward-looking statements generally relate to:

- the timing of the commencement 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; and
- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading 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 website 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.

Although we were profitable for the fiscal year ended December 31, 2006, we have a history of operating losses, expect continuing losses and may never again achieve profitability.

Although we recognized net income of $2,791,273 for the year ended December 31, 2006, we have incurred losses in each year since our amalgamation in 1996 until this year and may incur substantial and continuing losses for the foreseeable future. As of December 31, 2006, our accumulated deficit was $46,897,047.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and revenue earned from subcontracts. We have not commercially introduced any products. Although we expect our new marketing partner, Bradley Pharmaceuticals, Inc., to commercially launch Elestrin in mid-2007 for which we will be entitled to receive royalties on the net sales, 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 our LibiGel product which commenced in December 2006. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the commercial success and net sales of Elestrin, on which we will receive royalties;
- the timing and cost of obtaining third party reimbursement; and
- the costs of licensure or acquisition of new products.

In order to generate new and significant revenues, we must successfully develop our own proposed products and enter into collaborative agreements with others who can successfully commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, 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 other 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 will need to raise substantial additional capital to fund our operations. We believe that our cash and short-term investments of $11,449,829 at December 31, 2006, together with payments we are currently entitled to receive from Bradley under our sublicense agreement with Bradley, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for 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 and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the commercial success and net sales of Elestrin, on which we will receive royalties;
- 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 one or more 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 we expect will be commercially introduced in mid-2007 by our marketing partner, Bradley Pharmaceuticals, Inc., none of our products have been commercially introduced nor do we expect them to be for several years. We cannot assure you that any of our other proposed products will:

- be successfully developed;
- prove to be safe and efficacious 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 it is our understanding that Procter & Gamble (P&G) is planning to commercially launch Intrinsa, its testosterone patch, in Europe, it is also our understanding P&G has not made any final decision as to whether it will continue to pursue regulatory approval of Intrinsa in the United States. Should P&G decide not to move forward with the development and subsequent marketing of Intrinsa in the U.S., that decision may have an adverse effect on the potential size of the U.S. female sexual dysfunction (FSD) market, the potential market for our LibiGel product and our ability to find a development partner to share in the cost of such development if we choose to seek such a partner.

In December 2004, the FDA s Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of P&G s Intrinsa testosterone patch for hypoactive sexual desire disorder. The panel s main concern was the desire to have long-term 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. Currently, the FDA has not explicitly publicly stated nor set any type of public policy or guidance document as to what size or duration of a safety trial would be required for approval.

It is our understanding that P&G is planning to commercially launch Intrinsa, its testosterone patch for FSD, in Europe. It is also our understanding that P&G has not made any final decision as to whether it will continue to pursue regulatory approval of Intrinsa in the United States. It is possible that P&G will decide not to continue to develop Intrinsa in the U.S. which will adversely affect the potential size of the U.S. female sexual dysfunction market and the potential for our LibiGel product. In addition, it may adversely effect our ability to find a development partner to share in the cost of development if we decide to seek such a partner.

Several pharmaceutical products have been found to have potentially life threatening side effects and have been subsequently removed from the market. These drugs had been previously approved for sale by the FDA. The withdrawals of approved drugs from the market create an increased risk for the pharmaceutical industry in general in that certain proposed products may not receive the required regulatory approval on a timely basis or ever. The withdrawal of Vioxx by Merck & Co., Inc. in September 2004 has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, these withdrawals have resulted and may continue to result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilence after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

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 negatively affected 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 have recently 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, will receive 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 market acceptance of the product, and its success is also now dependent upon the success of Bradley in marketing and selling the product. We cannot assure you that Bradley will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of our agreement. Any breach by Bradley 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 IPL AG 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 owing 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 IPL AG 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 three 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 three of our hormone therapy product to third parties, Bradley Pharmaceuticals, Inc., Solvay Pharmaceuticals, B.V. and Teva Pharmaceuticals USA, Inc. Both Solvay and Teva 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 partnered 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. Any 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 now 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 Bradley Pharmaceuticals, Inc. 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 partners, will not succeed in developing similar technologies and products more rapidly than we do, commercially introducing such technologies and products to the marketplace prior than 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 showing 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 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 quickly recruited.

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.

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 has fluctuated over a wide range. In 2006, our common stock traded in a range from a low of $1.48 to a high of $4.80, and our daily trading volume ranged from 4,500 shares to 3,016,500 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 American Stock Exchange, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC; and
- economic conditions in the United States and abroad.

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% in one trading day and over 50% 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 300,000 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.

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

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act requires our management beginning with our fiscal year ended December 31, 2007 to assess the effectiveness of our internal controls over financial reporting (ICFR) and beginning with our fiscal year ended December 31, 2008 to provide a report by our registered independent public accounting firm addressing our management s assessment and independent audit of ICFR. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. While we feel that our key controls are currently effective, we have not yet completed a formal assessment of our ICFR. We continue to enhance our ICFR by adding additional resources in key functional areas and bringing all of our operations up to the level of documentation, segregation of duties, and systems security necessary, as well as transactional control procedures required, which we believe to be necessary under current and proposed standards issued by the Public Company Accounting Oversight Board and the SEC.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effects on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the American Stock Exchange. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in ICFR, we will be unable to assert that our ICFR is effective. If we are unable to assert that our ICFR is effective (or if our auditors are unable to attest that management s report is fairly stated, they are unable to express an opinion on our management s evaluation or on the effectiveness of the internal controls or they issue an adverse opinion on ICFR), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective ICFR in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective ICFR could have an adverse effect on our common stock price.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our principal executive office is located in a leased facility in Lincolnshire, Illinois. In December 2003, we entered into a lease agreement for approximately 4,000 square feet of office space for approximately $6,700 per month. In March 2004, we signed an amendment to this lease effective April 1, 2005. Pursuant to that amendment, we have moved to approximately 6,800 square feet in the same building for rent equal to approximately $12,000 per month. We further amended this lease in February 2007 to extend the term of the lease until March 2008. Our CaP development operations are located in Smyrna, Georgia where we lease approximately 11,840 square feet of laboratory space for approximately $6,700 per month. This lease expires in October 2007. Additionally, we rent approximately 1,500 square feet of furnished lab and office space within the Bucks County Biotech Park in Pennsylvania for approximately $3,300 per month. This lease is renewable in one year increments beginning in July 2007. Management of our company considers our leased properties suitable and adequate for our current and foreseeable needs.

Item 3. LEGAL PROCEEDINGS

Not applicable.

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, 2006.

