

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

**FORM 10-K**

(Mark one)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2006

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**  
(State or other jurisdiction of incorporation or organization)

**58-2301143**  
(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  
**Common Stock, par value \$0.0001 per share**

Name of Each Exchange on Which Registered  
**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  NO

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

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

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

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

Large accelerated filer:

Accelerated filer:

Non-accelerated filer:

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

The aggregate market value of the registrant's common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sales price at which the common stock was last sold as of June 30, 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**

<a href="#">Item 1.</a>	<a href="#">DESCRIPTION OF BUSINESS</a> <a href="#">General</a> <a href="#">Business Strategy</a> <a href="#">Hormone Therapy Market</a> <a href="#">Description of Our Hormone Therapy Products</a> <a href="#">Description of Our CaP Technology and Products</a> <a href="#">Sales and Marketing</a> <a href="#">Research and Product Development</a> <a href="#">Manufacturing</a> <a href="#">Patents, Licenses and Proprietary Rights</a> <a href="#">Competition</a> <a href="#">Governmental Regulation</a> <a href="#">Employees</a> <a href="#">Forward-Looking Statements</a> <a href="#">Available Information</a>
<a href="#">Item 1A.</a>	<a href="#">RISK FACTORS</a>
<a href="#">Item 1B.</a>	<a href="#">UNRESOLVED STAFF COMMENTS</a>
<a href="#">Item 2.</a>	<a href="#">PROPERTIES</a>
<a href="#">Item 3.</a>	<a href="#">LEGAL PROCEEDINGS</a>
<a href="#">Item 4.</a>	<a href="#">SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</a>
<a href="#">Item 4A.</a>	<a href="#">EXECUTIVE OFFICERS OF THE REGISTRANT</a>
<a href="#">Item 5.</a>	<a href="#">MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER REPURCHASES OF EQUITY SECURITIES</a> <a href="#">Market Price</a> <a href="#">Number of Record Holders; Dividends</a> <a href="#">Recent Sales of Unregistered Equity Securities</a> <a href="#">Issuer Purchases of Equity Securities</a> <a href="#">Stock Performance Graph</a>
<a href="#">Item 6.</a>	<a href="#">SELECTED FINANCIAL DATA</a>
<a href="#">Item 7.</a>	<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a> <a href="#">General Overview</a> <a href="#">Financial Overview</a>

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

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,” “projects,” “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.

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## 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 progesterone.

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

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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

2

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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

3

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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 progesterin 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 progesterin) 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

4

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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-progesterin 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 Intrinsic patch and products being developed by Vivus, Inc.

5

In December 2004, the FDA's Reproductive Health Drugs Advisory Committee panel voted unanimously against recommending the approval of Procter & Gamble's Intrinsic 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 Intrinsic, the panel voted that Intrinsic provides a clinically meaningful benefit for women with hypoactive sexual desire disorder.

Procter & Gamble has since withdrawn its NDA for Intrinsic 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 Intrinsic 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 Intrinsic 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

6

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.

7

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,

8

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.

9

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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

10

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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

11

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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 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 sublicensees.

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

12

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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

13

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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

14

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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 sublicensees.

**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, NANOVAULT, 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.

19

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," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained in the notes to our financial statements and elsewhere in this report, including under the caption "Management's Discussion and Analysis of Financial Condition and Results of 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;

20

- 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](http://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.

21

#### 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

22

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

23

- 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;

24

- 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 affect 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 pharmacovigilance 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.

25

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**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.

26

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**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.

27

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**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

28

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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.

29

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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.

30

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**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

31

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.

32

#### 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.).

33

**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 Xtremedics, Inc.

34

## 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
<b>2006</b>		
	<b>High</b>	<b>Low</b>
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

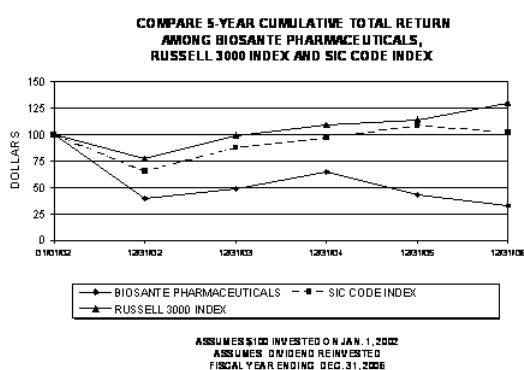
We did not purchase any shares of our common stock or other equity securities of ours during the fourth quarter ended December 31, 2006. Our Board of Directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other securities on the open market or otherwise, other than in connection with the cashless exercise of outstanding warrants and stock options.

35

#### 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.

36

#### 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)				
<b>Statement of Operations Data:</b>					
Licensing revenue	\$ 14,136	\$ 45	\$ 10	\$ 65	\$ 2,770
Grant revenue	247	181	68	—	—
Other revenue	55	32	—	—	—
<b>Total revenue</b>	<b>14,867</b>	<b>258</b>	<b>78</b>	<b>65</b>	<b>2,770</b>
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
<b>Total expenses</b>	<b>12,076</b>	<b>10,310</b>	<b>12,344</b>	<b>6,111</b>	<b>6,645</b>
(Loss) income before other expenses	2,791	(9,651)	(12,016)	(5,959)	(3,811)
<b>Net (loss) income</b>	<b>\$ 2,791</b>	<b>\$ (9,651)</b>	<b>\$ (12,016)</b>	<b>\$ (5,959)</b>	<b>\$ (3,811)</b>
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
<b>Balance Sheet Data:</b>					
	As of December 31,				
	2006	2005	2004	2003	2002
	(in thousands)				
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

37

#### 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 progesterone. 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/progesterone 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.

38

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 sublicensees. 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

39

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.

40

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	<u>\$ 1,537,671</u>	<u>\$ 820,895</u>	<u>\$ 196,776</u>	<u>\$ 160,000</u>	<u>\$ 360,000</u>

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 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

47

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.

48

## 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

50

## BIOSANTE PHARMACEUTICALS, INC.

Balance Sheets  
December 31, 2006 and 2005

	December 31, 2006	December 31, 2005
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
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
	<u>22,208,474</u>	<u>9,346,996</u>
PROPERTY AND EQUIPMENT, NET (Note 4)	<u>137,040</u>	<u>215,566</u>
OTHER ASSETS		

Security deposits		25,326	11,992
		<u>\$ 22,370,840</u>	<u>\$ 9,574,554</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>			
<b>CURRENT LIABILITIES</b>			
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
<b>TOTAL CURRENT LIABILITIES</b>		<u>4,299,610</u>	<u>2,666,034</u>
<b>LONG TERM LIABILITIES</b>			
Leasehold retirement liability		—	21,500
Deferred revenue		—	68,182
<b>TOTAL LONG TERM LIABILITIES</b>		<u>—</u>	<u>89,682</u>
<b>TOTAL LIABILITIES</b>	<b>\$</b>	<b>4,299,610</b>	<b>\$ 2,755,716</b>
<b>STOCKHOLDERS' EQUITY (Note 6)</b>			
<b>Capital stock</b>			
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
		<u>64,968,278</u>	<u>56,653,617</u>
Deferred unearned compensation		—	(146,459)
Accumulated deficit		(46,897,047)	(49,688,320)
		<u>18,071,231</u>	<u>6,818,838</u>
	<b>\$</b>	<b>22,370,840</b>	<b>\$ 9,574,554</b>

See accompanying notes to the financial statements.

51

**BIOSANTE PHARMACEUTICALS, INC.**  
**Statements of Operations**  
**Years ended December 31, 2006, 2005 and 2004**

	Year Ended December 31,		
	2006	2005	2004
<b>REVENUE</b>			
Licensing revenue	\$ 14,136,364	\$ 45,455	\$ 10,000
Grant revenue	247,257	180,896	67,886
Other revenue	55,000	32,000	—
	<u>14,438,621</u>	<u>258,351</u>	<u>77,886</u>
<b>EXPENSES</b>			
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
	<u>12,075,691</u>	<u>10,310,573</u>	<u>12,344,517</u>
<b>OTHER - Interest income</b>	<u>428,343</u>	<u>401,186</u>	<u>250,424</u>
<b>NET INCOME (LOSS)</b>	<b>\$ 2,791,273</b>	<b>\$ (9,651,036)</b>	<b>\$ (12,016,207)</b>
<b>Income (loss) per common share (Note 2):</b>			
Basic	\$ 0.13	\$ (0.50)	\$ (0.70)
Diluted	\$ 0.13	\$ (0.50)	\$ (0.70)
<b>Weighted average number of common and common equivalent shares outstanding:</b>			
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.

52

**BIOSANTE PHARMACEUTICALS, INC.**  
**Statements of Stockholders' Equity**  
**Years ended December 31, 2006, 2005 and 2004**

	Class C Special Shares		Common Stock		Deferred Unearned Compensation	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
<b>Balance, December 31, 2003</b>	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	—	—	—	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)
<b>Balance, December 31, 2004</b>	<b>391,286</b>	<b>398</b>	<b>18,955,181</b>	<b>56,455,451</b>	<b>(497,959)</b>	<b>(40,037,284)</b>	<b>15,920,606</b>
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)
<b>Balance, December 31, 2005</b>	<b>391,286</b>	<b>398</b>	<b>19,007,800</b>	<b>56,653,219</b>	<b>(146,459)</b>	<b>(49,688,320)</b>	<b>6,818,838</b>
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
<b>Balance, December 31, 2006</b>	<b>391,286</b>	<b>\$ 391</b>	<b>22,975,040</b>	<b>\$ 64,967,887</b>	<b>\$ —</b>	<b>\$ (46,897,047)</b>	<b>\$ 18,071,231</b>

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
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>			
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	—
<b>Net cash used in operating activities</b>	<b>(4,996,735)</b>	<b>(8,297,509)</b>	<b>(10,442,443)</b>
<b>CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>			
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)
<b>Net cash provided by (used in) investing activities</b>	<b>4,955,656</b>	<b>7,240,359</b>	<b>(16,201,867)</b>
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES</b>			
Proceeds from sale or conversion of shares	7,384,288	197,768	18,680,008
<b>Net cash provided by financing activities</b>	<b>7,384,288</b>	<b>197,768</b>	<b>18,680,008</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>7,343,209</b>	<b>(859,382)</b>	<b>(7,964,302)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>310,643</b>	<b>1,170,025</b>	<b>9,134,327</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 7,653,852</b>	<b>\$ 310,643</b>	<b>\$ 1,170,025</b>
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.

60

## 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/progesterone 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/progesterone 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 progesterone 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.

61

## 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)
	<u>\$ 137,040</u>	<u>\$ 215,566</u>

62

## 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)
	<u>\$ —</u>	<u>\$ —</u>

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)
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

63

**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.

64

**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.

65

**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 reprize 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.

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 progesterone 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 sublicensees.

*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

72

**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.

73

**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.

74

**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
<b>Total</b>	<b>1,011,479</b>	<b>\$ 3.61</b>	<b>1,678,129</b>

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.

75

**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).

76

**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.

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

77

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

<u>Exhibit No.</u>	<u>Exhibit</u>	<u>Method of Filing</u>
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)

78

Exhibit No.	Exhibit	Method of Filing
<a href="#">10.1</a>	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)

79

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)
<a href="#">10.10</a>	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)

80

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)

81

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)
<a href="#">10.27</a>	Amendment No. 6 to the License Agreement, dated October 20, 2006 between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Filed herewith
<a href="#">10.28</a>	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)
<a href="#">10.36</a>	Description of Non-Employee Director Compensation Arrangements	Filed herewith

Exhibit No.	Exhibit	Method of Filing
<a href="#">10.37</a>	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)
<a href="#">23.1</a>	Consent of Deloitte & Touche LLP	Filed herewith
<a href="#">31.1</a>	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Furnished herewith
<a href="#">31.2</a>	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Furnished herewith
<a href="#">32.1</a>	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
<a href="#">32.2</a>	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.

## CONFIDENTIAL

January 21, 1998

Mr. Stephen M. Simes  
1173 RFD  
Long Grove, IL 60047

Dear Stephen:

I am pleased to confirm our agreement with you concerning your employment by Ben-Abraham Technologies, Inc. (the "Company"), which is subject to review, approval, and ratification by the Company's Board of Directors.

- I. **Employment.** Subject to the terms and conditions described in this Employment Agreement (the "Agreement"), the Company agrees to employ you as the President, Chief Operating Officer, and Executive Vice Chairman of the Company, and you accept this employment on the following terms and conditions.
- II. **Duties.**
1. You agree to spend substantially all of your business hours on the Company's business. You will diligently perform the duties of your position, within guidelines to be determined by Avi Ben-Abraham, who is the Company's Chief Executive Officer and the Chairman of the Board of Directors. In particular, you will actively manage the day-to-day business of the Company and shall set corporate policies, under the direction of the Board of Directors. More particularly, your duties shall include the day-to-day responsibility for running and administering the Company. Said responsibilities shall include, but not be limited to, the following specific areas: shareholder relations, fundraising, Nasdaq listing, direction of R&D, licensing and other business development activities, budgeting and fiscal controls, and all personnel matters. You will report to Dr. Ben-Abraham, who will be responsible for evaluating your job performance in accordance with the Company's annual performance review process. The Company agrees that during the term of this Agreement, as it may be extended, no one other than Dr. Ben-Abraham shall serve as CEO, except you.
  2. During the term of this Agreement, you will also serve as a Director of the Company and will perform all such duties incident to such service. Towards this end, the Company shall nominate you as a nominee for director and solicit proxies for your election for so long as this Agreement is in effect.
  3. While you are employed by the Company, except as otherwise permitted by the Company's Conflict of Interest policy or this Agreement, you will not engage in any business activity or outside employment that conflicts with the Company's interests or adversely affect the performance of your duties for the Company.
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4. You shall be based at, and shall perform your duties at an office located in, Chicago, Illinois, or the surrounding suburban area, where the corporate headquarters of the Company shall also be located. The Company agrees that the other officers and executives of the Company (except for those who are directly involved in the research and development activities of the Company that are currently conducted in Atlanta, Georgia) shall also be located in the same corporate headquarters. However, you shall also travel to other locations at such times as may be appropriate for the performance of your duties under this Agreement.
- III. **Term.** This Agreement is effective January 20, 1998 (the "Effective Date"), and will terminate on December 31, 2000, unless earlier terminated pursuant to Section V of this Agreement (the "Base Term"). Commencing January 1, 2001, and on each January 1st thereafter, the term of your employment will be automatically extended for three (3) additional years unless on or before October 1st immediately preceding any such extension, either party gives written notice to the other of the cessation of further extensions, in which case no further automatic extensions will occur. In the event that the Company elects not to renew this Agreement other than for "cause" as defined herein, you will be paid the amount described in Section V.C.2 below.
- IV. **Compensation.**
- A. **Base Salary.** The Company agrees to pay you an annual base salary of Two Hundred Thirty Thousand Dollars (\$230,000) in accordance with the Company's standard payroll practices ("Base Salary"). Beginning January 20, 1999 or sooner if you raise Two Million Dollars (\$2,000,000), your Base Salary shall be increased to Two Hundred and Fifty Thousand Dollars (\$250,000). In subsequent years, the Board of Directors shall have the sole discretion to establish your Base Salary, except that, at a minimum, it shall be adjusted upward consistent with changes to the Consumer Price Index.
  - B. **Annual Bonus.** You will be eligible to receive an annual performance bonus not to exceed 50% of your Base Salary in effect during the year under review. The amount of said bonus shall be determined in the sole discretion of the Compensation Committee and approved by the Board of Directors.
  - C. **Options.**
    1. Upon execution of this Agreement, the Company will grant you six hundred thousand (600,000) stock options to purchase Subordinate Voting Shares of stock of the Company at the lowest permissible price when this agreement is executed, one hundred thousand of which shall vest at the time of the grant. The remainder shall vest in twelve equal quarterly installments over the Initial Term of this Agreement with the first installment vesting on April 21, 1998. The remaining unvested options shall vest immediately upon a termination without cause by the Company.