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and the offices held, as of March 15, 2007, are as follows:

Name	Age	Title
Stephen M. Simes	55	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	46	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 or her successor is elected and qualified or until his or her 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 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 closing 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 during on the American Stock Exchange.

American Stock Exchange

2005	High	Low
First Quarter	$ 5.94	$ 3.92
Second Quarter	$ 4.27	$ 3.15
Third Quarter	$ 4.35	$ 3.15
Fourth Quarter	$ 4.58	$ 2.81

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

Number of Record Holders; Dividends

As of March 15, 2007, there were 381 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, 2006, 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, 2006. 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, 2002 until December 31, 2006, 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, 2002, 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 the results of operations and balance sheet data of our company:

	Year Ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands, except per share data)				
Statement of Operations Data:					
Licensing revenue	$ 14,136	$ 45	$ 10	$ 65	$ 2,770
Grant revenue	247	181	68		
Other revenue	55	32			
Total revenue	14,867	258	78	65	2,770
Interest income	429	401	250	87	64
Expenses					
Research and development	3,856	6,311	9,008	3,691	4,787
General and administration	3,525	3,547	2,678	2,327	1,766
Licensing expense	3,500				
Stock compensation expense	1,077	351	556		
Depreciation and amortization	118	101	102	93	92
Total expenses	12,076	10,310	12,344	6,111	6,645
(Loss) income before other expenses	2,791	(9,651)	(12,016)	(5,959)	(3,811)
Net (loss) income	$ 2,791	$ (9,651)	$ (12,016)	$ (5,959)	$ (3,811)
Basic and diluted net (loss) income per share	$ 0.13	$ (0.50)	$ (0.70)	$ (0.54)	$ (0.51)
Weighted average number of shares outstanding	21,191	17,145	17,145	11,039	7,503

	As of December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short term investments	$ 11,450	$ 9,102	$ 17,269	$ 9,134	$ 4,884
Total assets	22,371	9,575	17,827	9,565	5,880
Stockholders equity	18,071	6,819	15,921	8,684	4,624

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 notes thereto.

General Overview

We are a biopharmaceutical company that licenses and 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 vaccine adjuvants or immune system boosters and drug delivery systems.

Hormone Therapy Products. Our hormone therapy products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen. Our hormone therapy products include Elestrin, LibiGel, Bio-E/P-Gel, LibiGel-E/T, Bio-T-Gel and triple hormone contraceptives. We license the technology underlying our hormone therapy products, except Bio-T-Gel and triple hormone contraceptives, from Antares Pharma IPL AG. Bio-T-Gel was developed and is fully-owned by us. Our license agreement with Antares required us to pay an up-front license fee to Antares, certain development and regulatory milestone payments and to pay royalties to Antares based on a percentage of the net sales of any products our sublicensees sell incorporating the licensed technology. We license the technology underlying our proposed triple hormone contraceptives from Wake Forest University Health Sciences (formerly known as Wake Forest University) 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 subsequently marketed.

We have entered into several sublicense agreements covering our hormone therapy products, including an 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, a development and license agreement with Teva Pharmaceuticals USA, Inc., pursuant to which Teva USA agreed to develop our proposed Bio-T-Gel product 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, and royalty payments to us if a product incorporating the licensed technology gets approved and subsequently marketed.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the agreement, we received an upfront payment of $2.625 million. In addition, in March 2007, Bradley paid us $5.25 million which was triggered by FDA approval of Elestrin in the U.S. and has agreed to pay us an additional $2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. Bradley also has agreed to pay us additional sales-based milestone payments, plus royalties on sales of Elestrin. It is our understanding that Bradley is planning to commercially launch Elestrin in mid-2007.

We completed our pivotal Phase III clinical trial of Elestrin in April 2005, submitted an NDA for Elestrin with the FDA in February 2006 and received FDA approval for Elestrin in December 2006. The Elestrin FDA approval is a non-conditional and full approval with no Phase IV development commitments. In addition, we received three years of marketing exclusivity for Elestrin. Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel.

CaP Technology and Proposed Products. Our strategy with respect to CaP 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, under a subcontract with DynPort Vaccine Company LLC, we provided BioVant 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 have completed this subcontract and recorded approximately $300,000 in revenue over the life of the subcontract with $82,985 being recorded in 2006. 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. We recorded revenue of $164,271 in 2006 related to this subcontract.

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 this 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 revenue of $136,364 in 2006 related to this contract. 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. Prior to mid-July 2007, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses. We believe these collaborations may enable us to accelerate the development of potential improved vaccines and vaccines that can be delivered other than by injection as well as delivery by non-injected routes products that now must be injected.

Financial Overview

All of our revenue to date has been derived from upfront and milestone 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 Bradley, our marketing partner for Elestrin, expects to commercially launch Elestrin in mid-2007, at which point we will then be entitled to receive

royalties on any net sales of Elestrin and milestone payments upon the achievement of certain sales-based milestones.

To date, we have used primarily equity financing and licensing 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, we recognized $14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in December 2006. Upon execution of the Bradley agreement, we received an upfront payment of $2.625 million. In addition, in March 2007, Bradley paid us $5.25 million and has agreed to pay us an additional $2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. We also received approximately $7.2 million in net proceeds from a private placement of our common stock and warrants to purchase shares of our common stock and $243,675 in proceeds from stock option exercises during 2006. Our cash, cash equivalents and short-term investments were $11,449,829 as of December 31, 2006.

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. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we will need to raise substantial additional capital to fund our operations. We believe that our cash and short-term investments of December 31, 2006, together with payments we expect to receive from Bradley under our sublicense agreement with Bradley, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. However, we may seek to obtain additional financing prior to that time, or we may choose to sublicense another product for development and commercialization.

We spent an average of approximately $300,000 to $350,000 per month on research and development activities in 2006. Additionally, we recognized a license expense to Antares during fourth quarter of 2006 in the amount of $3,500,000, as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in December 2006. Our research and development expenses decreased $2,455,780 or 39 percent, to $3,855,660 for the year ended December 31, 2006 from $6,311,440 for the year ended December 31, 2005, primarily as a result of the lower spending on the Elestrin NDA and only one month of LibiGel Phase III trial expenses. We expect our research and development expenses to be higher in 2007 and beyond compared to 2006 as a result of the commencement of our Phase III clinical development program for LibiGel, which began in December 2006. Specifically, we expect our research and development expenses to remain at the average 2006 levels until late in the second quarter of 2007, when we expect them to increase to approximately $600,000 to $800,000 per month. The amount of our actual research and development expenditures may fluctuate from quarter-to-quarter and year-to-year depending upon: (1) resources available; (2) our development schedule, including the timing of our clinical trials; (3) results of studies, clinical trials and regulatory decisions; (4) whether we or our licensees are funding the development of our proposed products; and (5) competitive developments.