2

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2. Upon execution of this Agreement, the Company agrees to grant you a combination of an additional four hundred thousand (400,000) Subordinate Voting Shares and/or stock options to purchase Subordinate Voting Shares of stock of the Company during the Initial Term of this Agreement at the lowest permissible price when this agreement is executed. Exercise of these options shall be subject to the stock price being equal to or greater than One Dollar (\$1.00) per share at the time the options and/or shares vest. These options shall vest in twelve equal quarterly installments over the Initial Term of this Agreement and shall be exercisable at such time as the foregoing condition precedent is satisfied.
  3. In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, reverse stock split, combination of shares, rights offering, extraordinary dividend or divestiture (including a spin-off) or any other change in the corporate structure or shares of the Company, (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation), in order to prevent dilution or enlargement of your rights, the Company (or the board of the surviving corporation) shall make appropriate adjustment as to the number of securities subject to this Option.

All of the options granted pursuant to this Section IV.C.3 (the "Anti-Dilution Options") shall automatically vest in accordance with the same vesting schedule set forth in Sections IV.C.1 and IV.C.2 above. (As an illustration, if 200,000 of the 1,000,000 shares and/or options granted pursuant to Section IV.C.1 and IV.C.2 above were vested at the time of the grant of the Anti-Dilution Options pursuant to this Section IV.C.3, then 20% of the Anti-Dilution Options would automatically vest immediately at the time of the grant, and the remaining 80% would vest simultaneously with the vesting of the remaining shares and/or options granted pursuant to Section IV.C.1 and IV.C.2).

In the event that your employment is terminated by the Company other than for justifiable cause (as hereinafter defined), or if the Company elects not to renew this Agreement, or if you are not nominated by the Company for reelection to the Board of Directors other than for justifiable cause (as hereinafter defined), all outstanding stock options and shares that are held by you or your estate will immediately become exercisable and all restrictions against disposition, if any, which have not otherwise lapsed shall immediately lapse, and the period within which they may be exercised will be one year following such termination of employment.

- D. **Benefits.** In addition to the other compensation to be paid under this Section IV, you will be entitled to participate in all benefit plans available to all full-time, eligible employees hereafter established by the Company, in accordance with the terms and conditions of such plans, which the Company shall adopt promptly

3

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following the date hereof. These plans shall include, but not be limited to, the following: a 401(k) plan; group hospitalization, health, dental, disability (for which the Company agrees to obtain the maximum long-term disability insurance benefit allowed by applicable law), and term life insurance (in the amount of \$1.1 million); and supplementary long-term disability insurance.

- E. **Reimbursement of Business Expenses.** In addition to payment of compensation under this Section IV, the Company agrees to reimburse you for all reasonable out-of-pocket business expenses incurred by you on behalf of the Company, provided that you properly account to the Company for all such expenses in accordance with the rules and regulations of the Internal Revenue Service promulgated under the Internal Revenue Code of 1986, as amended, and in accordance with the standard policies of the Company relating to reimbursement of business expenses.
- F. **Automobile Allowance.** The Company shall provide you with a monthly stipend of One Thousand Dollars (\$1,000.00) for your automobile use.
- G. **Vacation.** You are entitled to four (4) weeks of paid vacation per calendar year.

V. **Termination.**

- A. **Early Termination.** Subject to the respective continuing obligations of the parties pursuant to Sections VI, VII and VIII, this Section sets forth the terms for early termination of this Agreement.
- B. **Termination for Cause.** The Company may terminate this Agreement and your employment immediately for cause. For this purpose, "cause" means any of the following: (1) fraud, (2) theft or embezzlement of the Company's assets, (3) a violation of law involving moral turpitude, (4) your repeated and willful failure to follow instructions of the Board provided that the conduct has not ceased or the offense cured within thirty (30) days following written warning from the Company that sets forth in reasonable detail the facts claimed to provide the basis for such termination. In the event of termination for cause pursuant to this Section V.B, you will be paid at the usual rate your annual Base Salary, car allowance, and any out-of-pocket expenses, through the date of termination specified in any notice of termination and any amounts to which you are entitled under any Company benefit plan in accordance with the terms of such plan.

C. **Termination Without Cause.** Either you or the Company may terminate this Agreement and your employment without cause on thirty (30) days written notice. In the event of termination of this Agreement and of employment pursuant to this Section V.C, compensation will be paid as follows:

1. if the termination is by you without cause, you will be paid at the usual rate of your annual Base Salary, car allowance, and any out-of-pocket expenses incurred on behalf of the Company and accounted for pursuant

4

to Section IV.E through the date of termination specified in such notice (but not to exceed thirty (30) days from the date of such notice); or

2. Notwithstanding any provision to the contrary contained herein, in the event your employment is terminated by the Company at any time for any reason other than justifiable cause, disability or death, the Company shall:
  - (i) pay you a severance benefit, in a lump sum payable no later than the fifth business day following the date of termination, an amount equal to your total compensation over the preceding twelve months, including the car allowance;
  - (ii) continue to provide you, at the Company's expense, with term life insurance, as provided herein until the earlier of (A) the expiration of the "Severance Period" (which shall mean the longer of these two periods: one year from the date of termination or the remaining term of this Agreement), or (B) your obtaining full-time employment;
  - (iii) continue to allow you to participate, at the Company's expense, in the Company's group hospitalization, health, dental and disability insurance programs until the earlier of (A) the expiration of the Severance Period, or (B) your becoming eligible to participate in another employer's corresponding group insurance and disability plans;
  - (iv) provide you with outplacement services at a qualified agency selected by you and the use of an office and reasonable secretarial support for one year (unless you become otherwise employed within such period);
  - (v) reimburse out-of-pocket expenses incurred by you on behalf of the Company and accounted pursuant to Section IV.E; and
  - (vi) reimburse you for any and all unused vacation days accrued to the date of such termination.

D. **Termination for Good Reason.** You may terminate this Agreement upon thirty (30) days written notice to the Company for good reason. For this purpose, "good reason" means: (i) the assignment to you of any duties inconsistent with your positions, duties, responsibilities and status with the Company as of the date hereof, or a change in your reporting responsibilities, titles or offices, or any removal of you from or any failure to re-elect you to any of such positions; (ii) the failure of the Company to continue in effect any fringe benefit or compensation plan, retirement plan, life insurance plan, health or disability plan in which you were participating (except as such change is prompted in good faith by a change in the law), or the taking of any action by the Company, which could reasonably be expected to adversely affect your participation in or materially reduce your benefits under any such plans or deprive you of any material fringe benefit

5

enjoyed by you, (iii) the reduction of your salary or car allowance or failure to increase such salary as is provided in Section IV.A above, or any other breach of this Agreement by the Company; or (iv) the occurrence of a Change in Control as defined in Section IX. In any such case the Company will pay you the amounts, and provide you the benefits, all as set forth in Section V.C.2 above.

E. **Termination In The Event of Death or Permanent Disability.** This agreement and your employment will terminate in the event of your death or permanent disability.

1. In the event of your death, Base Salary and car allowance will be terminated as of the end of the month in which death occurs.
2. For the purposes of this Agreement, the term "disability" shall mean your inability, due to illness, accident or any other physical or mental incapacity, to substantially perform your duties for a period of four (4) consecutive months or for a total of six (6) months (whether or not consecutive) in any twelve (12) month period during the term of this Agreement.
3. Upon your "disability", the Company shall have the right to terminate your employment. Notwithstanding any inability to perform your duties, you shall be entitled to receive your compensation (including bonuses, if any) as provided herein until the later of (i) the date of your termination of employment for disability in accordance with this Agreement, or (ii) the date upon which you begin to receive long-term disability insurance benefits under the policy provided by the Company pursuant to this Agreement. Any termination pursuant to Section V.E.2 shall be effective on the date thirty (30) days after which you shall have received written notice of the Company's election to terminate.

F. **Entire Termination Payment.**

1. The compensation provided for in Sections V.B, V.C, V.D and V.E for early termination of this Agreement will constitute your sole remedy for such termination. You will not be entitled to any other termination or severance payment which might otherwise be payable to you under any other agreement between you and the Company or under any policy of the Company. This Section will not have any effect on distributions to which you may be entitled at termination from any qualified tax plan or any other plan (other than a severance payment or similar plan).
2. Notwithstanding any other provisions of this Agreement or any other agreement, contract or understanding heretofore or hereafter entered into between you and the Company, if any "payments" (including, without limitation, any benefits or transfers of property or the acceleration of the vesting of any benefits) in the nature of compensation under any

6

arrangement that is considered contingent on a Change in Control for purposes of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), together with any other payments that you have the right to receive from the Company or any corporation that is a member of an "affiliated group" (as defined in Section 1504(a) of the Code without regard to Section 1504(b) of the Code) of which the Company is a member, would constitute a "parachute payment" (as defined in Section 280G of the Code), such payments will be reduced to the largest amount as will result in no portion of such payments being subject to the excise tax imposed by Section 4999 of the Code; provided, however, that you will be entitled to designate those payments that will be reduced or eliminated in order to comply with the foregoing provision.

G. **Required Resignations Upon Early Termination or Expiration.** You agree that upon any termination of your employment with the Company or expiration of this Employment Agreement, such termination or expiration under this Agreement will automatically and without further action be deemed to constitute your simultaneous resignation from all director, officer, trustee, agent and any other positions within the Company, all of its affiliates (including but not limited to any entity that is a shareholder of the Company and any subsidiaries and any parent of the Company), the Company's employee benefit plans, trusts and foundations (charitable or otherwise) or any other similar position associated with the Company. Simultaneously upon such termination of employment or expiration of this employment agreement, you agree to execute and deliver to the Company any and all documents, agreements, certificates, letters or other written instruments confirming all such resignations.

VI. **Inventions.**

A. You agree that all Inventions (as defined below) you make, conceive, reduce to practice or author (either alone or with others) during or within one year after the term of this Agreement will be the Company's sole and exclusive property. You will, with respect to any such Invention: (i) keep current, accurate, and complete records, which will belong to the Company and be kept and stored on the Company's premises while you are employed by the Company; (ii) promptly and fully disclose the existence and describe the nature of the Invention to the Company in writing (and without request); (iii) assign (and you do hereby assign) to the Company all of your rights to the Invention, any applications you make for patents or copyrights in any country, and any patents or copyrights granted to you in any country; and (iv) acknowledge and deliver promptly to the Company any written instruments, and perform any other acts necessary in the Company's opinion to preserve property rights in the Invention against forfeiture, abandonment, or loss and to obtain and maintain patents and/or copyrights on the Invention and to vest the entire right and title to the Invention in the Company.

7

B. "Inventions," as used in this Section, means any discoveries, improvements, creations, ideas and inventions, including without limitation software and artistic and literary works (whether or not they are described in writing or reduced to practice) or other works of authorship (whether or not they can be patented or copyrighted) that: (i) relate directly to the Company's business or the Company's research or development during the term of this Agreement; (ii) result from any work you perform for the Company; (iii) use the Company's equipment, supplies, facilities or trade secret information; or (iv) you develop during any time that Section II above obligates you to perform your employment duties.

The requirements of this Section do not apply to an Invention for which no equipment, supplies, facility or trade secret information of the Company was used and which was developed entirely on your own time, and which neither (1) relates directly to the Company's business or to the Company's actual or demonstrably anticipated research or development, nor (2) results from any work you performed for the Company. Except as previously disclosed to the Company in writing, you do not have, and will not assert, any claims to or rights under any Inventions as having been made, conceived, authored or acquired by you prior to your employment by the Company.

VII. **Proprietary Information.**

A. Except as required in your duties to the Company, you will never, either during or after your employment by the Company, use or disclose Proprietary Information to any person not authorized by the Company to receive it. When your employment with the Company ends, you will promptly turn over to the Company all records and any compositions, articles, devices, apparatus and other items that disclose, describe or embody Proprietary Information, including all copies, reproductions and specimens of the Proprietary Information in your possession, regardless of who prepared them.

- B. "Proprietary Information," as used in this Section VII, means any nonpublic information concerning the Company, including information relating to the Company's research, product development, engineering, purchasing, product costs, accounting, leasing, servicing, manufacturing, sales, marketing, administration and finances. This information includes, without limitation: (i) trade secret information about the Company and its products; (ii) "Inventions," as defined in Section VI.B; (iii) information concerning any of the Company's past, current or possible future products. Proprietary information or confidential information also includes any information which is not generally disclosed and which is useful or helpful to the Company and/or which would be useful or helpful to competitors. More specific examples include financial data, sales figures for individual projects or groups of projects, planned new projects or planned advertising programs, areas where the Company intends to expand, lists of suppliers, lists of customers, wage and salary data, capital investment plans, projected earnings, changes in management or policies of the Company, testing

8

data, manufacturing methods, suppliers' prices to us, or any plans we may have for improving any of our products. This information is confidential or Proprietary Information regardless of its form, e.g. oral, written, electronic or other, and whether or not it is labeled as "proprietary" or "confidential." The Company's Proprietary Information or confidential information includes our information and that of our affiliates and third parties concerning or relating to us.

VIII. Competitive Activities.

- A. You agree that during your employment with the Company, you will not alone, or in any capacity with another person or entity, (i) directly or indirectly engage in any employment or activity that competes with the Company's business at the time your employment with the Company ends, within any state in the United States or within Canada, (ii) interfere with the Company's relationships with any of its current or potential customers.
- B. You also agree that for a period of one year after the termination of this Agreement for any one of the following reasons: (i) for "cause" as defined above, (ii) voluntarily by you without "good reason" as defined above; or (iii) in the event of a non-renewal of the Agreement by you other than for "good reason", you will abide by clauses (ii) and (iii) of Section VIII.A above.

IX. Change in Control.

- A. For purposes of this Agreement, a "Change in Control" of the Company will mean the following:
- (i) the sale, lease, exchange or other transfer, directly or indirectly, of substantially all of the assets of the Company (in one transaction or in a series of related transactions) to a person or entity that is not controlled by the Company;
  - (ii) the approval by the shareholders of the Company of any plan or proposal for the liquidation or dissolution of the Company;
  - (iii) a change in control of the Company of a nature that would be required to be reported in response to Item 5(f) of Schedule 14A of Regulation 14A or to Item 1 of Form 8-K promulgated under the Securities Exchange Act of 1934, as amended (the "Act"), provided that, without limitation, a Change in Control shall be deemed to have occurred if (i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Act) is or shall become the beneficial owner, directly or indirectly, of securities of the Company representing 30% or more of the Company's then outstanding securities; or (ii) during any period of twenty-four (24) consecutive months, individuals who at the beginning of such period constitute the entire Board of Directors shall cease for any reason to constitute a majority thereof unless the election, or the nomination for

9

election by the Company's stockholders, of each new director was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of the period.

- B. If a Change in Control occurs, the Option will become immediately exercisable in full and will remain exercisable for the remainder of its term, regardless of whether you remain in the employ or service of the Company.
- C. For purposes of this Section IX, you shall be entitled to the severance benefits provided in Section V.D if the date of termination occurs either (i) while there is to the Company's knowledge actively pending a proposed transaction, which, if consummated, could reasonably be expected to result within one (1) year in a Change in Control, or (ii) within two (2) years following a Change in Control; unless, in the case of either (i) or (ii), your employment is terminated or this Agreement is not renewed because of death or disability or by the Company for "cause" or voluntarily by you other than for "good reason".

X. Miscellaneous.

- A. No Adequate Remedy. You understand that if you fail to fulfill your obligations under this Agreement, the damages to the Company would be very difficult to determine. Therefore, in addition to any other rights or remedies available to the Company at law, in equity, or by statute, you hereby consent to the specific enforcement of this Agreement by the Company through an injunction or restraining order issued by an appropriate court.
- B. Governing Law. The laws of Illinois will govern the validity, construction, and performance of this Agreement.
- C. Arbitration. Any and all disputes which arise concerning the rights, duties or obligations of either party under any provision of this Agreement shall be resolved exclusively by binding arbitration in accordance with the following terms and conditions. The party seeking arbitration shall commence a proceeding in arbitration in Chicago, Illinois under the Rules of the American Arbitration Association. Within one month from one of the party's request for arbitration, the party requesting arbitration shall appoint one arbitrator and within one month of the date of such appointment, the other party shall appoint an arbitrator. Within three weeks of the date that the second arbitrator is appointed, and prior to any examination of the merits of the case, the two arbitrators shall mutually select a third arbitrator. If either of the parties fails to appoint an arbitrator or if the two arbitrators fail to appoint the third arbitrator within the periods referred to above, one shall be appointed in accordance with the Rules within fifteen (15) days of the expiry date of the respective period referred to above. The three arbitrators so selected shall constitute the arbitral panel. The arbitral panel shall make its decisions by the majority of its members. The arbitral panel shall render its decision and award in writing within ninety (90) days from its final constitution.

10

There shall be no appeal from the decision and award of the arbitral panel, which shall be final and binding on the parties and may be entered in any court having jurisdiction thereof.

- D. Rights in the Event of Dispute. If, with respect to any alleged failure by the Company to comply with any of the terms of this Agreement, you hire legal counsel with respect to this Agreement or institute any negotiations or institute or respond to legal action to assert or defend the validity of, enforce your rights under, or recover damages for breach of this Agreement, the Company shall pay, as they are incurred, your actual expenses for attorneys' fees and disbursements, together with such additional payments, if any, as may be necessary so that the net-after-tax payments to you equal such fees and disbursements, provided that such payments shall be reimbursed by you to the Company if the Arbitration panel rules in favor of the Company and further decides that such reimbursement is appropriate. Further, pending the resolution of any such claim or dispute, you shall not be deemed terminated for purposes of this Agreement.
- E. Mitigation. You are not required to mitigate the amount of any payments to be made pursuant to this Agreement by seeking other employment or otherwise, nor shall the amount of any payments provided for in this Agreement be reduced by any compensation earned by you as the result of your self-employment or your employment by another employer after the date of termination of your employment with the Company.
- F. Construction. Wherever possible, each provision of this agreement will be interpreted so that it is valid under the applicable law. If any provision of this agreement is to any extent invalid under the applicable law, that provision will still be effective to the extent it remains valid under the applicable law. The remainder of this agreement also will continue to be valid, and the entire agreement will continue to be valid in other jurisdictions.
- G. Waivers. No failure or delay by either the Company or you in exercising any right or remedy under this agreement will waive any provision of the agreement. Nor will any single or partial exercise by either the Company or you of any right or remedy under this agreement preclude either the Company or you from otherwise or further exercising these rights or remedies, or any other rights or remedies granted by any law or any related document.
- H. Entire Agreement. This Agreement is the entire agreement between the parties and replaces all other oral negotiations, commitments, writings and understandings between the parties concerning the matters in this agreement. This Agreement can only be modified by mutual written consent of the parties. You acknowledge that you have been advised to seek legal counsel to review this Agreement with you before you sign it.

11

- I. Successors and Assigns. Except as otherwise provided in Section IX, this Agreement will be binding upon and inure to the benefit of the successors and assigns of the Company whether by way of merger, consolidation, operation of law, purchase or other acquisition of substantially all of the assets or business of the Company, and any such successor or assign will absolutely and unconditionally assume all of the Company's obligations under this Agreement.

- J. Notices. All notices, requests and demands given to or made pursuant hereto will, except as otherwise specified herein, be in writing and be delivered or mailed to any such party at its address which:

12

1. In the case of the Company will be:  
Ben-Abraham Technologies  
225 Peachtree Street, NE  
Suite 1400, South Tower  
Atlanta, GA 30303  
Attention: Avi Ben-Abraham, CEO

2. In the case of employee will be:  
Stephen M. Simes  
1173 RFD  
Long Grove, IL 60047

Any party may, by notice to the other party, designate a changed address. Any notice, if mailed properly addressed, postage prepaid, registered or certified mail, will be deemed dispatched on the registered date or that date stamped on the certified mail receipt, and will be deemed received within the second business day thereafter or when it is actually received, whichever is sooner.

K. Captions. The various headings or captions in this agreement are for convenience only and will not affect the meaning or interpretation of this agreement.

Would you please confirm that this agreement is in accordance with your understanding and that you have received a copy of this letter by signing and dating it where indicated below, and returning an executed copy for our records.

Very truly yours,

BEN-ABRAHAM TECHNOLOGIES, INC.

/s/ Avi Ben-Abraham

\*By: Avi Ben-Abraham, M.D.  
Its: Chief Executive Officer

Agreed to and confirmed as of January 21, 1998:

/s/ Stephen M. Simes  
Stephen M. Simes

\*Subject to approval by the Company's Board of Directors.

/s/ ABA

13

**CONFIDENTIAL**

April 15, 1999

Mr. Stephen M. Simes  
1173 RFD  
Long Grove, IL 60047

Dear Stephen:

As you are aware, Ben-Abraham Technologies, Inc. (the "Company") has agreed to sell securities (the "Transaction") to certain investors on the date hereof pursuant to a Private Placement Memorandum dated March 19, 1999 and certain Securities Purchase Agreements (the "Securities Purchase Agreements") with such purchasers (the "Purchasers"). The Securities Purchase Agreements specify, as a condition to closing, that (i) the certain letter agreement dated as of January 21, 1998 between you and the Company regarding your employment (the "Employment Agreement") be amended; and (ii) you waive certain rights you may have under such Employment Agreement. Terms not defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

1. The first two sentences of **Section 11.1** of the Employment Agreement are hereby amended in their entirety to read as follows:

"You agree to devote, on a full-time basis, all of your business house to the Company's business. You will diligently perform the duties of your position within guidelines to be determined by the Board of Directors."

2. **Section IV.C.3** of the Employment Agreement is hereby amended in its entirety to read as follows:

"In the event the Company issues a stock dividend, or effectuates a stock split or exchange of any shares of the Company, whether by way of reorganization, reclassification, conversion or other means, the Company shall make appropriate adjustments to the terms of the Option in order to prevent dilution or enlargement of your rights."

Notwithstanding the foregoing, the Company has agreed to issue to you concurrently with the closing of the Transaction additional options to purchase that number of subordinate voting shares of the Company equal to the product of (i) five percent (5%) multiplied by (ii) the number of subordinate voting shares sold in the Transaction (excluding any shares issuable pursuant to warrants). You acknowledge that any future sales of securities by the Company will not entitle you to additional options.

14

3. In the event the Transaction would be deemed a "Change of Control", or cause a "Change of Control" to have occurred, as such term is defined in **Section IX.A** of the Employment Agreement, you hereby agree to waive, only with respect to any deemed "Change of Control" arising out of or related to the Transaction (which, for greater certainty, includes the change in constitution of the Board of Directors), any rights you have under **Section IX.B**, including without limitation the right for the Option to become immediately exercisable.

4. Except as otherwise specifically set forth herein, the Employment Agreement shall remain in full force and effect.

You hereby acknowledge that the Company and the Purchasers are entering into the Securities Purchase Agreements in reliance upon on this letter. Please indicate your agreement to the foregoing by signing the enclosed copy of this letter where indicated and returning such executed copy to the Company.

Very truly yours,

Ben-Abraham Technologies, Inc.

By: /s/ Louis W. Sullivan  
Its: Chairman, Board of Directors and  
Chairman, Compensation Committee

ACCEPTED AND AGREED:

/s/ Stephen M. Simes  
Stephen M. Simes

Dated: 4/15/99

15

**AMENDMENT TO EMPLOYMENT AGREEMENT**

February 19, 2007



Mr. Stephen M. Simes  
1173 RFD  
Long Grove, IL 60047

Dear Stephen:

The Compensation Committee of the Board of Directors of BioSante Pharmaceuticals, Inc. (the "Company") has decided to clarify certain sections, as outlined below, of that certain letter agreement dated as of January 21, 1998, as amended (the "Employment Agreement"), between you and the Company. Terms not defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

1. Section III of the Employment Agreement is hereby amended in its entirety to read as follows:

"III. **Term.** This Agreement is effective January 20, 1998 (the "Effective Date"), and will terminate on December 31, 2000, unless earlier terminated pursuant to Section V of this Agreement (the "Base Term"). On January 1, 2001, the term of your employment will be extended for three (3) additional years unless on or before October 1st immediately preceding such extension, either party gives written notice to the other, in which case no automatic extension will occur. Commencing on January 1, 2002 and on each January 1st thereafter, the term of your employment will be automatically extended for one (1) additional year unless on or before October 1st immediately preceding any such extension, either party gives written notice to the other of the cessation of further extensions, in which case no further automatic extensions will occur. For the avoidance of any doubt, the parties hereby understand and acknowledge that absent any termination or non-renewal of this Agreement in accordance with the provisions of this Agreement, the term of this Agreement at any given time will be at least two years and will be no more than three years. In the event that the Company elects not to renew this Agreement other than for "cause" as defined herein, you will be paid the amount described in Section V.C.2 below."

2. Section V.C.2(iii) of the Employment Agreement is hereby amended in its entirety to read as follows:

"(iii) continue to allow you and your family to participate, at the Company's expense, in the Company's group hospitalization, health, dental and disability insurance programs until the earlier of (A) the expiration of the Severance Period,

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or (B) your becoming eligible to participate in another employer's corresponding group insurance and disability plans;"

Please confirm that this agreement is in accordance with your understanding and that you have received a copy of this letter by signing and dating this letter where indicated below, and returning an executed copy to the Company.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

/s/ Louis W. Sullivan, M.D.

By: Louis W. Sullivan, M.D.

Its: Chairman of the Board

Agreed to and confirmed as of February 19, 2007:

/s/ Stephen M. Simes

Stephen M. Simes

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**THIRD AMENDMENT TO LEASE**

THIS AMENDMENT, Made and entered into as of the 14<sup>th</sup> day of August, 2006, by and between Highlands Park Associates, Landlord, and BioSante Pharmaceuticals, Inc., Tenant.

**W I T N E S S E T H :**

WHEREAS, under date of September 15, 1997, Landlord and Tenant entered into a written lease (the "Lease") which Lease was subsequently amended on September 18, 2003, and on August 30, 2004, covering the premises located at 4600 A&B Highlands Parkway, Smyrna, Cobb County, Georgia 30082, and

WHEREAS, the parties desire to amend said Lease as set out hereinafter,

NOW, THEREFORE, for One (\$1.00) Dollar and other valuable consideration paid by each of the parties to the other, receipt of which is hereby acknowledged, it is agreed between the parties as follows:

This Amendment is effective immediately, and is subject to all the terms and conditions of the aforementioned Lease as amended, which Lease shall remain in full force and effect, except that:

1. SECTION 2 TERM. The Term of the Lease is extended through October 31, 2008, at midnight, subject to the early termination provision herein. Either party may terminate this Lease effective October 31, 2007, at midnight, provided that at any time on or before August 31, 2007, at midnight, the terminating party delivers to the other party (a) written notice of its intent to terminate early, together with (b) an early termination fee payable to the other party of Two Hundred Fifty (\$250.00) Dollars. If such notice is and payment is not so made, then the Lease shall not terminate early.
2. SECTION 3(a), RENT. Beginning November 1, 2006, Monthly Minimum Base Rent shall be Six Thousand Four Hundred Forty Seven and 35/100ths (\$6,447.35) Dollars.
3. SECTION 3(b), RENT. The increase in Minimum Base Rent described herein shall continue to apply. The next date of increase in Minimum Base Rent shall be November 1, 2007 and thereafter on each November 1<sup>st</sup> during the remaining Term of the Lease.
4. EXHIBIT B, SECTION 49, RESTORATION IMPROVEMENTS. Further to Exhibit B, Section 49. Landlord hereby notifies Tenant of Landlord's request to restore the Premises as per this Section 49. Tenant hereby acknowledges receipt of such notice (notwithstanding the Notice requirements in Section 36 of the Lease) together with its obligation to so restore. The final, detailed plans and specifications for the restoration work shall be provided by Tenant and approved by Landlord, which approval shall not be unreasonably withheld or delayed. The restoration work shall be completed in good and workmanlike condition and according to all applicable governmental requirements. The restoration work shall be substantially complete before the expiration of the Term of the Lease. If the Premises are not surrendered to Landlord with the restoration work substantially complete before the expiration of the Term, then the Term shall be

extended one additional calendar month through November 30, of the calendar year of expiration of the Term, at midnight. All rentals and other charges under the Lease shall be due for said extension period.