Pursuant to an amendment entered into with the University of California in August 2006, our license agreement with the University of California no longer requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve specific research and development milestones within a specified time period. In addition, we are no longer obligated to pay the University of California future specified minimum annual royalties which equaled in excess of $3 million. 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 this amendment.

Our general and administrative expenses for the year ended December 31, 2006 increased $588,723 or 21 percent, compared to general and administrative expenses for the year ended December 31, 2005. This increase was due to an increase in legal and business development costs, including costs associated with a personnel-related matter, net of insurance reimbursement. Our general and administrative expenses may fluctuate from year-to-year depending upon the amount of legal, public and investor relations, accounting and corporate governance and other fees and expenses incurred.

Our non-cash stock based compensation expense for the year ended December 31, 2006 increased $725,332 or 206%, compared to non-cash stock based compensation expense for the year ended December 31, 2005. The primary reason for the increase in stock based compensation expense is $746,616 of expense that was recorded related to a March 2006 issuance of stock options with immediate vesting to the non-employee members of our Board of Directors, which were fully expensed on the grant date due to the terms of those awards.

Although we recognized net income of $2,791,273 for the year ended December 31, 2006 primarily due to recognizing $14 million in licensing revenue as a result of the execution of our sublicense agreement with Bradley and subsequent FDA approval of Elestrin in 2006, we have incurred losses in each year since our amalgamation in 1996 until this year and expect to incur substantial and continuing losses for the foreseeable future. As of December 31, 2006, our accumulated deficit was $46,897,047. Although we expect Bradley to commercially launch Elestrin in mid-2007 for which we will be entitled to receive royalties on the net sales of Elestrin, 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 the Phase III clinical trial program for our LibiGel product which commenced in December 2006. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the commercial success and net sales of Elestrin, on which we will receive royalties and potential sales-based milestone payments; and
- the costs of licensure or acquisition of new products.

Critical Accounting Policies

Our significant accounting policies are described in Note 2 to our financial statements included in Item 8 of this Form 10-K. 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 most 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 recognize revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees and most recently, from subcontract revenue. Licensing income is recognized when we have completed all of our obligations under the licensing or subcontract arrangements which are required for the payment to be non-refundable. Licensing income also includes reimbursement for certain research and development expenses, which we recognize as both revenue and expense at the time the expense is incurred. To date, we have not recognized any royalty revenue.

Research and Development Costs

Research and development (R&D) costs are charged to expense as incurred. Costs associated with production of non-out licensed products are capitalized only when FDA approval has occurred. 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,		
	2006	**2005**	**2004**
Revenue	$ 14,438,621	$ 258,351	$ 77,886
Expenses	12,075,691	10,310,573	12,344,517
Research and development	3,855,660	6,311,440	9,007,846
General and administrative	3,525,418	3,546,695	2,678,187
Licensing expense	3,500,000		
Interest income	428,343	401,186	250,424
Net income (loss)	$ 2,791,273	$ (9,651,036)	$ (12,016,207)
Net income (loss) per share (basic and diluted)	0.13	(0.50)	(0.70)
Weighted average number of shares outstanding	21,190,946	19,392,116	17,145,387

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 during 2005 primarily due to the recognition of $14.0 million in licensing revenue as a result of our sublicense agreement with Bradley.

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. We expect our research and development expenses to be higher in 2007 and beyond compared to 2006 as a result of the commencement of our Phase III clinical development program for LibiGel, which began in December 2006. Specifically, we expect our research and development expenses to be approximately $600,000 to $800,000 per month during 2007 starting late in the second quarter of 2007.

Our general and administrative expenses for the year ended December 31, 2006 decreased one percent compared to general and administrative expenses for 2005.

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. We expect interest income to increase during 2007 compared to 2006 as we expect our invested average cash balance to be higher as a result of our current cash balance and receipt during 2007 of additional payments from Bradley.

The transition from net loss for the year ended December 31, 2005 to net income for the year ended December 31, 2006 was the result of the recognition of $14.0 million in licensing revenue as a result of our sublicense agreement with Bradley offset somewhat by the related recognition of $3.5 million in licensing expense.

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Revenue for the year ended December 31, 2005 increased 232 percent compared to revenue during 2004 primarily due to $157,780 received from our Dynport subcontract in 2005 versus $67,886 in 2004 and $23,116 received from our University of Nebraska subcontract in 2005.

Research and development expenses for the year ended December 31, 2005 decreased 30 percent compared to research and development expenses for 2004 primarily as a result of the completion of the Phase III clinical trial of our Elestrin product in 2005, partially offset by the costs associated with the preparation of the Elestrin NDA.

Our general and administrative expenses for the year ended December 31, 2005 increased 32 percent compared to general and administrative expenses for 2004 primarily as a result of increased legal and personnel-related expenses.

Interest income for the year ended December 31, 2005 increased 60 percent compared to interest income during 2004 primarily as a result of significantly higher average interest rates on our invested funds, partially offset by lower invested cash and short-term investment balances during 2005.

The overall decrease in the net loss for the year ended December 31, 2005 compared to 2004 was primarily the result of decreased clinical trial costs as described above partially offset by the increased legal and personnel-related expenses.

Liquidity and Capital Resources

Working Capital

We were 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 our first FDA approved product during the fourth quarter of 2006, we are no longer a development stage company for purposes of accounting treatment.

All of our revenue to date has been derived from upfront and milestone 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 partner for our Elestrin product, Bradley Pharmaceuticals, Inc., expects to commercially launch Elestrin in mid-2007, at which

point we will then be entitled to receive royalties on any net sales of Elestrin and milestone payments upon the achievement of certain sales-based milestones.

To date, we have used primarily equity financing and licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. In July 2006, we completed a private placement of 3,812,978 shares of our common stock and associated warrants to purchase 1,334,542 shares of our common stock at a purchase price of $2.00 per unit. The private placement resulted in net proceeds of approximately $7.2 million, after deduction of transaction expenses. Also in July 2006, we reached an agreement with our employment practices liability insurance carrier pursuant to which in August 2006, the carrier paid us $500,000 in settlement of our claim against the carrier for coverage in the personnel-related matter. In 2006, we also received $243,675 in proceeds from stock option exercises.

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, we received an upfront payment of $2.625 million. In addition, in March 2007, Bradley paid us $5.25 million which was triggered by FDA approval of Elestrin by Bradley in the U.S. and has agreed to pay us an additional $2.625 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. These payments are net of license fees we are required to pay Antares as a result of our receipt of such payments from Bradley. Bradley also has agreed to pay us additional sales-based milestone payments, plus royalties on sales of Elestrin.