5. Section 6 of the Second Amendment to Lease dated August 30, 2004 is omitted.

IN WITNESS WHEREOF, the parties herein have hereunto set their hands and seals the date and year first above written.

**LANDLORD: HIGHLANDS PARK ASSOCIATES**

By: Dennard Properties, Inc.  
Managing General Partner  
/s/ Don W. Dennard

By: Don W. Dennard  
Its: President

**TENANT: BIOSANTE PHARMACEUTICALS, INC.**

/s/ Stephen M. Simes  
(Signature)

By: Stephen M. Simes  
(Print Name)

Its: CEO, President  
(Title)

[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

**Amendment No. 6**

to the

**License Agreement  
dated 13th of June 2000**

by and between

**Antares Pharma IPL AG, Zug, Switzerland as Licensor  
(formerly known as Permateg Technologies AG)**

and

**BioSante Pharmaceuticals, Inc., Lincolnshire, IL, USA as Licensee**

WHEREAS, Antares Pharma IPL AG, Zug, Switzerland ("Antares") and BioSante Pharmaceuticals, Inc., Lincolnshire, Illinois, United States of America ("BioSante") have previously entered into a License Agreement dated June 13, 2000 ("License Agreement"), as amended in a series of five amendments, as follows: Amendment No. 1, dated May 20, 2001; Amendment No. 2, dated July 5, 2001; Amendment No. 3, dated August 30, 2001; Amendment No. 4, dated August 8, 2002; and Amendment No. 5, dated December 30, 2002 (collectively the Amendments and with the License Agreement, the "Agreement"); and

NOW THEREFORE, Antares and BioSante agree pursuant to this Amendment No. 6 dated October 20, 2006 to the Agreement ("Amendment No. 6") to amend the Agreement as follows:

1. License Grant. The licenses granted under the Agreement are hereby amended as follows:

(a) Paragraph 1.10 of the Agreement is hereby amended and restated in its entirety as follows:

"Products" shall have the meaning set forth in Exhibit B of this License Agreement."

(b) Exhibit B of this Agreement is hereby amended and replaced in its entirety as follows:

"A. Products shall include all estrogen gels, all testosterone gels, all E and T gels, and all E and P gels, whether or not if any of the above gel formulations contain lauryl alcohol, except as noted in Section B below.

[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

B. BIOSANTE owns on an exclusive worldwide basis, free and clear of any claims by ANTARES, its product and formulation currently known as and referred to as Bio-T-Gel (XX), and has no obligation to share information regarding Bio-T Gel with ANTARES, including data generated during development.

C. Notwithstanding the above, AP-108l (gel containing norelgestromin and ethinyl estradiol and which is a competitor to Ortho Evra) shall not be included in Products.

D. Notwithstanding the above, Nestorone (gel formulation made pursuant to Joint Development Agreement with The Population Council) shall not be included in Products.

E. Notwithstanding the above, Antares shall retain its rights to testosterone gels for prevention or treatment of diseases in males in the Territory but only for products for which regulatory approval is sought and obtained by submission of (what in the United States would be known as) a full New Drug Application, and not an Abbreviated New Drug Application, "paper NDA" under section 505(b)(2) of the United States FD&C Act, or other form of application that relies on clinical studies conducted by others as to which the applicant does not have a right of reference."

(c) Paragraph I-1 of Amendment No. 4 to the License Agreement is no longer applicable and is deleted in its entirety.

(d) Paragraph 2.1 of the Agreement is hereby amended and replaced in its entirety as follows:

"2.1.1 ANTARES hereby grants to BIOSANTE an exclusive license, with the right to grant sublicenses as provided in this License Agreement, to Develop the Products in the field of transdermal gel preparations ("Field") in the Territory for purposes of obtaining Approvals, and upon receipt of the Approvals, to Market and sell the Products in the Field in the Territory, and to use the Patents and Know-How exclusively for that purpose, all in accordance with provisions contained in this Agreement. It is the parties' intention that any product characterized by its marketing approval, as opposed to Products, developed by BIOSANTE and based on PERMATECH'S Technology will be and remain the property of BIOSANTE but BIOSANTE will not be allowed to use or market the products in case this License Agreement between ANTARES and BIOSANTE is terminated.

2

2.1.2 ANTARES hereby grants to BIOSANTE a non-exclusive license, with the right to grant sublicenses as provided in this License Agreement, under the Patents and Know-How, to make and have made Bio-E-Gel in the Territory.

2.1.3 ANTARES additionally grants to BIOSANTE a non-exclusive license with the right to grant sublicenses as provided in this License Agreement, to conduct the following activities: investigation, research, conduct clinical trials and perform market research in any country outside of the Territory. For purposes of clarity the above license shall not include a license or right to apply or seek any regulatory approval/marketing authorization for any Product outside the Territory."

(e) Paragraph B(2) of Amendment No. 5 to the License Agreement is no longer applicable and is deleted in its entirety.

(f) Paragraph 2.2 of the Agreement is hereby amended by the deletion of "(with only the commercial terms redacted)" from the last sentence therein.

(g) Paragraph 2.2 of the Agreement is hereby further amended by the insertion of the following sentence after the end of the sentence beginning with "Furthermore, BIOSANTE undertakes . . ." with the following sentence:

"Additionally, BIOSANTE covenants that any and all sublicense agreements, in which Bio-E-Gel is sublicensed, shall provide that (i) all up-front, sublicense and milestone payments due from such sublicense agreement shall be paid into an interest bearing escrow account established for the benefit of both ANTARES and BIOSANTE and shall be the account designated by both ANTARES and BIOSANTE ("Escrow Account") and (ii) that ANTARES is a third party beneficiary of such sublicense agreement solely with respect to subsection (i) above. The parties agree that the terms of the Escrow Account shall provide that (a) ANTARES is responsible for all costs and fees to establish and maintain the Escrow Account, (b) seventy-five (75%) of funds deposited shall immediately be released to BIOSANTE, and (c) the remaining twenty-five (25%) of funds deposited plus any and all interest accrued shall be released to ANTARES upon thirty days from deposit."

2. Credit for Sublicense Payments for Bio-E-Gel. In the event that BioSante (i) terminates a sublicense agreement for Bio-E-Gel ("Sublicense Agreement") prior to February 15, 2007 and where such termination is based on BioSante failing to receive regulatory approval for Bio-E-Gel by the FDA (as defined below) and (ii) has to return all or a portion of the upfront consideration received pursuant to such Sublicense Agreement, then Antares will credit the pro rata portion of such upfront consideration that it received to future payments due by BioSante for Bio-E-Gel.

3. Disclosure of Confidential Information. Each party may disclose non-public confidential information of the other party to subcontractors or potential licensees who are under a binding obligation of confidentiality to such party, at least as strict as in the Agreement and so long as such party remains responsible for the potential licensees' compliance.

3

[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

4. Patent Prosecution and Maintenance. From the effective date of this Amendment No. 6, Antares will, at its cost and expense, file, prosecute, and maintain the Patents, including, but not limited to, those listed on Appendix A hereto. If Antares determines to abandon or not file any Patent, then Antares shall provide BioSante with written notice at least thirty (30) days or if less, as long as reasonably practicable, prior to the date such abandonment or failure to file would become effective for BioSante to act in its stead, provided, that BioSante has received from Antares any and all reasonable documentation and information it reasonably needs to make a decision and take the necessary action in reasonable sufficient time to avoid abandonment. For purposes of clarity, discontinuance shall be elected on a country-by-country basis. BioSante may elect at its sole discretion to continue prosecution or maintenance of any discontinued Patent at its sole expense. BioSante shall then own any such Patent, and Antares shall execute such documents and perform such acts, at BioSante's cost, as may be reasonably necessary for BioSante to continue prosecution or maintenance, including assigning and transferring ownership of such Patent to BioSante and directing its counsel to transfer the complete file to BioSante or its counsel as BioSante may request. Upon the assignment or transfer of any Patent to BioSante, Antares shall not be thereafter entitled to any royalties from sales of a Product sold in a country where such Patent was abandoned and where such Patent claims such Product.

5. Patent Reports and Updates. Antares will (at its sole cost and expense) provide BioSante with a complete paper, organized file set of material prosecution documents for each of the Patents. Going forward, Antares will at its sole cost and expense copy BioSante on all material communications with respective patent offices in the Territory and provide BioSante with twice-yearly update summaries reviewed by its patent counsel regarding each of the Patents

(including filing, prosecution, and maintenance status in each country in the Territory). Additionally, Antares will, at BioSante's expense, make its counsel reasonably available to consult with BioSante and potential licensees regarding the status of the Patents.

- 6. **Patent Enforcement.** To the extent BioSante consents in writing, BioSante's exclusive sublicensee(s) in the United States shall have those rights possessed by BioSante as set forth in section 8.2.2 and 8.2.4 of the Agreement.
- 7. **LibiGel Package.** BioSante will promptly provide Antares with a copy of all material filings and submissions submitted to date to the United States Food and Drug Administration ("FDA") regarding LibiGel and the minutes from the BioSante LibiGel meeting held with the FDA on or about XXXXXXXXXXXX (collectively, the "LibiGel Package").
- 8. **XXXXXXXXXXXXXXXXXX.** BioSante consents to Antares' engagement of XXXXXXXXXXXXXXXXXXXX in Europe for work on testosterone gel for women; provided that Antares agrees that no BioSante confidential information is used or disclosed in connection with the engagement.
- 9. **Steering Committee.** Antares and BioSante will each send at least one representative who is an officer to a steering committee meeting to be held on a twice-yearly basis alternating

between Antares' facility and BioSante's facility. Each party will provide a summary update twice-yearly to the other of its activities being conducted to establish that it is in substantial compliance with its material obligations under the Agreement.

- 10. **Further Sublicensing.** BioSante may, in connection with the exercise of its sublicense rights under the Agreement, authorize (i) its sublicensee(s) to solely grant a further sublicense to their contract manufacturer(s) for the sole purpose of manufacturing Product for such sublicensee(s) to the extent that BioSante has such license right itself or (ii) an exclusive sublicensee of BioSante ("Sublicensee") the right to further sublicense Bio-E-Gel subject to Antares' written consent (not to be unreasonably withheld), provided, that all payments due to BioSante from its Sublicensee, directly or indirectly, for the grant of such further sublicense by the Sublicensee shall be paid into the Escrow Account and disbursed in accordance with the procedures and allocation percentages provided in Paragraph 2.2 of the Agreement.
- 11. **Audits of Sublicensees.** With respect to any audits that Antares may conduct of sublicensees pursuant to Sections 2.2 and 3.5.2.4 of the Agreement, Antares agrees that it and any independent certified public accounting firm retained by Antares to conduct the audit will treat any information obtained from the sublicensee during the course of the inspection and audit as confidential pursuant to Section 7 of the Agreement, and if requested by the sublicensee will execute a commercially reasonable confidentiality agreement before beginning the audit in which Antares and such public accounting firm agree to maintain the confidentiality of the sublicensees' books and records and to use all information received from the sublicensee only for such audit purpose.
- 12. **Effect of Termination on Sublicensee.** Antares agrees that if so provided in a sublicense agreement signed by BioSante and its sublicensee of its rights hereunder and where such sublicense has been granted in accordance with the Agreement, then a termination of the Agreement due to BioSante's breach that is not caused by the sublicensee will not terminate the sublicensee's license rights and that in such case the sublicense agreement (and all future payments and performance under the sublicense agreement by the sublicensee) will continue between the sublicense and Antares. In the event the aforesaid termination was caused by BioSante's non-payment of monies due to Antares, such continuation of the sublicense agreement between sublicense and Antares shall not effect BioSante's obligation to pay Antares for any and all monies due from BioSante to Antares as of the date of termination.
- 13. **Representation.** Antares hereby represents that, to its knowledge as of the effective date of this Amendment No. 6, Bio-E-Gel does not infringe any patent or other proprietary right of any third party in the United States.
- 14. **Amended and Restated Agreement.** The parties will exercise good faith efforts to prepare and execute an amended and restated agreement of this Agreement as it exists as of the execution of this Amendment No. 6 as soon as practicable, and no later than within 90 days, following execution of this Amendment No. 6, with ANTARES to prepare a full and complete initial draft of same at its expense. After preparation of such initial draft by ANTARES, each party will be responsible for its own costs and expenses incurred in the completion of such amended and restated agreement. For clarity, such amended and restated agreement shall strictly conform in all respects to this Agreement as it exists as of the execution of this Amendment No. 6.

- 15. **Headings.** The captions to the paragraphs/section in this Amendment No. 6 are not a part of this Amendment No. 6 or the Agreement, and are included merely for convenience of reference only and shall not affect its meaning or interpretation.
- 16. **Counterparts.** This Amendment may be signed in any number of counterparts with the same effect as if the signatures thereto and hereto were upon the same instrument.
- 17. **Construction.** This Amendment No. 6 (i) was drafted by both parties and thus any rule of contract interpretation calling for documents to be construed against the drafter shall not apply to the construction of this Amendment, and (ii) shall not affect the construction of the Agreement as it existed before the effective date of this Amendment.
- 18. **Miscellaneous.** Antares and BioSante confirm and acknowledge that the Agreement is in full force and effect, that there have been no uncured events of breach to date, and that each is in material compliance with the Agreement. Nothing in this Amendment No. 6 shall constitute an admission of wrongdoing by either party vis a vis the other and each party expressly denies any wrongdoing. Except for the changes made by this Amendment No. 6 to the Agreement, the Agreement remains in full force and effect without modification.

IN WITNESS WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the 20<sup>th</sup> day of October, 2006.

**Antares Pharma IPL AG**

By: /s/ Jack E. Stover

Name: Jack E. Stover

Title: President & CEO

Date: 10/20/06

/s/ Dario Carrara

Dario Carrara

Managing Dir. Swiss Operations

10/20/06

**BioSante Pharmaceuticals, Inc.**

By: /s/ Stephen M. Simes

Name: Stephen M. Simes

Title: President \* CEO

Date: 10/20/06

[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

**Appendix A  
Patents**

- 1. U.S. Appl. No. 10/798,111
- 2. U.S. Appl. No. 10/343,570
- 3. U.S. Appl. No. 10/798,161
- 4. U.S. Appl. No. 11/371,042
- 5. U.S. Patent. No. 5,891,462
- 6. U.S. Appl. No. 11/441,311
- 7. XXXXXXXXXXXXXXXXXXXX

October 27, 2006

Antares Pharma IPL AG  
c/o Antares Pharma Inc.  
Princeton Crossroads Corporate Center  
250 Phillips Boulevard, Suite 290  
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to clarify paragraph 12 of Amendment No. 6 (dated as of October 20, 2006) of the Agreement. Specifically, it is BioSante's understanding that in the event that a sublicense agreement is assigned to Antares under that paragraph 12, any moneys that the sublicensee owed BioSante as a result of events (such as sales or milestone-triggering events) that occurred before the effective date of the termination of the Agreement would still be owed and paid to BioSante, even if the actual payment date were to fall after the effective date of the termination.

If this clarification is agreeable to Antares, please countersign below and return a copy of this letter to me. Thank you.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Phillip B. Donenberg  
Phillip B. Donenberg  
Chief Financial Officer

Agreed and Accepted:

ANTARES PHARMA IPL AG

By: /s/ Jack E. Stover  
Jack E. Stover  
President and CEO

DATED: October 27, 2006

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, IL 60069

November 6, 2006

Antares Pharma IPL AG  
c/o Antares Pharma Inc.  
Princeton Crossroads Corporate Center  
250 Phillips Boulevard, Suite 290  
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to seek clarification of two paragraphs of Amendment No. 6 (dated as of October 20, 2006) of the Agreement.

With respect to paragraph 6, BioSante would like to clarify that in the event that it and/or its sublicensee assert any of the Patents listed in Appendix A to Amendment No. 6 against an infringer, Antares would agree if commercially reasonable and if requested to join as a coplaintiff (to assure standing) at the sole cost and expense of the party making the request (BioSante or the sublicensee, as the case may be).

With respect to paragraph 12, BioSante we would like to clarify that the provisions of this paragraph would also apply if the Agreement is terminated due to BioSante's bankruptcy, by inserting the phrase "or bankruptcy" after the phrase "BioSante's breach" in the third line.

If this is agreeable, please countersign below and return a copy of this letter to me.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes  
Name and title:  
Stephen M. Simes  
President & CEO

Agreed and Accepted:

ANTARES PHARMA IPL AG

By: /s/ Jack E. Stover  
Name and title:

Jack E. Stover  
President & CEO

DATED: November 6, 2006

BioSante Pharmaceuticals, Inc.  
111 Barclay Boulevard  
Lincolnshire, IL 60069

November 7, 2006

Antares Pharma IPL AG  
c/o Antares Pharma Inc.  
Princeton Crossroads Corporate Center  
250 Phillips Boulevard, Suite 290  
Ewing, NJ 08618

Re: License Agreement between Antares Pharma IPL AG ("Antares") and BioSante Pharmaceuticals, Inc. ("BioSante"), dated June 13, 2000, as amended in six amendments (collectively, the "Agreement")

Gentlemen:

I write to provide language to embody a clarification and amendment to the Agreement.

With respect to the proposed sublicense of Bio-E-Gel to Bradley Pharmaceuticals, Inc. ("Sublicensee") by BioSante ("Sublicense Agreement"), BioSante and Antares agree that Antares shall receive twenty-five percent (25%) of all up-front, sublicense and milestone payments due from such Sublicense Agreement as provided in Amendment No. 6 of the Agreement dated October 20, 2006 ("Amendment No. 6"), and in the event that BioSante is to receive at least seven million dollars upon the regulatory approval of Bio-E-Gel in the United States, then BioSante shall not be obligated to pay any additional milestone payments on the regulatory approval of Bio-E-Gel for the United States other than twenty-

five percent (25%) of the payment it receives for regulatory approval of Bio-E-Gel from Sublicensee for the United States. For purposes of clarity, if Sublicensee is obligated to pay seven million dollars to BioSante upon regulatory approval of Bio-E-Gel in the United States, then Antares shall receive twenty-five percent of such amount - \$1,750,000 to be paid as provided in paragraph 1(g) in Amendment No. 6.

Additionally, because the escrow account contemplated by Amendment No. 6 has not been established and we are on the verge of executing the Sublicense Agreement for Bio-E-Gel with the Sublicensee, we ask Antares' agreement that the escrow requirement of Amendment No. 6 is satisfied if the Sublicensee pays directly upon signing to Antares twenty-five percent (25%) of all payments due to BioSante or its Affiliates upon signing by wire to the following account:

Bank name and address:  
Wells Fargo Bank, N.A.  
6<sup>th</sup> and Marquette  
Minneapolis, MN 55479  
Account name: Antares Pharma, Inc.  
Account number: 323-869-1379  
ABA: 121000248

Except for the changes made by this letter, the Agreements remains in full force and effect without modification.

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If this is agreeable, please countersign below and return a copy of this letter to me.

Very truly yours,

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes  
Name: Stephen M. Simes  
Title: President & CEO

Agreed and Accepted:

ANTARES PHARMA IPL AG

By: /s/ Robert Apple  
Name: Robert Apple  
Title: CFO

DATED: November 7, 2006

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(e) All rights and interests not expressly granted to Company are reserved by BPA.

(f) Company and its Affiliates and sublicensees shall not sell or otherwise distribute Products to customers outside of the Territory or to any party who the Company or BPA has reasonable grounds to believe is likely to export the Products outside the Territory. Company shall require its distributors who sell or otherwise distribute Products to make a covenant similar to that provided by Company in this Section 2(f) with respect to Products. All inquiries or orders received by Company for the Products to be delivered outside the Territory shall be referred to BPA. BPA and its Affiliates and sublicensees shall not sell or otherwise distribute Products to customers within the Territory or to any party who the Company or BPA has reasonable grounds to believe is likely to import the Products into the Territory. BPA shall require its distributors who sell or otherwise distribute Products to make a covenant similar to

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that provided by BPA in this Section 22(f) with respect to Products. All inquiries or orders received by BPA for the Products to be delivered within the Territory shall be referred to Company.

(g) Within thirty (30) days of the Effective Date, BPA shall provide Company with a written report setting forth a summary and status of all Patents and Know How as of such date. Thereafter, on each anniversary of the Effective Date during the term of this Agreement, BPA shall provide Company with a detailed written report setting forth a summary and status of (i) all additional BPA Know How that BPA may develop or acquire or that BPA has not previously disclosed to Company pursuant to this Section 21(a) and (ii) all BPA Patents that have not been previously disclosed to Company pursuant to this Section 21(a).

(h) During the term of this Agreement, BPA shall, at Company's request, exercise commercially reasonable efforts to enforce the exclusivity of the license rights granted to BPA pursuant to the Prime License Agreement if such rights are violated by Antares or any third-party licensee of BPA outside the Territory.

3. Up-Front License Fees, Royalties and Milestones.

(a) In consideration of the rights granted herein, the Company shall pay to BPA:

(i) a royalty of XXX% of Net Sales of the Product distributed or sold in the Territory in all years during the Royalty Term, as adjusted as provided below.

(1) Generic Competition. If a Generic Equivalent is reasonably notified by either party under Section 14(b) to infringe a Patent available for a Product in a country in the Territory during the Royalty Term, and Company furnishes evidence that the marketing of such Generic Equivalent has led to a reduction in sales of the affected Product in such country of the Territory by more than XXXXX percent (XXX%), and (i) in the case of notification of infringement XXXXXXXXXXXXXXXX, BioSante takes no action against the third party, but Company does take action under Section 14(b)(i), or (ii) in the case of notification of infringement XXXXXXXXXXXXXXXX, Company takes action under Section 14(b)(ii), then the royalty rates set forth in Section 3(a)(i) with respect to such Product in such country shall be reduced by XXXXX percentage XXXXX (i.e. from XXX % to XXX %) on a going-forward basis for such Products in such country, during all times in which the Generic Equivalent with respect to such Products remains on sale in such country.

(2) Single Royalty. The royalty provided in Section 3(a)(i), as adjusted, shall not increase for a Product by reason of such Product being covered by more than one Valid Claim or such Product being covered both by one or more Valid Claims and by Know How.

(ii) milestone payments as follows:

(1) \$3.5 million on signing of this Agreement; and

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(2) \$7 million that becomes fully earned and accrued in favor of BPA on receipt of FDA approval to commence marketing a Product for the Launch Indication in the United States ("FDA Approval"), provided that Company may for its convenience delay the actual payment of such milestone until the earlier of fourteen weeks after FDA Approval or first commercial sale of a Product in the United States; and

(3) \$3 million on the first anniversary of achievement of the milestone described in Section 3(a)(ii)(2); provided, however, that in the event that FDA Approval is received for the lowest dose that BPA tested in Phase III clinical trials, BPA shall be entitled to an additional \$500,000 (total of \$3.5 million) for this milestone.

(iii) additional milestone payments as follows:

(1) \$XXXXXX upon the first achievement of \$XXXXXX of Net Sales of the Product in the Territory in a calendar year;

(2) and additional \$XXXXXX upon the first achievement of \$XXXXXX of Net Sales of the Product in the Territory in a calendar year;

(3) an additional \$XXXXXX upon the first achievement of \$XXXXXX of Net Sales of the Product in the Territory in a calendar year;

(4) an additional \$XXXXXX upon the first achievement of \$XXXXXX of Net Sales of the Product in the Territory in a calendar year;

(5) after the achievement of the milestone provided in Section 3(a)(iii)(4) and after commercial launch of the Product in the Territory for the Launch Indication, a bonus sales milestone of either (A) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX but less than \$XXXXXX or (B) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX (but not both (A) and (B));

(6) after the achievement of the milestone provided in Section 3(a)(iii)(5), a bonus sales milestone of either (A) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX but less than \$XXXXXX or (B) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX (but not both (A) and (B)); and

(7) after the achievement of the milestone provided in Section 3(a)(iii)(6), a bonus sales milestone of either (A) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX but less than \$XXXXXX or (B) an additional \$XXXXXX if Net Sales of the Product in the Territory in the immediately following calendar year is at least \$XXXXXX (but not both (A) and (B)).

Company shall make each of the payments provided in 3(a)(iii) within ten (10) business days after the occurrence of the applicable milestones. Company shall make the payments provided in

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3(a)(ii), and (iii) above only once, upon the first achievement of the applicable milestone by the first Product in a country in the Territory, no matter how many additional times the applicable milestone is achieved.

With the exception of the initial payment required by 3(a)(ii)(1), Company shall make the payments provided in 3(a)(ii) and 3(a)(iii) above into an escrow account identified to Company by BPA that is established for the benefit of both BPA and Antares. BPA agrees that each such payment by Company into such escrow account shall satisfy Company's obligation for such payment to BPA notwithstanding any dispute that may arise concerning the operation of the escrow account. Antares is a third party beneficiary of this Agreement solely with respect to this provision concerning payments into the escrow account. Company shall make the initial payment required by 3(a)(ii)(1) by paying 75% (\$2,625,000) to BioSante and 25% (\$875,000) to Antares by wire transfer as follows:

For Antares:

Bank name and address:  
XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX

Account name: XXXXXXXX  
Account number: XXXXXXXX  
ABA: XXXXXXXX

For BioSante:

XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXX  
ABA XXXXXXXX



4. Reports and Payments.

(a) On or before the last business day of January, April, July, and October of each year of this Agreement, the Company shall submit to BPA a written report with respect to the preceding calendar quarter (the "Payment Report") stating:

- (i) Gross sales and Net Sales made by the Company during such quarter and an itemization of deductions from gross sales to Net Sales;

7

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- (ii) In the case of transfers of Products to an Affiliate of the Company for sale, rental, or lease of such Products by the Affiliate to third parties, Net Sales by the Affiliate to third parties during such quarter;
- (iii) A calculation under Section 3 of the amounts due to BPA, making reference to the application subsection thereof.

(b) Simultaneously with the submission of each Payment Report, the Company shall make payments to BPA of the amounts due for the calendar quarter covered by the Payment Report.

(c) Inspections and Audit. Company shall keep full, true and accurate books of account containing particulars and reasonable supporting documentation which may be necessary for the purpose of determining the Net Sales of Products, royalties due thereon and the statements provided by Company pursuant to Section 4(a) above. Such records shall be kept at Company's principle place of business, and shall be open at all reasonable times and upon reasonable advance notice to the inspection of Antares, BPA, or an independent certified public accounting firm retained by Antares or BPA, and reasonably acceptable to Company, for the purpose of verifying any payment made under this Agreement. The party initiating the inspection and audit (Antares or BPA) shall bear the full cost of any such audit, unless the audit discloses that the amount due during any period audited exceeds the amount paid by (i) ten percent (10%) or more during the first two (2) years following first commercial sale of a Product in any country in the Territory; or (ii) five percent (5%) or more thereafter, in which case Company shall bear the full cost of such audit. Any additional royalty found in such audit to be due BPA shall be paid by Company within thirty (30) days after such finding.

(d) Interest. In the event any amount due and payable under this Agreement is not paid by the due date, then the party owing such amount shall pay to the other party, without being requested by such other party, interest on the total outstanding amount at one and one half percent (1.5%) per month, in United States Dollars.

5. Product Approvals.

(a) Launch Indication Approval. BPA shall use its commercially reasonable efforts for the good faith prosecution of its pending NDA for Bio-E-Gel for the Launch Indication; *provided*, BPA's commercially reasonable efforts shall include, at a minimum, performing all regulatory and clinical work for FDA Approval in the United States of Product for the Launch Indication (except for changes arising out of non-FDA required marketing, packaging, or manufacturing changes) at its sole expense not to exceed a fully burdened cost of \$XXXXXX. After the Effective Date, Company will have the right to participate in all formal meetings with the FDA regarding such FDA Approval. BPA agrees to provide Company with copies of all correspondence and documents to and from FDA and all notices received from FDA and to also provide Company with regular updates as Company may reasonably request. If further or additional regulatory work and clinical studies are required by the FDA in order to obtain such FDA Approval and the fully burdened cost to BPA will exceed \$XXXXXX, Company shall

8

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have the option, but not the obligation, to fund the excess. If Company declines to fund the excess, and if BPA also declines to fund the excess, then either party shall be permitted to terminate this Agreement and such termination will be deemed not to be caused by the breach of either party and will be deemed not to be a termination by Company under Section 16(d). In the event of termination under this Section 5(a), BPA agrees to refund to Company the \$3,500,000 initial payment paid by Company to BPA pursuant to Section 3(a)(ii)(1), less any amount actually paid by Company to Antares on account of such initial payment under the Prime License Agreement; *provided, however*, BPA shall use its commercially reasonable efforts to obtain a refund of any portion of sub-licensee payments paid to Antares under the Prime License Agreement, and shall promptly pay over to Company any such amounts recovered from or credited by Antares.