Our cash, cash equivalents and short-term investments available to fund current operations were $11,449,829 and $9,101,531 at December 31, 2006 and 2005, respectively. Our deferred revenue was $68,182 and $204,545 at December 31, 2006 and 2005, respectively, related to unamortized portion of the allergy materials transfer and option agreement in which the revenue will be recognized equally over a 22-month development review period ending mid-year 2007. The increase in our cash and short term investment balances was primarily due to the completion of a $7.2 million private placement which occurred in July 2006 and our receipt during fourth quarter of 2006 of an upfront payment of $2.625 million as a result of our sublicense agreement with Bradley, partially offset by our use of cash to fund operations. We expect our cash balance to increase during 2007 compared to December 31, 2006 as we receive additional cash payments from Bradley due during first quarter 2007 and fourth quarter 2007, which will be offset as we continue to use cash to fund our operations. We do not have any outstanding debt.

Our business operations to date have consisted mostly of 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. 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, or we may choose to sublicense another product for development and commercialization.

We believe that our cash and short-term investments of December 31, 2006, together with payments we expect to receive from Bradley under our sublicense agreement with Bradley, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for 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 and costs of our research and development programs;
- the scope, timing and results of our clinical trials;
- patient recruitment and enrollment in our current and future clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the commercial success and net sales of Elestrin, on which we will receive royalties and potential sales-based milestone payments;
- 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, commercial introduction of our products or restrict us from acquiring new products that we believe may be beneficial to our business.

Uses of Cash and Cash Flow

We used cash in operating activities of $4,996,735 for the year ended December 31, 2006 versus cash used in operating activities of $8,297,509 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 expect to receive from Bradley during the first and fourth quarters of 2007, which were recorded as revenue in 2006. Net cash provided by investing activities was $4,955,656 for the year ended December 31, 2006 versus cash provided by investing activities of $7,240,359 for the year ended December 31, 2005. Redemption of short-term investments provided $13,004,723 in cash during 2006, and we used $8,009,812 to purchase short-term investments and $39,255 to purchase computer equipment during 2006. We used $392,375 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 $7,384,288, approximately $7.2 million of which resulted from our July 2006 private placement and $243,675 of which were due to 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.

We used cash in operating activities of $8,297,509 for the year ended December 31, 2005 versus cash used in operating activities of $10,442,443 for the year ended December 31, 2004. The decrease in cash used in operating activities primarily reflects the decreased net loss. Net cash provided by investing activities was $7,240,359 for the year ended December 31, 2005 versus cash used in investing activities

of $16,201,867 for the year ended December 31, 2004, resulting from the completion of our $16.4 million private placement in May 2004. Redemption of short-term investments provided $7,700,150 in cash during 2005, and we used $392,375 to purchase short-term investments and $67,416 to purchase computer equipment during 2005. We used $16,098,663 to purchase short-term investments and $103,204 to purchase additional office equipment during 2004. Net cash provided by financing activities during the year ended December 31, 2005 was $197,768 and resulted from option and warrant exercises. Net cash provided by financing activities during the year ended December 31, 2004 was $18,680,008 and was primarily the result of our $16.4 million private placement, which closed in May 2004.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2006. We have, however, several potential financial commitments, including product development milestone payments to the licensors 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, 2006:

	Payments Due by Period				
	Total	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 277,083	$ 240,307	$ 36,776	$	$
Obligation for Settlement Agreement	550,588	550,588			
Commitments Under License Agreement with Wake Forest	710,000	30,000	160,000	160,000	360,000
Total Contractual Cash Obligations	$ 1,537,671	$ 820,895	$ 196,776	$ 160,000	$ 360,000

We expect to continue to spend capital on:

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- general administrative expenses, involving investor relations, legal and accounting fees and expenses; and
- the licensure or acquisition of new products, general business development including out-licensing of our products in our territories.

The amount of capital we may need will depend on many factors, including the:

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our pre-clinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;

- time and cost necessary to seek marketing partners to market our products for us;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

In addition, our license agreement with the licensor of our hormone therapy products requires us to make certain payments as development milestones are achieved. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

- enter into additional leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

Under the terms of the license agreements with the University of California and Wake Forest University Health Sciences, we have the right to terminate the license agreements for any reason, with our only obligation being the payment of monies owed at the date of termination. Pursuant to an amendment entered into with the University of California in August 2006, our license agreement with the University of California no longer requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve specific research and development milestones within a specified time period.

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 July2006, 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 clarifies 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. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We do not anticipate that the adoption of FIN 48 will have a material impact on our results of operations or financial condition.

In September 2006, the FASB issued SFAS 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. The statement will be effective for us January 1, 2008 though early adoption is permitted. We have not yet determined the impact, if any, that the adoption of SFAS 157 will have on our results of operations or financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 is effective for fiscal years ending on or after November 15, 2006, with early application encouraged. We do not anticipate that the adoption of SAB 108 will have a material impact on our results of operations or financial condition.

In February 2007, the FASB issued FAS 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 is effective for fiscal years beginning after November 15, 2007. 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 have not yet determined the impact, if any, that the adoption of SFAS 159 will have on our results of operations or financial condition.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Description

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2006 and 2005

Statements of Operations for the years ended December 31, 2006, 2005 and 2004

Statements of Stockholders Equity for the years ended December 31, 2006, 2005 and 2004

Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004

Notes to the Financial Statements for the years ended December 31, 2006, 2005 and 2004
49

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, 2006 and 2005, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2006. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of BioSante Pharmaceuticals, Inc. as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 26, 2007

BIOSANTE PHARMACEUTICALS, INC.

Balance Sheets

December 31, 2006 and 2005

	December 31, 2006	December 31, 2005
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 7,653,852**	**$ 310,643**
Short-term investments	**3,795,977**	**8,790,888**
Accounts receivable	**10,510,529**	
Prepaid expenses and other sundry assets	**248,116**	**245,465**
	22,208,474	**9,346,996**
PROPERTY AND EQUIPMENT, NET (Note 4)	**137,040**	**215,566**
OTHER ASSETS		
Security deposits	**25,326**	**11,992**
	$ 22,370,840	**$ 9,574,554**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 10)	**$ 621,818**	**$ 1,139,566**
Due to Licensor - Antares (Note 3)	**2,625,000**	
Provision for contingencies (Note 11)	**550,588**	**750,000**
Accrued compensation	**368,522**	**492,980**
Other accrued expenses	**65,500**	**147,125**
Deferred revenue	**68,182**	**136,363**
TOTAL CURRENT LIABILITIES	**4,299,610**	**2,666,034**
LONG TERM LIABILITIES		
Leasehold retirement liability		**21,500**
Deferred revenue		**68,182**
TOTAL LONG TERM LIABILITIES		**89,682**
TOTAL LIABILITIES	**$ 4,299,610**	**$ 2,755,716**
STOCKHOLDERS EQUITY (Note 6)		
Capital stock		
Issued and Outstanding		
2006 - 391,286; 2005 - 391,286 Class C special stock	**391**	**398**
2006 - 22,975,040; 2005 - 19,007,800 Common stock	**64,967,887**	**56,653,219**
	64,968,278	**56,653,617**
Deferred unearned compensation		**(146,459)**
Accumulated deficit	**(46,897,047)**	**(49,688,320)**
	18,071,231	**6,818,838**
	$ 22,370,840	**$ 9,574,554**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

Statements of Operations

Years ended December 31, 2006, 2005 and 2004

	Year Ended December 31, 2006	2005	2004
REVENUE			
Licensing revenue	$ 14,136,364	$ 45,455	$ 10,000
Grant revenue	247,257	180,896	67,886
Other revenue	55,000	32,000	
	14,438,621	258,351	77,886
EXPENSES			
Research and development	3,855,660	6,311,440	9,007,846
General and administration	3,525,418	3,546,695	2,678,187
Licensing expense	3,500,000		
Stock compensation expense	1,076,832	351,500	556,541
Depreciation and amortization	117,781	100,938	101,943
	12,075,691	10,310,573	12,344,517
OTHER - Interest income	428,343	401,186	250,424
NET INCOME (LOSS)	$ 2,791,273	$ (9,651,036)	$ (12,016,207)
Income (loss) per common share (Note 2):			
Basic	$ 0.13	$ (0.50)	$ (0.70)
Diluted	$ 0.13	$ (0.50)	$ (0.70)
Weighted average number of common and common equivalent shares outstanding:			
Basic	21,190,946	19,392,116	17,145,387
Diluted	21,483,911	19,392,116	17,145,387

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

Statements of Stockholders Equity

Years ended December 31, 2006, 2005 and 2004

	Class C Special Shares		Common Stock		Deferred Unearned	Accumulated	
	Shares	Amount	Shares	Amount	Compensation	Deficit	Total
Balance, December 31, 2003	404,102	$ 404	13,548,875	$ 36,704,938	$	$ (28,021,077)	$ 8,684,265
Conversion of shares							
October 1, 2004	(1,816)	(1)	1,816	4,541			4,540
October 8, 2004	(10,000)	(4)	10,000	25,004			25,000
December 16, 2004	(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net							
May 14, 2004			2,949,000	16,370,247			16,370,247
Issuance of common shares							
Option exercises - various			142,670	234,495			234,495
Warrant exercises - various			2,317,670	1,990,120			1,990,120
Board compensation - various			2,988	16,000			16,000
Treasury shares cancellation - December 15, 2004			(18,838)				
Stock option compensation - executive officers				1,054,500	(497,959)		556,541
Section 16B short swing profit				53,105			53,105
Net loss						(12,016,207)	(12,016,207)
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**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

Statements of Cash Flows

Years ended December 31, 2006, 2005 and 2004

	December 31, 2006	2005	2004
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net income (loss)	**$ 2,791,273**	**$ (9,651,036)**	**$ (12,016,207)**
Adjustments to reconcile net income (loss) to net cash used in operating activities			
Depreciation and amortization	**117,781**	**100,938**	**101,943**
Employee & director compensation - noncash	**1,076,832**	**351,500**	**572,541**
Changes in other assets and liabilities affecting cash flows from operations			
Prepaid expenses and other sundry assets	**(15,985)**	**52,128**	**(126,269)**
Accounts receivable	**(10,510,529)**		
Accounts payable and accrued liabilities	**(745,332)**	**(101,834)**	**1,039,664**
Provision for contingencies	**(199,412)**	**750,000**	
Due to licensor - Antares	**2,625,000**	**(3,750)**	**(14,115)**
Deferred revenue	**(136,363)**	**204,545**	
Net cash used in operating activities	**(4,996,735)**	**(8,297,509)**	**(10,442,443)**
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES			
Redemption of short term investments	**13,004,723**	**7,700,150**	
Purchase of short term investments	**(8,009,812)**	**(392,375)**	**(16,098,663)**
Purchase of capital assets	**(39,255)**	**(67,416)**	**(103,204)**
Net cash provided by (used in) investing activities	**4,955,656**	**7,240,359**	**(16,201,867)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES			
Proceeds from sale or conversion of shares	**7,384,288**	**197,768**	**18,680,008**
Net cash provided by financing activities	**7,384,288**	**197,768**	**18,680,008**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**7,343,209**	**(859,382)**	**(7,964,302)**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**310,643**	**1,170,025**	**9,134,327**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 7,653,852**	**$ 310,643**	**$ 1,170,025**
Income tax paid	**$**	**$**	**$**
Interest paid	**$**	**$**	**$ 1,426**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

1. ORGANIZATION

In 1996, a predecessor company, Ben-Abraham Technologies, Inc. (BAT), purchased Structured Biologicals, Inc. (SBI). The resulting company was renamed BioSante Pharmaceuticals, Inc. in 1999. 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 Smyrna, Georgia and Doylestown, Pennsylvania laboratory facilities. In addition to its nanoparticle technology, the Company also has been developing its pipeline of hormone therapy products to treat hormone deficiencies in 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 our first FDA approved product during the fourth quarter of 2006, BioSante is no longer a development stage company (See Note 3).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These financial statements are expressed in U.S. dollars.

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

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

Short-term Investments

Short-term investments, which consist of market 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.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

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 (R&D) 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 Income (Loss) Per Share

The basic and diluted net income (loss) per share is computed based on the weighted average number of the aggregate of common stock and Class C shares outstanding, all being considered as equivalent of one another. Basic income (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The computation of diluted income (loss) 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.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

Stock-based Compensation

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

	2006	**2005**	**2004**
Net income/(loss)			
As reported	**$ 2,791,273**	$ (9,651,036)	$ (12,016,207)
Stock-based compensation included in net income/(loss) as reported	**1,076,832**	351,500	572,541
Total stock-based employee compensation determined under fair value based method for all awards	**(1,076,832)**	(784,329)	(1,042,589)
Pro forma net income/(loss)	**$ 2,791,273**	$ (10,083,865)	$ (12,486,255)
Basic and diluted net income/(loss) per share			
As reported	**$ 0.13**	$ (0.50)	$ (0.70)
Pro forma	**$ 0.13**	$ (0.52)	$ (0.73)

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

The weighted average fair value of the options at the date of grant for options granted during 2006, 2005 and 2004 was $3.11, $3.79, and $4.32, 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:

	2006	**2005**	**2004**
Expected option life (years)	**10**	10	10
Risk free interest rate	**4.10 %**	3.96 %	4.75 %
Expected stock price volatility	**73.94 %**	73.91 %	100.28 %
Dividend yield			

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue. There were no such warrants issued in 2006.