(b) Transfer of NDA. Upon FDA Approval of Bio-E-Gel for the Launch Indication, BPA agrees to assign, and hereby assigns, all right, title and interest in and to its NDA for Bio-E-Gel for the Launch Indication to Company, shall promptly transfer all documentation related to such NDA to Company and agrees to take all such further commercially reasonable action and promptly execute such further documents as may be reasonably necessary or desirable to give full effect to such assignment (including without limitation filing any related documents with the FDA). After such transfer Company shall be solely responsible for (i) post FDA Approval regulatory obligations for the Product, including without limitation the preparation and submission of annual reports, the reporting of adverse events, and cooperating with governmental regulatory agencies; (ii) communication with third parties regarding the Product in the Field in the Territory, including without limitation responding to complaints and medical inquiries; (iii) investigating all complaints and adverse drug experiences related to the Product in the Field in the Territory; and (iv) conducting any voluntary or involuntary recalls of Product in the Territory, including without limitation recalls required by any governmental authority and recalls deemed reasonably necessary by Company or BPA.

(c) Post-Approval Studies. In the event the FDA requires a Phase IV study, BPA shall conduct such study but shall only be responsible for XXX% of the fully burdened cost and expense of any Phase IV commitment up to a maximum of \$XXXXXX, with Company responsible for the excess. BPA shall from time to time invoice Company for Company's share of such costs and expenses, and Company shall pay such invoices within thirty (30) days of receipt.

(d) Pre-Approval Changes. Without limiting BPA's responsibilities pursuant to Section 5(a), Company shall be solely responsible, at its own expense, for all regulatory or clinical work, requirements, cost or expense arising out of any marketing, manufacturing or packaging changes initiated or requested by Company in writing prior to FDA Approval. By way of example and not limitation, Company has requested that BPA develop XXXXXXXX formats of Product for detailing and sample purposes, which such development BPA has commenced, and Company shall going forward direct such development at its discretion and shall be responsible for all such fully burdened development costs and expenses for such formats incurred after the Effective Date. If Company determines to discontinue such

9

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development, it shall give reasonable advance written notice to BPA, and BPA shall then have the right, but not the obligation, to continue such development at its sole cost and expense.

(e) New Indications. Company shall have the right, in its sole discretion, to conduct development and commercialization of the Product for any New Indication in the Territory, subject to and in accordance with the terms and conditions of this Agreement. If Company decides to pursue any such New Indication, Company shall be solely responsible at its sole cost and expense for accomplishing all Product development and commercialization, including without limitation (1) any pre-clinical, clinical and regulatory work, additional clinical testing or other studies and manufacturing requirements relating to the Product for such New Indication; (2) all FDA and other regulatory obligations post approval for such New Indication; and (3) any other Product and medical requirements relating to the sale or marketing of the Product for such New Indication. Subject to Section 5(f), Company agrees to provide BPA with copies of all correspondence and documents to and from FDA and all notices received from FDA regarding such New Indication and to also provide BPA with regular updates as BPA may reasonably request.

(f) Data Sharing. BPA and Company agree to provide one another immediate, full and free access to the clinical data and results generated by or on behalf of each (including by Affiliates and sublicensees of such party and, in the case of BPA, information received from Antares) with respect to the Products, and each agrees that the other may utilize all such data and results directly or through permitted (sub) licensees in pursuit of product approvals in their respective geographical areas (the Territory for Company and all other areas for BPA). BPA shall use commercially reasonable efforts to obtain such data from other licensees or sublicensees, but BPA shall have no obligation to share or provide any such information and data regarding Products with Company under this Section 5(f) if such information is not freely available to BPA with the right to share same with Company. For the avoidance of doubt, BPA shall have the absolute right to freely share all such data and results obtained from Company with Antares.

(g) Adverse Events. The parties shall promptly notify each other of any material information related to adverse events with Products to the extent required by applicable law to allow the parties to timely comply with their adverse event and safety data reporting legal obligations worldwide (including as these legal obligations may be updated in future). Each party shall require its Affiliates and Product licensees and sublicensees to comply with this Section 5(g).

6. Diligence; Compliance With Law.

(a) The Company shall use its best commercially reasonable efforts to manufacture, market, sell and distribute Products for commercial sale and distribution throughout the Territory.

- (i) Company shall provide a minimum of XXXXXXXXXXXX sales representatives to detail the Product for the commercial launch for Launch Indication in the

10

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Territory at the time of such commercial launch, and a minimum of XXXXXXXXXXXX sales representatives to detail the Product for the Launch Indication in the Territory XXXXXXXXXXXX after such commercial launch. Without limiting the foregoing, Company shall provided a minimum cumulative total of XXXXXXXXXXXX PDEs as of XXXXXXXXXXXX after commercial launch of the Product for the Launch Indication in the Territory, a minimum cumulative total of XXXXXXXXXXXX PDEs as of XXXXXXXXXXXX after such commercial launch and a minimum cumulative total of XXXXXXXXXXXX PDEs as of XXXXXXXXXXXX after such commercial launch. Company shall use promotional and sales efforts for the Product for the Launch Indication in the Territory that is not less than such promotional and sales efforts and financial commitment for other products of similar size and market potential promoted and sold by Company in the Territory and not less than such promotional and sales efforts and financial commitment made by other similarly situated pharmaceutical companies for products of similar size and market potential. Company shall use best commercially reasonable efforts to fully launch its promotion and sale of the Product for the Launch Indication in the Territory within XXXXXXXXXXXX following FDA Approval, but no later than XXXXXXXXXXXX following receipt of commercial quantities of salable Product for commercial sale after FDA Approval. Failure to launch with XXXXXXXXXXXX following receipt of such commercial quantities of Product after FDA Approval shall be deemed a material breach of this Agreement.

(ii) During the term of the Agreement the Company shall not make, have made, market, sell, offer for sale, or distribute transdermal estrogen-only products (delivered as a gel and not with a patch or another transdermal delivery method) for once daily application that directly compete with the Product for the Launch Indication in the Territory. However, in the event that Company is acquired by a third party that is marketing a competing product in at the time of acquisition, this Section 6(a)(ii) shall not require the acquiring company to discontinue sales of such product so long as the acquiring company complies in all other respects with the obligations to diligently sell and promote the Product.

(b) The Company shall at all times comply with and adhere to all statutes, ordinances, laws, regulations, and the like in its conduct of all of its activities under this Agreement, including without limitation in the manufacture, marketing, advertising, promotion, distribution, and sale of the Products.

(c) The Company shall promptly provide BPA with copies of all promotional materials used by Bradley for marketing the Product in the Field in the Territory. The Company shall also provide BPA an annual summary report of its commercialization of the Product, including copies of the Company's actual draft sales and marketing plans, and afford BPA a reasonable opportunity to provide input into same and meet with the Company to discuss; *provided, however*, that this shall not be construed as a right of BPA to approve such sales and marketing plans. In addition, the Company shall provide BPA a mid-year update to such report summarizing any further developments in the commercialization of the Product.

11

(d) The Company shall provide BPA with copies of all correspondence and documents to and from FDA and all notices received from FDA concerning the Product, and also provide BPA with regular updates as BPA may reasonably request.

7. **Proprietary Rights.** Company acknowledges and agrees that as between Company and BPA, BPA shall have and obtain title to and ownership in the formulation of the Products, the Patents and the Know How (as that term is defined in the Prime License Agreement), including, but not limited to, any and all improvements, developments, and inventions thereof that cover the Products, if any. For the avoidance of doubt, any inventions made by Company during the term of the Agreement that do not cover the Products shall remain the property of Company. Nothing in this Agreement shall be interpreted to grant any ownership, license or other right to any party in or to any improvement, development or invention of Company arising from its research and development activities generally to the extent such activities are not directed toward the Product. Nothing in this Agreement shall be interpreted to cause any information relating to Company's research and development activities generally to the extent such activities are not directed toward the Product to be considered the Confidential Information of any party other than Company.

8. **Manufacturing.**

(a) The Company shall use its best commercially reasonable efforts to have the Product manufactured at all times in sufficient quantities to supply any demand and any government or commercial requirements, and at all times shall ensure that such manufacture complies with applicable law.

(b) **Technology Transfer.**

(i) Promptly after the Effective Date, BPA and its Affiliates shall, and BPA shall use its good faith efforts to cause its contractors, including without limitation DPT Laboratories, Ltd., 4040 Broadway, Suite 401, San Antonio, TX, 78209 ("DPT"), who have been manufacturing Product (in any and all forms) to, perform all technology transfer required to establish all then-current manufacturing processes (including analytical methods) for Products (in any and all forms) at Company's manufacturing facility or the manufacturing facility of Company's chosen supplier. To be clear, this technology transfer shall include without limitation the transfer by BPA of all manufacturing data and Know How and copies of any FDA correspondence with respect to manufacture of Product. Company shall have the right to share all such manufacturing data and Know How with any manufacturer the Company engages to manufacture Product, under terms of confidentiality and non-use no less stringent than those present in this Agreement. Notwithstanding anything to the contrary in this Section, Company's right and ability to receive such information from DPT is subject to the Research and Development Services Agreement between BPA and DPT dated as of May 28, 2003 (the "DPT Agreement"), and Company may be required by DPT to undertake certain confidentiality obligations provided in Section 8 of the DPT Agreement and exclusivity obligations provided in Section 7 of the DPT Agreement, in each case as imposed on BPA in accordance with the DPT Agreement, in order to receive information from DPT, it being understood, however, that such exclusivity obligation is conditioned upon DPT honoring its obligations under the DPT Agreement and the DPT Agreement being in full force and effect. If requested by Company, BPA shall use commercially reasonable efforts (not requiring the payment of money or

12

assumption of other obligations) to assist Company in negotiating with DPT a commercially reasonable manufacturing price for the Product for the benefit of Company.

(ii) At the request of Company, BPA shall reasonably assist Company with arranging for manufacture of Product to be performed after the Effective Date by DPT, including without limitation by facilitating introductions of Company's representatives to, and the commencement of discussions with such representatives with, such contacts within DPT as are then reasonably available to BPA or any of its Affiliates, and offering assistance and consultation to Company's representatives with respect to the conduct of any such discussions with DPT. BPA shall request that DPT, and give DPT the right to, work collaboratively with and disclose BPA Confidential Information to Company regarding the manufacture of Product in the Field in the Territory subject to this Agreement and the Prime License Agreement. Company shall request that DPT, and give DPT the right to, work collaboratively with and disclose Company Confidential Information to BPA regarding the manufacture of Product in the Field in the Territory subject to this Agreement and the Prime License Agreement.

(iii) Promptly after the Effective Date, BPA shall assign to Company, and Company shall accept assignment, of the DPT Agreement, *provided that* BPA shall remain responsible for any obligations that it may have to DPT under the DPT Agreement that are due and existing at the time of such assignment (including, to be clear, indemnification obligations for actions occurring prior to the time of such assignment). Company agrees that any confidential information of BPA held by DPT shall remain the property of BPA and be governed by the confidentiality provisions of this Agreement. Upon the termination or expiration of this Agreement, the Company shall reassign the DPT Agreement to BPA and BPA shall accept assignment, *provided that* the Company shall remain responsible for any obligations that it may have to DPT under the DPT Agreement that are due and existing at the time of such reassignment (including, to be clear, indemnification obligations for actions occurring prior to the time of such reassignment).

(c) **Tag Along Manufacturing.** BPA shall have the right to place orders for reasonable quantities of Product for sale by BPA or BPA's licensees outside the Territory when Product is being made by or for Company; *provided, however*, if BPA and BPA's licensees intend to order sufficient quantities of Product to comprise a complete manufacturing batch of Product, BPA and its licensees shall place their own order for such Product independently of Company's orders. Company shall give BPA as much advance notice as reasonably possible, but in no event less than best commercially reasonable notice, for each manufacturing run to enable BPA to exercise its rights under this Section 8(c). BPA shall pay Company's actual out of pocket cost for such manufacture including any surcharges imposed by the manufacturer for partial batches and special packaging and labeling requirements. BPA shall make payments for its orders either directly to the manufacturer or to Company, and shall take delivery either directly from manufacturer or from Company, with the details of same to be negotiated in good faith between BPA and Company (subject to the default rules of the Uniform Commercial Code if agreement on the details is not reached). In the event that the manufacturer is not able to fill the entire quantity ordered by Company and BPA, it shall fill the orders on a pro rata basis.

13

9. **Confidentiality.**

(a) **Confidential Information.** In connection with this Agreement, the parties may provide to each other Confidential Information, including without limitation each party's invention disclosures, proprietary materials and/or technologies, economic information, business or research strategies, trade secrets and material embodiments thereof. As used herein, "**Confidential Information**" means any information of a confidential or proprietary nature disclosed by a party to this Agreement to the other party, including, in the case of Company, royalty reports or development reports submitted pursuant to this Agreement. For the avoidance of doubt, any such Confidential Information related to the Product shall be considered BPA's Confidential Information.

(b) **Confidentiality and Non Use.** The recipient of the disclosing party's Confidential Information shall use such Confidential Information solely to exercise its rights and perform its obligations under this Agreement, and in the case of BPA only, under the Prime License Agreement (including, without limitation, the right to use and disclose such Confidential Information in regulatory applications and filings), unless otherwise mutually agreed in writing. The recipient of a disclosing party's Confidential Information shall maintain such Confidential Information in confidence, and shall disclose such Confidential Information only to those of its employees, agents, consultants, sublicensees, attorneys, accountants, advisors, and in the case of BPA only, licensor with respect to the Product who have a reasonable need to know such Confidential Information and who are bound by obligations of confidentiality and non-use no less restrictive than those set forth herein. The recipient of the other party's Confidential Information shall take the same degree of care that it uses to protect its own confidential and proprietary information of a similar nature and importance (but in any event no less than reasonable care).

(c) **Exclusions.** Confidential Information shall not include information that: (i) is in the recipient's possession prior to receipt from the disclosing party as demonstrated by contemporaneous documentation; (ii) is or becomes, through no fault of the recipient, publicly known; (iii) is furnished to the recipient by an unaffiliated third party without breach of a duty to the disclosing party; (iv) is independently developed by the recipient without use of, application of or reference to the disclosing party's Confidential Information as demonstrated by contemporaneous documentation.