Revenue Recognition

The Company recognizes revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees and from subcontracts. Licensing income is recognized when the Company has completed all of its obligations under the licensing or subcontract arrangements which are required for the payment to be non-refundable. Licensing income also includes reimbursement for certain research and development expenses, which the Company recognizes as both revenue and expense at the time the expense is incurred. Any ancillary payments related to the products being licensed, such as royalties and milestone payments to the head licensor, are recorded as expenses in the period the revenue is recognized.

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 the enacted tax rates that will be in effect when these differences reverse. A valuation allowance is provided against deferred income tax assets in circumstances where management believes the recoverability of a portion of the assets is not reasonably assured.

Reclassifications

Certain 2004 and 2005 amounts have been reclassified to conform to 2006 presentation.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 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 clarifies 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. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We do not anticipate that the adoption of FIN 48 will have a material impact on our results of operations or financial condition.

In September 2006, the FASB issued SFAS 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. The statement will be effective for us January 1, 2008 though early adoption is permitted. We have not yet determined the impact, if any, that the adoption of SFAS 157 will have on our results of operations or financial condition.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108 *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a current year misstatement. The SEC staff believes that registrants should quantify errors using both a balance sheet and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 is effective for fiscal years ending on or after November 15, 2006, with early application encouraged. We do not anticipate that the adoption of SAB 108 will have a material impact on our results of operations or financial condition.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

In February 2007, the FASB issued FAS 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 is effective for fiscal years beginning after November 15, 2007. 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 have not yet determined the impact, if any, that the adoption of SFAS 159 will have on our results of operations or financial condition.

3. LICENSE AGREEMENTS

In June 1997, the Company 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 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 milestones and 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 for the treatment of 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 is also 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% 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 licensing income in the statement of operations during 2006. No shares were issued to Paladin in either 2005 or 2004.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

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.

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

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. under which Teva USA and the Company collaborate on the development of the Company s proposed Bio-T-Gel product for the U.S. market. Upon signing the U.S. development and license agreement, the Company received an upfront payment of $1.5 million. In addition, Teva agreed to pay the Company royalties on sales of the product commercialized in this collaboration. In exchange, the Company granted Teva exclusive rights to develop and market a certain hormone therapy product. Teva USA also agreed under the agreement to be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product. Teva USA has discontinued development of Bio-T-Gel and indicated to BioSante a desire to formally terminate this agreement. Accordingly, BioSante is in the process of exploring various alternatives with respect to the Bio-T-Gel product, including licensing the product to another third party or continuing the development of the product. BioSante believes the decision by Teva to discontinue the development of Bio-T-Gel is based on strategic decisions by Teva.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

In September 2005, the Company signed a Material Transfer and Option Agreement for an exclusive option to obtain an exclusive, worldwide license to use the Company s calcium phosphate nanotechnology (CaP) in the development of a series of allergy products. The partner company will fund 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 the Company received a nonrefundable $250,000 upfront payment. The Company is recognizing revenue from this 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. 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.

In November 2006, BioSante entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States. Upon execution of the sublicense agreement, the Company received an upfront payment of $2.625 million. In addition, Bradley has agreed to pay BioSante $10.5 million, $7 million of which is due during the first quarter of 2007 triggered by FDA approval of Elestrin by Bradley in the U.S. and an additional $3.5 million which is due on the one-year anniversary of such approval during the fourth quarter of 2007. Upon receipt of these additional payments, BioSante will be obligated to pay Antares Pharma IPL AG, the Company s licensor of the transdermal estradiol gel formulation in Elestrin, 25 percent of such payments resulting in BioSante receiving a net aggregate of $10.5 million from Bradley. Bradley also has agreed to pay BioSante additional sales-based milestone payments, plus royalties on sales of Elestrin. It is BioSante s understanding that Bradley is planning to commercially launch Elestrin in mid-2007.

4. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2006 and 2005 consist of the following:

	2006	2005
Computer equipment	**$ 101,083**	$ 194,905
Office equipment	**155,191**	155,191
Laboratory equipment	**129,433**	129,433
Leasehold improvements Laboratory	**520,339**	498,840
	906,046	978,367
Accumulated depreciation and amortization	**(769,006)**	(762,803)
	$ 137,040	$ 215,566

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

5. INCOME TAXES

The components of the Company s net deferred tax asset at December 31, 2006 and 2005 were as follows:

	2006	2005
Net operating loss carryforwards	**$ 14,669,434**	$ 15,916,677
Amortization of intangibles	**674,141**	809,462
Research & development credits	**2,308,522**	2,115,222
Stock option expense	**749,290**	342,785
Other	**258,321**	426,157
	18,659,708	19,610,303
Valuation allowance	**(18,659,708)**	(19,610,303)
	$	$

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2006, the Company had approximately $38,859,429 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 19 years. The net operating loss carryforwards expire in the years 2011-2025. 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 $2,308,522 of research and development credits, which are available to reduce future income taxes, if any, through the year 2025.

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:

	2006	2005	2004
Tax at U.S. federal statutory rate	**$ 962,989**	$ (3,329,607)	$ (4,145,591)
State taxes, net of federal benefit	**90,716**	(313,659)	(393,531)
Research and development credits	**(135,632)**	(255,723)	(208,454)
Change in valuation allowance	**(950,595)**	3,702,476	4,918,402
Other, net	**32,522**	196,513	(170,826)
	$	$	$

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

6. STOCKHOLDERS EQUITY

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.

On May 14, 2004, the Company completed a private placement of 2,949,000 shares of its common stock and warrants to purchase 442,350 shares of its common stock at a purchase price of $6.00 per unit to certain institutional and other accredited investors. The private placement resulted in net proceeds to the Company of approximately $16.4 million, after deduction of transaction expenses. The Company also issued warrants to purchase 92,646 shares of common stock to its placement agent in this private placement and its placement agent in its prior August 2003 private placement. The exercise price of the warrants is $7.00 per share.

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, 2006.

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, 2006 and 2005.

Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share. There were 22,975,040 and 19,007,800 shares of common stock issued and outstanding as of December 31, 2006 and 2005, respectively.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

b) *Warrants*

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

Amount	Exercise Price	Expiration
717,172	$ 2.15	August 8, 2008
534,996	$ 7.00	August 10, 2009
1,334,542	$ 2.75	October 21, 2011

Pursuant to the Company s private placement financing in May 1999, warrants to purchase an aggregate of 1,156,250 shares of common stock were issued at an exercise price of $3.00 per share with a term of five years. All of these warrants were exercised in 2004 except for 75,000 which expired in May 2004.

In June 2000, a five-year warrant to purchase 25,000 shares of common stock at an exercise price of $8.80 was issued to a communications firm for various consulting services. The Company recognized expense of approximately $18,000 for this warrant grant during 2000 and 2001. This warrant was exercised in 2004.

Pursuant to the Company s private placement financing in April 2001, warrants to purchase an aggregate of 462,500 shares of common stock were issued at an exercise price of $5.00 per share with a term of five years. Warrants to purchase an aggregate of 31,250 shares were exercised during 2005, no warrants to purchase shares were exercised in 2006, and warrants to purchase an aggregate of 367,187 shares were cancelled upon their expiration in April 2006.

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 6,575 shares were exercised during 2005, no warrants to purchase shares of common stock were exercised in 2006 and warrants to purchase an aggregate of 717,172 shares of common stock remained outstanding and were exercisable as of December 31, 2006.

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, 2006.

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

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

c) Options

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 of 116,340 shares of common stock to pay the exercise price of such options. The 116,340 shares of common stock withheld to pay the exercise price of the options were cancelled by the Company.

7. 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.

As of December 31, 2006, 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 $1,076,832 and $351,500 for the year ended December 31, 2006 and 2005, 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, 2006, 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. The shares of common stock provided upon stock option exercise are reserved in our authorized shares total and are provided for out of treasury shares or any other designation. 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

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

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. In certain instances, stock options have been granted to directors which were exercisable immediately. In these instances, 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 2006, 2005 and 2004 was $3.11, $3.79, and $4.32, 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:

	2006	2005	2004
Expected option life (years)	**10**	10	10
Risk free interest rate	**4.10 %**	3.96 %	4.75 %
Expected stock price volatility	**73.94 %**	73.91 %	100.28 %
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 American Stock Exchange. Since the Company has a limited history with option exercises, the expected life was set to the entire life of the option grant. The discount rate used is as published in *The Wall Street Journal* as of the grant date. 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, 2006 is presented below:

Options	Option Shares	Weighted Average Exercise Price
Outstanding December 31, 2005	1,425,530	$ 3.41
Granted	362,500	3.87
Exercised	(152,894)	2.51
Forfeited or expired	(623,657)	3.65
Outstanding December 31, 2006	1,011,479	$ 3.61
(weighted average contractual term)	*7.4 years*	
Exercisable at December 31, 2006	803,646	$ 3.51
(weighted average contractual term)	*7.0 years*	

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

The aggregate intrinsic values of the Company s outstanding and exercisable options as of December 31, 2006 were $137,908 and $137,908, respectively.

A summary of the Plan s non-vested options at December 31, 2005 and activity under the Plan during the year ended December 31, 2006 is presented below:

Options	Option Shares	Weighted Average Grant Date Fair-Value
Outstanding December 31, 2005	398,000	$ 3.61
Granted	362,500	3.87
Vested	(348,610)	3.56
Forfeited	(204,057)	3.52
Non-Vested at December 31, 2006	207,833	$ 3.65

As of December 31, 2006, there was $410,686 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 1.65 years.

As a result of a March 2006 issuance of stock options with immediate vesting to the non-employee members of our Board of Directors, $746,616 of non-cash, stock based compensation expense was recorded in the year ended December 31, 2006.

Cash received from option exercises under the Plan for the years ended December 31, 2006, 2005 and 2004 was $243,675, $41,518 and $234,495 respectively. The intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004 was $218,613, $17,480 and $961,353 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, 2006, 2005 and 2004 was $1,076,832, $784,329 and $1,042,589.

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 2006, 2005 and 2004 totaled $45,327, $71,188, and $62,701, respectively.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

9. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space and laboratory facilities which were extended in 2006 and expire in 2007 and 2008. The future minimum lease payments during 2007 and 2008 are $240,307 and $36,776, respectively.

Rent expense amounted to $236,824, $219,516, and $218,545 for the years ended December 31, 2006, 2005 and 2004, respectively.

10. RELATED PARTY TRANSACTIONS

Included in current liabilities are $25,353 and $29,398, which represent amounts due to current directors and officers of the Company as of December 31, 2006 and 2005, 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.

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares in 2000. The Company expects to fund the development of the products, has made and will continue to make milestone payments and once regulatory approval to market is received, pay royalties on the sales of products. In 2006, the Company paid $875,000 to Antares and recorded a liability of $2,625,000 due to Antares to be paid upon BioSante s receipt of payments from Bradley Pharmaceuticals Inc. related to the Elestrin FDA approval milestone.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

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 payments due under this agreement are as follows:

Year	Minimum Amount Due
2007	30,000
2008	30,000
2009	60,000
2010	70,000
2011	80,000
2012	80,000
2013	80,000
2014	80,000
2015	80,000
Thereafter	120,000

$22,500 of the 2007 minimum payment was accrued during 2006. 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.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

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. Within the first 18 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to the Company of a license fee. The Company has the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

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 are secured by an irrevocable letter of credit, which is supported by the Company s short-term investment account. The outstanding balance under the letter of credit and corresponding accrued liability is $550,588 as of December 31, 2006 and will continue to decrease as payments are made through December 2007.

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. SUBSEQUENT EVENTS

In March 2007, the Company announced that it received a $7.0 million milestone payment under the terms of its Elestrin (estradiol gel) licensing agreement with Bradley Pharmaceuticals, Inc. The payment was the first of two triggered by the December 2006 FDA approval of Elestrin. BioSante is entitled to receive an additional payment for this milestone in the amount of $3.5 million in December 2007. The net amount received by BioSante after BioSante s payment to its licensor was $5.25 million. The net amount to BioSante of the December 2007 payment will be $2.625 million.

BIOSANTE PHARMACEUTICALS, INC.