(d) **Legal Disclosures.** It shall not be a violation of this Section 9 to disclose Confidential Information to the extent required to be disclosed under applicable law, *provided that* the recipient, to the extent possible and in accordance with applicable law, shall give the disclosing party prior written notice of the proposed disclosure and shall cooperate fully with the disclosing party to minimize the scope of any such required disclosure.

(e) **Survival.** All obligations of confidentiality and non-use imposed under this Section 9 shall survive for five (5) years after the termination or expiration of this Agreement.

(f) **Communications with BPA's Licensor.** For clarity and without limitation, during the term of this Agreement, the Company shall not directly communicate with BPA's

14

licensor with respect to the Product unless specifically provided for in this Agreement or unless otherwise specifically authorized in writing by BPA.

10. Warranty.

(a) BPA represents and warrants to, and covenants with, Company as follows:

- (i) Title; Encumbrances. As of the Effective Date, (a) it is the sole and lawful owner or exclusive licensee of the entire right, title and interest in the Patents and Know How in the Territory; and (b) there are no material outstanding liens, security interests, pledges, charges, mortgages, restrictions, interests and/or encumbrances of any kind in or burdening any of the Patents or Know How in the Territory.
- (ii) Prime License Agreement. As of the Effective Date, (a) the Prime License Agreement is in full force and effect; (b) the copy of the Prime License Agreement that BPA has disclosed to Company on or before the Effective Date is a true and accurate copy of such agreement as in effect as of the Effective Date; (c) the Prime License Agreement is fully enforceable against Antares to the same extent as it would have been against Permateg upon execution thereof; (d) BPA has made all payments and fulfilled all material obligations due and/or owed under the Prime License Agreement for which the payment or other obligation arose on or before the Effective Date; (e) BPA is not in material breach of the Prime License Agreement and has received no notice of breach thereunder; and (f) the only Patents that as of the Effective Date have been in-licensed were in-licensed pursuant to the Prime License Agreement.
- (iii) Other Licenses. As of the Effective Date, BPA has not granted, and shall not grant during the term of this Agreement, expressly or otherwise, any assignment, license or other extension or rights, covenant not to sue, or other similar interest or benefit, exclusive or otherwise, to, under or in the Patents or the Trademark, in the Field and in the Territory, that remains in effect or in force as of the Effective Date, other than to Company pursuant to this Agreement.
- (iv) Non-infringement of Third Party Rights. To the best knowledge of BPA's executive officers without a duty of inquiry, no patents or trade secret rights owned or controlled by an unaffiliated third party dominate, or would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of Products (in the case of all activities other than manufacture, in the Territory), and BPA has received no written claims relating to any claims of such domination, infringement or misappropriation.
- (v) Claims. As of the Effective Date, (a) there are no claims, actions, suits or proceedings commenced, pending or threatened against it or any of its Affiliates that will, could or might in any way materially affect or relate to the rights and benefits granted to Company hereunder; and (b) BPA has not received written notice that any third party intends to challenge the patentability or validity of any Patent or Trademark.
- (vi) Third-Party Activities; Grounds. As of the Effective Date, to the best knowledge of BPA's executive officers without a duty of inquiry, BPA is unaware of any (a) activities by third parties that would constitute material infringement or misappropriation of

15

the Patents or Trademark (in the case of pending claims, evaluating them as if they were issued); and (b) grounds existing on which any claims, actions, suits or proceedings might be commenced against Company with respect to the Patents or Trademark.

(vii) Patents. Exhibit A contains a complete list of all Patents that it or any of its Affiliates owns or controls, as of the Effective Date, that cover the Products or their manufacture.

(viii) Clinical Data. As of the Effective Date, (a) the NDA pending for the Product contains a complete data package that is to the best knowledge of BPA's executive officers without a duty of inquiry and BPA's good faith belief sufficient for FDA Approval of such NDA; (b) BPA has disclosed all material pre-clinical and clinical data regarding the Product in the Territory to both the FDA and Company; (c) BPA has provided Company with copies of all correspondence and documents to and from FDA and all notices received from FDA regarding the Product or the NDA; (d) BPA has performed all clinical studies regarding the Product in material compliance with all applicable laws and guidelines and good clinical practice; (e) to the extent post-FDA Approval studies are required by the FDA as further described in Section 5(c) for the Launch Indication for the Product, BPA shall perform all such studies in material compliance with all applicable law and guidelines and good clinical practice.

(ix) Safety and Efficacy Data. As of the Effective Date, BPA has disclosed to Company all material safety- and efficacy-related data and information (including without limitation toxicology, carcinogenicity and mutagenicity data and information) generated by, disclosed to and/or known to BPA (or that BPA reasonably should know) regarding Products and any information required to fairly and accurately interpret such data and information and make BPA's disclosures thereof to Company complete, accurate and not misleading.

(x) No Debarment. As of the Effective Date, in the course of developing Products, BPA has not, and to its knowledge no other party has, engaged any person who has been debarred by the FDA or is the subject a debarment proceedings by the FDA, and BPA hereby covenants that it and its Affiliates shall not do so during the Term.

(xi) Competing Products. During the term of the Agreement BPA shall not make, have made, market, sell, offer for sale, or distribute transdermal estrogen-only products (delivered as a gel and not with a patch or another transdermal delivery method) for once daily application that directly compete with the Product for the Launch Indication in the Territory. However, in the event that BPA is acquired by a third party that is marketing a competing product in at the time of acquisition, this Section 10(a)(xi) shall not require the acquiring company to discontinue sales of such product so long as the acquiring company complies in all other respects with the terms of this Agreement.

(b) Other than as expressly provided in this Agreement, neither party makes any warranty and makes no representation, express or implied, regarding the Product, Patents or the Trademark or Materials. IN PARTICULAR, BUT WITHOUT LIMITATION OF THE GENERALITY OF THE PRECEDING SENTENCE, EACH PARTY HEREBY EXPRESSLY DISCLAIMS AND DOES NOT GIVE ANY WARRANTY AND MAKES NO REPRESENTATION WITH RESPECT TO THE PRODUCTS, PATENTS, AND

16

TRADEMARK AND MATERIALS OR ANY CLINICAL TRIALS CONDUCTED BY EITHER PARTY REGARDING THE PRODUCT AND THE RESULTS THEREOF, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF COMPLETENESS, ACCURACY, VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE THEREOF, IN PARTICULAR WITH RESPECT TO FDA APPROVAL OF THE NDA. ALL LIABILITIES, REPRESENTATIONS, AND WARRANTY BY EACH PARTY ARE EXPRESSLY DISCLAIMED.

(c) IN NO EVENT WILL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, EVEN IF ADVISED OF THE POSSIBILITY THEREOF. THE ALLOCATION OF LIABILITY IN THIS PARAGRAPH REPRESENTS THE AGREED AND BARGAINED FOR UNDERSTANDING WITH RESPECT TO THE ALLOCATION OF RISKS INHERENT IN THIS AGREEMENT.

11. Prohibition Against Use of Names; Confidentiality of Agreement.

(a) Neither party shall use the name, insignia, or symbols of the other party, its faculties or departments, or any variation or combination thereof, or the name of any director, officer, employee, agent or representative of such other party for any advertising, packaging or other promotional or publicity purpose without such other party's prior written consent; *provided, however*, that either party may identify the other party if required by law, regulation, court order or the rules of any securities exchange on which the identifying party's stock is traded. Upon execution of this Agreement, BPA and Company may each issue a press release in the form annexed hereto as Exhibit C1 and Exhibit C2, respectively. Either party may issue future press releases regarding this Agreement with the prior written approval of the other party, such approval not to be unreasonably withheld or delayed (and in any event provided within three (3) days). Once the content of a press release has been approved by the other party, a party may release future press releases that contain substantially the same content without additional approval. Upon issuing any press release, the party doing so shall simultaneously copy the other party.

(b) Subject to the provisions of this Section 11, including the exception for any public disclosures made in compliance with the terms of Section 11(a), the parties agree that the terms of this Agreement are confidential and will not be disclosed by either party to any third party (except to a party's professional advisor) without advance written permission of the other party, *provided that* either party may make any filings or disclosures of this Agreement or its terms required by law or regulation in any country so long as such party uses its reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consults with the other party, and permits the other party to participate, to the extent practicable, in seeking a protective order or other confidential treatment, *and further provided that* either party may disclose the terms of this Agreement to a third party (and its professional advisors) when such disclosure is reasonably necessary in connection with (i) a merger, acquisition, placement, investment, or other such transaction with such third party, or (ii) the sale of securities to or other financing from such third party or a financing underwritten by such third party, in which case disclosure may be made to any person or entity to whom such third party sells such securities (and its

17

professional advisers). Advance written permission for disclosure will not be required when a party is ordered to disclose information concerning the Agreement by a competent tribunal or such disclosures are required by law, regulation, or stock exchange rules, except that such party will make all reasonable efforts to limit any disclosure as may be required in the course of legal proceedings by entry of an appropriate protective and confidentiality order, and will provide the other party with as much advance notice of such circumstances as is practicable.

12. Compliance with Governmental Obligations.

(a) Each party shall comply upon reasonable notice from the other party with all governmental requests related to the Product or this Agreement directed to either party, including without limitation by providing all information, data and assistance necessary to comply with legitimate governmental requests related to the Product or this Agreement. Each party shall promptly notify the other party of all such governmental requests.

(b) The Company shall ensure that its activities under this Agreement including but not limited to marketing, sale and commercial distribution of the Product comply with all government regulations in force and effect including, but not limited to, federal, state, and municipal legislation and regulations.

13. Indemnity and Insurance.

(a) The Company will indemnify and hold BPA, its Affiliates and their respective officers, directors, employees and agents (collectively the "BPA Indemnitees") harmless against any and all losses, damages, liabilities, judgments, fines, amounts paid in settlement, expenses and costs of defense (including without limitation reasonable attorneys' fees) (collectively "Losses") resulting from any action, suits, claims, demands, or prosecutions brought or initiated by a third party (each a "Third Party Claim") to the extent such Third-Party Claim arises out of (i) the breach or alleged breach of any representation, warranty or covenant by Company contained herein; (ii) the negligence or willful misconduct of any Company Indemnitee; and (iii) the development, manufacture, storage, handling, use, sale, offer for sale or importation of Product by or for Company and its Affiliates, sublicensees and distributors; *provided that* such indemnity shall not apply to the extent BPA has an indemnification obligation pursuant to Section 13(b)(ii) for such Loss.



(c) Either party may immediately terminate this Agreement upon written notice should the other party file a petition under any bankruptcy or insolvency act or have any such petition filed against it that is not dismissed within ninety (90) days.

(d) If FDA Approval in the United States of Product for the Launch Indication is obtained, but the total of (i) Company's share of the fully burdened cost of post-approval studies required by FDA and (ii) the fully burdened cost of any additional studies required to obtain approval by the FDA for the lowest dose of the Product that BPA tested in Phase III clinical trials together exceeds \$XXXXXX, Company shall have the right to terminate this Agreement and return the rights granted hereunder to BPA upon ninety (90) days prior written notice to BPA; *provided, however*, that Company must within thirty (30) days after the effective date of such termination pay BPA \$XXXXXX plus any further amounts that as of the effective date of such termination had accrued or were due BPA under any other provisions of this Agreement, excluding, however, any milestone payments under Sections 3(a)(ii)(2) (\$7 million) or 3(a)(ii)(3) (\$3.0 million or \$3.5 million) regardless of whether or not such milestone payment has then accrued. For clarity, Company shall not have the obligation to pay BPA under this Section 16(d) if Company terminates this Agreement under Section 5(a).

(e) If not terminated under (b)-(d) above, this Agreement shall expire upon the expiration of the Royalty Term in the Territory with respect to the Product. Upon such expiration, the licenses granted under Sections 2(a) and 2(b) shall survive, the licenses granted in Section 2(a) shall automatically become non-exclusive, irrevocable, fully paid-up, and royalty-free licenses, and the license granted in Section 2(b) shall automatically become an exclusive, irrevocable, fully paid-up and royalty-free license.

22

(f) Upon any termination of this Agreement other than termination by Company pursuant to subsections (b) or (c) above (and, to be clear, other than expiration of this Agreement), the licenses granted under Sections 2(a) and 2(b) to Company shall terminate and any and all information, trademarks, documents, Patents, and Know How (as that term is defined in Section 1.6 of the Prime License Agreement) relating to the Product, including all copies in whatever form or media, shall be immediately provided to and assigned to BPA; *provided, however*, Company may maintain one copy of any such information solely for purposes of exercising its legal rights hereunder. After such transfer Company agrees to provide BPA with copies of all correspondence and documents to and from FDA and all notices received from FDA and to also provide BPA with regular updates as BPA may reasonably request. Further, upon any such termination of this Agreement, Company assigns all right, title and interest in and to the NDA to BPA, shall promptly transfer all documentation related to such NDA to BPA, and agrees to take all such further best commercially reasonable action and promptly execute such further documents as may be reasonably necessary or desirable to give full effect to such assignment, including without limitation submitting a letter to the FDA requesting transfer and any related documents with the FDA to effect such transfer. After such transfer of the NDA to BPA, Company agrees to cooperate with BPA, at Company's own expense for a reasonable transition period, regarding (i) post FDA Approval regulatory obligations for the Product, including without limitation the preparation and submission of annual reports, the reporting of adverse events, and cooperating with governmental regulatory agencies; (ii) communication with third parties regarding the Product, including without limitation responding to complaints and medical inquiries; (iii) investigating all complaints and adverse drug experiences related to the Product; and (iv) giving such notice as BPA may request to the FDA and to DPT or any other contract manufacturer of Product.

(g) Upon termination of this Agreement by Company pursuant to subsections (b) or (c) above, the licenses granted in Sections 2(a) and 2(b) to Company shall survive such termination until expiration of the Royalty Term. In such case, upon expiration of the Royalty Term in the Territory with respect to the Product, the provisions of Section 16(e) shall take effect as if this Agreement had expired.

(h) If this Agreement terminates for any reason, Company shall have the right to sell any Product that it has in process or in inventory as of the effective date of notice of such termination, *provided* that Company pays all royalties and milestones due on Net Sales thereof in accordance with Section 3 and *further provided* that such sell-off period shall be limited to 90 days from termination. Upon termination of this Agreement, Company shall remain liable for any involuntary or voluntary recalls of Product sold pursuant to this Agreement.