Notes to the Financial Statements

December 31, 2006

13. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2006 and 2005 is as follows:

	2005 First	Second	Third	Fourth
Revenue	$ 28,677	$ 45,596	$ 87,106	$ 96,972
Research and development expenses	2,151,679	1,927,890	1,314,283	1,015,228
General and administrative expenses	720,495	775,174	704,966	849,920
Operating loss	(2,868,440)	(2,683,511)	(1,957,607)	(2,542,664)
Net loss available to common shareholders	(2,770,493)	(2,581,585)	(1,853,217)	(2,445,741)
Loss per share available to common shareholders:				
Basic and Diluted	$ (0.14)	$ (0.13)	$ (0.10)	$ (0.13)

	2006 First	Second	Third	Fourth
Revenue	$ 84,679	$ 175,251	$ 140,324	$ 14,038,367
Research and development expenses	1,018,877	1,114,588	766,592	996,654
General and administrative expenses	2,223,019	1,328,612	210,552	606,608
Licensing expense				3,500,000
Operating income/(loss)	(3,324,674)	(2,295,058)	(867,575)	8,850,237
Net income/(loss) available to common shareholders	(3,228,495)	(2,224,900)	(745,061)	8,989,729
Income/(Loss) per share available to common shareholders:				
Basic and Diluted	$ (0.17)	$ (0.11)	$ (0.03)	$ 0.44

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.

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, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required under Item 10 of this report is to be contained under the captions Election of Directors Information About Nominees, Election of Directors Other Information About Board Nominees, Corporate Governance Information About the Board of Directors and its Committees and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and 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.

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

During the fourth quarter of 2006, 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.

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.

Item 11. EXECUTIVE COMPENSATION

The information required under Item 11 of this report is to be contained under the captions Director Compensation and Executive Compensation in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and 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 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under Item 12 of this report is to be contained under the caption Security Ownership of Principal Stockholders and Management in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes outstanding options under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of December 31, 2006. Options granted in the future under the plan are within the discretion of the Compensation Committee of our Board of Directors and therefore cannot be ascertained at this time.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,011,479	$ 3.61	1,678,129
Equity compensation plans not approved by security holders	0	N/A	0
Total	1,011,479	$ 3.61	1,678,129

Under the American Stock Exchange rules, we are required to disclose in our annual report the number of outstanding options and options available for grant under our equity compensation plans as of January 1, 2006 and December 31, 2006. As of January 1, 2006, the number of securities to be issued upon exercise of outstanding options, warrants and rights were 1,425,530 shares at a weighted average exercise price of $3.41. The number of securities remaining available for future issuance under our equity compensation plans (excluding securities to be issued upon exercise of outstanding options, warrants and rights) was 417,530 shares. This information as of December 31, 2006 is contained in the table above. 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 which was amended in June 2006 to include an additional 1,000,000 shares available for issuance.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under Item 13 of this report is to be contained under the caption Related Party Relationships and Transactions in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and 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 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under Item 14 of this report is to be contained under the captions Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Audit, Audit-Related, Tax and Other Fees and Proposal Two Ratification of Selection of Independent Registered Public Accounting Firm Auditor Fees Pre-Approval Policy in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and 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 STATEMENTS, SCHEDULES

The exhibits to this report are listed on the Exhibit Index on pages 78-84. A copy of any of the exhibits listed or referred to above will be furnished at a reasonable cost, upon receipt from any such 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 (filed herewith).

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. Stock Option Agreement, dated December 7, 1997, between BioSante Pharmaceuticals, Inc. and Edward C. Rosenow, III, M.D. (incorporated by reference to Exhibit 10.5 to BioSante s Amendment No. 1 to the Registration Statement on Form 10-SB (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 10.5 to BioSante s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2001 (File No. 000-28637)).

F. 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)).

G. 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)).

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 27, 2007

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 on March 27, 2007 by the following persons on behalf of the registrant and in the capacities indicated.

Name and Signature	**Title**
/s/ Stephen M. Simes Stephen M. Simes	Vice Chairman, President and Chief Executive Officer
/s/ Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Chairman of the Board
/s/ Fred Holubow Fred Holubow	Director
/s/ Peter Kjaer Peter Kjaer	Director
/s/ Ross Mangano Ross Mangano	Director
Victor Morgenstern	Director
/s/ Edward C. Rosenow, III, M.D. Edward C. Rosenow, III, M.D.	Director

BIOSANTE PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2006

Exhibit No.	Exhibit	Method of Filing
2.1	Arrangement Agreement, dated October 23, 1996, between Structured Biologicals Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 2.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
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)

Exhibit No.	Exhibit	Method of Filing
10.1	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Filed herewith
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 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
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	Lease, dated September 15, 1997, between BioSante Pharmaceuticals, Inc. and Highlands Park Associates	Incorporated by reference to Exhibit 10.15 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.8	First Amendment to Lease, dated September 18, 2003, between BioSante and Highlands Park Associates	Incorporated by reference to Exhibit 10.28 contained in BioSante s 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.9	Second Amendment to Lease dated as of September 1, 2004, by and between BioSante Pharmaceuticals, Inc. and Highlands Park Associates	Incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on September 1, 2004 (File No. 001-31812)
10.10	Third Amendment to Lease dated as of August 14, 2006, by and between BioSante Pharmaceuticals, Inc. and Highlands Park Associates	Filed herewith
10.11	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)
10.12	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)
10.13	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)
10.14	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)

Exhibit No.	Exhibit	Method of Filing
10.15	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)
10.16	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)
10.17	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)
10.18	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)
10.19	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)
10.20	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 (2)	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)
10.21	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma) 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)

Exhibit No.	Exhibit	Method of Filing
10.22	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)
10.23	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)
10.24	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)
10.25	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)
10.26	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)
10.27	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
10.28	Exclusive Sublicense Agreement dated as of November 7, 2006 between BioSante and Bradley Pharmaceuticals, Inc. (2)	Filed herewith

Exhibit No.	Exhibit	Method of Filing
10.29	Registration Rights Agreement, dated May 6, 1999, between BioSante Pharmaceuticals, Inc. and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.13 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.30	Securities Purchase Agreement, dated May 6, 1999, between BioSante Pharmaceuticals, Inc. and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.14 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.31	Form of Subscription Agreement in connection with the April 2001 Private Placement	Incorporated by reference to Exhibit 10.19 to BioSante s Registration Statement on Form SB-2, as amended (File No. 333-64218)
10.32	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)
10.33	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)
10.34	Form of Subscription Agreement dated as of May 11, 2004 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 12, 2004 (File No. 001-31812)
10.35	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)
10.36	Description of Non-Employee Director Compensation Arrangements	Filed herewith

Exhibit No.	Exhibit	Method of Filing
10.37	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
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.

(2) Confidential treatment has been requested with respect to designated portions of this document. Such portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.