(i) In the event that the Prime License Agreement terminates for breach by BPA that is not caused by the action or inaction of Company, this Agreement together with all of BPA's rights and obligations hereunder (including all future payments and performance under this Agreement by Company) shall be deemed to be irrevocably assigned to Antares automatically without the need for any further action by any party, and this Agreement shall thereafter continue in full force and effect between Company as the direct licensee and Antares as licensor. For the avoidance of doubt, upon such assignment all obligations of Company to BPA other than confidentiality obligations shall cease to be of any further force or effect, with the exception of amounts due or payable to BPA on account of sales or other activities that

23

occurred prior to such assignment (even if the date for actual payment of such amounts is under the terms of this Agreement after such assignment), which shall be paid to BPA when they would otherwise be due under this Agreement.

(j) In the event that the Prime License Agreement terminates for liquidation or bankruptcy of BPA, this Agreement together with all of BPA's rights and obligations hereunder (including all future payments and performance under this Agreement by Company) shall be deemed to be irrevocably assigned to Antares automatically without the need for any further action by any party, and this Agreement shall thereafter continue in full force and effect between Company as the direct licensee and Antares as licensor. For the avoidance of doubt, upon such assignment all obligations of Company to BPA other than confidentiality obligations shall cease to be of any further force or effect, with the exception of amounts due or payable to BPA on account of sales or other activities that occurred prior to such assignment (even if the date for actual payment of such amounts is under the terms of this Agreement after such assignment), which shall be paid to BPA when they would otherwise be due under this Agreement.

17. **Notices.** Any notice required or permitted to be given under this Agreement shall be sufficient if sent by certified mail (return receipt requested), postage pre-paid, to the attention of the Chief Executive Officer of the respective company at the address set forth above or to such other address as a party may specify by notice hereunder.

18. **No Agency or Joint Venture.** The Company is not an agent, joint venturer or partner of BPA, and the parties do not intend to create an agency, joint venture or partner relationship. Company and BPA shall be independent contractors. Neither Company nor BPA shall have the authority to make any statements, representations or commitments of any kind, or take any action, which shall be binding on the other, without the prior consent of the party to do so, except as expressly provided for herein.

19. **Assignment.** Neither party may assign this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed. Such consent shall not be required for any assignment to a party that succeeds to all or substantially all of the assigning party's (or, in the case of Company, the Kenwood Therapeutics Products division of Company's) business or assets (whether by sale, merger, operation of law or otherwise), *provided* that such assignee agrees in writing to be bound by the terms and conditions of this Agreement. Notwithstanding the foregoing, Company may assign this Agreement without BPA's consent to its Kenwood Therapeutics Products division or other Affiliate of Company, *provided* that Company guarantees the performance of such assignee. Any purported assignment in contravention of this provision shall be null and void.

20. **Non-Waiver and Entirety.** Any failure of either party to enforce any obligations under this Agreement shall not be deemed a waiver of such obligations. This Agreement constitutes the entire agreement and understanding of the parties and supersedes all previous communication between the parties. Notwithstanding the foregoing, the parties acknowledge that certain rights granted to Company under this Agreement are derived from, and subservient to, the rights granted to BPA under the Prime License Agreement.

24

21. **Governing Law.** This Agreement is governed by and construed in all respects in accordance with the laws of the State of Illinois, USA and the United States of America (without regard to conflicts of laws principles), excluding the United Nations Convention on Contracts for the International Sale of Goods.

22. **Dispute Resolution.**

(a) **Conciliation.** The parties wish first to seek an amicable settlement of all disputes, controversies or claims arising out of or relating to this Agreement by conciliation in accordance with the UNCITRAL Conciliation Rules now in force. The conciliation shall take place in Chicago, Illinois (USA) before a conciliator. If assistance is needed in connection with the appointment of a conciliator or other administrative matters, JAMS Endispute, Inc., 222 S. Riverside Plaza, Chicago, Illinois, US (telephone 312-739-0200) shall be the institution to render such assistance. The language to be used in the conciliation proceedings shall be English.

(b) **Arbitration.** Subject to possible court proceedings under Section 22(d) of this Agreement, if any conciliation proceedings under Section 22(a) of this Agreement are terminated in accordance with Article 15 of the UNCITRAL Conciliation Rules or rejected in accordance with Article 2 of those Rules, without resolution of the disputes, controversies or claims, then all said disputes, controversies or claims shall be determined by arbitration in accordance with the UNCITRAL Arbitration Rules now in force, as supplemented by the IBA Rules on the Taking of Evidence in International Commercial Arbitration, as adopted June 1, 1999, insofar as said IBA Rules are not inconsistent with the express provisions of this Agreement. The language to be used in the arbitral proceedings shall be English. There shall be three (3) arbitrators, the place of arbitration shall be Chicago, Illinois (USA) and the appointing authority shall be JAMS Endispute, Inc. In rendering the award, the arbitrator shall follow and apply the substantive laws of the State of Illinois (without regard to conflict or choice of laws principles). The arbitrator shall have the authority to award compensatory damages only, subject to the limitations described in this Agreement. Each party shall pay the fees of its own attorneys, expenses of witnesses and all other expenses and costs in connection with the presentation of such party's case (collectively, "**Attorneys' Fees**"). The remaining cost of the arbitration, including without limitation, fees of the arbitrator, costs of records or transcripts and administrative fees (collectively, "**Arbitration Costs**") shall be borne equally by the parties. Notwithstanding the foregoing, the arbitrator in the award may apportion said Attorneys' Fees and Arbitration Costs, pursuant to Articles 38 through 40 of the UNCITRAL Arbitration Rules. The award rendered by the arbitrator shall be final, and judgment may be entered in accordance with the applicable law by any court having jurisdiction thereof.

(c) **Confidentiality.** The existence and resolution of any conciliation and/or arbitration shall be kept confidential, and the parties, the conciliator and the arbitrator shall not disclose to any person any information about such arbitration.

(d) **Court Proceedings.** Notwithstanding the arbitration provisions in Section 22(b) of this Agreement, either party shall have the right to sue in any court of competent jurisdiction to collect from the other party funds due and owing such party hereunder. Section 22(b) of this Agreement shall not be construed to prevent either party from seeking injunctive relief against

25

the other party from any judicial or administrative authority of competent jurisdiction to enjoin that party from breaching this Agreement pending the resolution of a dispute by arbitration, pursuant to said Section 22(b). Any action to confirm an arbitration award or any other legal action related to this Agreement between the parties may be instituted in any court of competent jurisdiction. BPA and Company each waive their right to a trial by jury in any such court proceedings.

23. **Severability.** Each party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the parties agree that it is their intent that the remainder of the Agreement shall continue in effect, and shall

substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the parties would have entered into this Agreement with such valid provisions.

24. Headings. Section headings contained in this Agreement are for convenience of reference only and shall not in any way affect the interpretation of this Agreement.

25. Further Assurances. Each party agrees to take or cause to be taken such further actions, and to execute, deliver and file or cause to be executed, delivered and filed such further documents and instruments, and to obtain such consents, as may be reasonably required or requested in order to effectuate fully the purposes, terms and conditions of this Agreement.

26. Execution. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[signature page follows]

26

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IN WITNESS THEREOF, BPA and the Company have caused this Agreement to be executed by their duly authorized representatives as of the day and year first written above.

BioSante Pharmaceuticals, Inc.

By /s/ Stephen M. Simes  
Stephen M. Simes  
Chief Executive Officer and President

Bradley Pharmaceuticals, Inc.

By /s/ Daniel Glassman  
Daniel Glassman  
President and Chief Executive Officer

27

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[PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIALITY UNDER RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. A COPY OF THIS EXHIBIT WITH ALL SECTIONS INTACT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.]

EXHIBIT A

PATENTS

(i) – **United States Patents**  
U.S. Patent No. 5,891,462  
U.S. Patent Application No. 10/798,111  
U.S. Patent Application No. 10/798,161  
XXXXXXXXXXXXXXXXXXXX

(ii) **Ex-U.S. Patents**  
PCT Application No. PCT/US04/007291  
Canadian Application No. 2,515,426  
Canadian Application No. 2,207,144  
China Application No. 200480005123.9  
Indonesian Application No. W-00200502415  
Israeli Application No. 170454  
Mexican Application No. PA/a/2005/008648  
New Zealand Patent No. 328021  
New Zealand Application No. NZ 541854  
South African Patent No. 97/4981

28

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EXHIBIT B

PRIME LICENSE AGREEMENT FLOW-THROUGH PROVISIONS

[See the License Agreement, dated June 13, 2000, between Permatec Technologie, AG (now known as Antares Pharma) and BioSante Pharmaceuticals, Inc., as amended by Amendments Nos. 1, 2, 3, 4, 5 and 6 thereto, that are Exhibits 10.21 through 10.27, respectively, to BioSante's Annual Report on Form 10-K for the year ended December 31, 2006. Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of Exhibits 10.21 through 10.26 and confidential treatment has been requested with respect to designated portions of Exhibit 10.27.]

29

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## BIOSANTE PHARMACEUTICALS, INC.

DESCRIPTION OF NON-EMPLOYEE DIRECTOR  
COMPENSATION ARRANGEMENTS

**Retainer and Meeting Fees.** Except as described below, each of our non-employee directors is paid a \$20,000 annual retainer and \$1,000 for each board or committee meeting attended in person and \$500 for each board or committee meeting attended via telephone. Our Chairman of the Board is paid a \$45,000 annual retainer and our Chairman of the Audit and Finance Committee is a paid a \$25,000 annual retainer.

**Stock Options.** Non-employee directors are granted options to purchase shares of BioSante common stock from time to time in the sole discretion of the board of directors.

**Reimbursement of Expenses.** Non-employee directors are reimbursed for actual expenses, include travel expenses, incurred in attending board and committee meetings.

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## BIOSANTE PHARMACEUTICALS, INC.

DESCRIPTION OF EXECUTIVE OFFICER  
COMPENSATION ARRANGEMENTS

BioSante Pharmaceuticals, Inc. has entered into employment agreements with each of its executive officers, copies of which agreements have been filed with the Securities and Exchange Commission, as exhibits to BioSante's annual report on Form 10-K. The following is a description of oral amendments to those employment agreements or additional oral compensation arrangements between BioSante and the following executive officers of BioSante:

Name of Executive Officer	Title	Base Salary	Bonus Arrangements	Stock Options	Other
Stephen M. Simes	Vice Chairman, President and Chief Executive Officer	\$394,000 per year.	\$140,400 for the year ended December 31, 2006 one-half paid in January 2007 and the remaining half to be paid in December 2007.	On January 12, 2007, the Compensation Committee of the BioSante Board of Directors granted Mr. Simes an option to purchase 250,000 shares of BioSante common stock at an exercise price of \$2.775 per share. Such option vests in three equal (or as nearly equal as possible) yearly installments, with the first installment beginning on the one-year anniversary of the date of grant.	<p>Under the BioSante Pharmaceuticals, Inc. 401(k) Savings Plan, participants, including executive officers, may voluntarily request that BioSante reduce pre-tax compensation by up to 100% (subject to certain special limitations) and contribute such amounts to a trust. BioSante contributed an amount equal to 50% of the amount that each participant contributed under this plan.</p> <p>Executive officers receive other benefits received by other BioSante employees, including health, dental and life insurance benefits. Executive officers also receive an auto allowance.</p> <p>Mr. Simes also receives reimbursement for excess long-term disability and excess life insurance premiums and taxes associated with the premiums.</p>
Phillip B. Donenberg	Chief Financial Officer, Treasurer and Secretary	\$219,000 per year.	\$41,714 for the year ended December 31, 2006 one-half paid in January 2007 and the remaining half to be paid in December 2007.	On January 12, 2007, the Compensation Committee of the BioSante Board of Directors granted Mr. Donenberg an option to purchase 50,000 shares of BioSante common stock at an exercise price of \$2.775 per share. Such option vests in three equal (or as nearly equal as possible) yearly installments, with the first installment beginning on the one-year anniversary of the date of grant.	<p>Under the BioSante Pharmaceuticals, Inc. 401(k) Savings Plan, participants, including executive officers, may voluntarily request that BioSante reduce pre-tax compensation by up to 100% (subject to certain special limitations) and contribute such amounts to a trust. BioSante contributed an amount equal to 50% of the amount that each participant contributed under this plan.</p> <p>Executive officers receive other benefits received by other BioSante employees, including health, dental and life insurance benefits. Executive officers also receive an auto allowance.</p>



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements Nos. 333-109474, 333-100238, and 333-53384 of BioSante Pharmaceuticals, Inc. (BioSante) on Form S-8 and Registration Statement Nos. 333-64218, 333-116110, and 333-136852 of BioSante on Form S-3 of our report dated March 26, 2007, appearing in the Annual Report on Form 10-K of BioSante Pharmaceuticals, Inc. for the year ended December 31, 2006.

*/s/ Deloitte & Touche LLP*

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DELOITTE & TOUCHE LLP  
Chicago, Illinois

March 26, 2007

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CERTIFICATION OF CEO PURSUANT TO SECTION 302 OF THE  
SARBANES OXLEY ACT OF 2002 AND SEC RULE 13A-14

I, Stephen M. Simes, certify that:

1. I have reviewed this annual report on Form 10-K of BioSante Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2007

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

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CERTIFICATION OF CFO PURSUANT TO SECTION 302 OF THE  
SARBANES OXLEY ACT OF 2002 AND SEC RULE 13A-14

I, Phillip B. Donenberg, certify that:

1. I have reviewed this annual report on Form 10-K of BioSante Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2007

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

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**CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen M. Simes, Vice Chairman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Stephen M. Simes  
Stephen M. Simes  
Vice Chairman, President and Chief Executive Officer  
March 27, 2007

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**CERTIFICATION OF CFO PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of BioSante Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip B. Donenberg, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Phillip B. Donenberg  
Phillip B. Donenberg  
Chief Financial Officer, Treasurer and Secretary  
March 27, 2007

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March 27, 2007

**VIA EDGAR**

Securities and Exchange Commission  
100 F Street, NE  
Washington, D.C. 20549

**Re: BioSante Pharmaceuticals, Inc.**  
**File No. 001-31812**

Ladies and Gentlemen:

On behalf of BioSante Pharmaceuticals, Inc., we are hereby furnishing for filing via EDGAR BioSante's Annual Report on Form 10-K for the year ended December 31, 2006.

Pursuant to General Instruction D.3. of Form 10-K, BioSante represents that the financial statements included in the Form 10-K do not reflect a change from the preceding fiscal year in any accounting principles or practices or in the method of applying such principles or practices other than BioSante adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment," on January 1, 2006.

Any questions or comments regarding this filing may be directed to the undersigned at (612) 607-7287.

Yours very truly,

/s/ Amy E. Culbert

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Amy E. Culbert  
Oppenheimer Wolff & Donnelly LLP  
Plaza VII  
45 South Seventh Street  
Suite 3300  
Minneapolis, MN 55402-1609

cc: Mr. Phillip B. Donenberg

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