BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 31, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2005

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

For the transition period from to .

Commission file number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Name of small business issuer in its charter)

Delaware	**58-2301143**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
111 Barclay Boulevard **Lincolnshire, Illinois** (Address of principal executive offices)	**60069** (Zip Code)

(847) 478-0500
(Issuer s telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:

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

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

None

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

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 ý NO o

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 ý NO o

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

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

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

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

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, 2005 (the last business day of the registrant s second quarter) as reported by the American Stock Exchange, was $53,713,222.

As of March 16, 2006, 19,099,649 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 2006 Annual Meeting of Stockholders to be held in June 2006.

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This annual report on Form 10-K contains forward-looking statements. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as may, will, should, expects, anticipates, contemplates, estimates, believes, plans, projected, predicts, potential or continue or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the heading Item 1. Description of Business Forward-Looking Statements. These factors may cause our actual results to differ materially from any forward-looking statement.

As used in this report, references to BioSante, the company, we, our or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks used in this report, including BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-E-Gel , Bio-E/P-Gel , LibiGel , LibiGel-E/T and Bio-T-Gel . This report also contains trademarks, trade name and service marks that are owned by other persons or entities.

PART I

Item 1. # DESCRIPTION OF BUSINESS

General

We are a development stage biopharmaceutical company that is developing a pipeline of 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. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen.

The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

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

Bio-E-Gel once daily transdermal bioidentical estrogen gel in development for treatment of menopausal symptoms in women.

LibiGel once daily transdermal bioidentical testosterone gel in 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.

We have not received FDA or any other government approval for any of our products and thus have not commercialized any of them in the United States or elsewhere.

Several of our hormone therapy products have undergone human clinical trials, which are required to obtain approval from the United States Food and Drug Administration (FDA) to market the products. In March 2005, we completed the pivotal Phase III clinical trial for our proposed

Bio-E-Gel product and in February 2006 we submitted the New Drug Application (NDA) to the FDA. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials, which we expect to begin during 2006.

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. We are pursuing the development of the following potential initial applications for our CaP technology:

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;

the creation of oral, buccal, intranasal, inhaled and longer acting delivery of drugs that currently must be given by injection (e.g., insulin); and

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 biodefense vaccines such as anthrax and ricin.

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

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

Business Strategy

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

Pursue the development of our hormone therapy products. We are focused on building a pipeline of hormone therapy products for the treatment of human hormone deficiencies. We have completed or are in the process of planning human clinical trials on several of our proposed hormone therapy products, a necessary step in the process of obtaining FDA approval to market the products. Our proposed Bio-E-Gel product completed its pivotal Phase III trial in March 2005 and we submitted an NDA to the FDA in February 2006. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials.

Continue to develop our nanoparticle-based CaP platform technology and seek assistance in the development through government agencies and corporate partner sublicenses. We have entered into and are seeking opportunities to enter into additional business collaborations, joint ventures or sublicenses with companies that have businesses or technologies complementary to our CaP technology business, such as vaccine and/or drug delivery pharmaceutical or biotechnology companies, and with various governmental entities focused on developing new vaccines and alternative drug delivery systems. We believe that this partnering strategy will enable us to capitalize on our partners strengths in product development, manufacturing and commercialization and thereby enable us to introduce into the market products incorporating our CaP technology sooner than we otherwise would be able. In addition, these collaborations have enabled us to minimize our spending on the development of products incorporating our CaP technology.

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

License or otherwise acquire other drugs that will add value to our current product portfolio. We will consider opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. 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 patients 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 we can introduce the products 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 libido and osteoporosis, and impotence, lack of sex drive, muscle weakness and osteoporosis in men. The primary goal of hormone therapy is to safely and conveniently 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 libido and osteoporosis. According to the North American Menopause Society, recent studies show that hot flashes occur in up to 85% of menopausal women and up to 40% experience some form of vaginal atrophy. Hormone therapy in women decreases the chance that women will experience the symptoms of menopause due to estrogen deficiency. According to industry estimates, approximately 10 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 2005. As the baby boomer generation ages, the number of women reaching menopause and needing estrogen or combined estrogen therapy is expected to increase.

There are several treatment options for women experiencing menopausal symptoms, which vary according to which symptoms a woman experiences and whether or not she has had a hysterectomy. Estrogen only products are only recommended for use by women who do not have a uterus. Estrogen is most commonly given orally in pill or tablet form. There are several potential side effects, however, with the use of oral estrogen, including insufficient absorption by the circulatory system, stomach upset, gallstones, blood clots as well as an increase in C-reactive protein, a possible marker for cardiovascular inflammation. Although transdermal, or skin, patches have been shown to avoid some of these problems, 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.

Women who have not had a hysterectomy must take estrogen in combination with progestogen (either progestin or progesterone) as estrogen alone may increase endometrial hyperplasia and endometrial cancer risks. In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone (conjugated estrogen plus progestin) therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of the estrogen/progestogen tablet combination from the WHI study because Prempro, the combination oral hormone therapy product used in the study, was shown to cause an increase in the risk of invasive breast cancer after an average follow-up period of 5.2 years. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of the orally delivered combined estrogen plus progestogen product among healthy postmenopausal women. Also in July 2002, the National Cancer Institute (NCI) published the results of an observational study in which it found that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. The markets for female hormone therapies for menopausal symptoms have 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.

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 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 Bio-E-Gel and Bio-E/P-Gel, use bioidentical estradiol, which is identical to the estrogen produced naturally by a woman s ovaries, and a progestogen, which is different than the type of progestogen in Prempro. No studies to date have evaluated the long-term effects of transdermal estrogen alone or estrogen combined with progestogen therapy. 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 by Novavax, Inc. and a transdermal gel by Solvay Pharmaceuticals, Inc.

Testosterone Therapy for Women. Though 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 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, 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 surgical menopause.

There is no pharmaceutical product currently approved in the United States or anywhere in the world for FSD. While several therapies have been tested to treat FSD, thus far testosterone therapy appears to be the only treatment that results in a consistent significant increase in the number of satisfying sexual events in women, which represents the key efficacy endpoint chosen by the FDA for pivotal clinical trials of FSD therapies. There are several testosterone therapy products for the treatment of FSD in development, including our LibiGel product, Proctor & Gamble s Intrinsa patch and products being developed by VIVUS, Inc.

In December 2004, the FDA s Reproductive Health Drugs Advisory Committee panel voted unanimously against recommending the approval of Procter & Gamble s Intrinsa testosterone patch for hypoactive sexual desire disorder (HSDD). The panel s main concern was a desire to have available additional safety data particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Despite the recommendation not to approve Intrinsa, the panel voted that Intrinsa provides a clinically meaningful benefit for women with hypoactive sexual desire disorder. Procter & Gamble has since withdrawn its New Drug Application, or NDA, for Intrinsa and it is our understanding that they have completed two additional Phase III studies in over 1,000 naturally menopausal women (i.e., with an intact uterus) and are determining when to resubmit an NDA to the FDA. 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. The FDA stated that it will accept epidemiologic and surrogate marker data as evidence of safety before approval and will expect longer term safety studies after approval. We are developing our Phase III development plan for submission to the FDA and are not waiting for any action by Procter & Gamble.

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 and another that has been approved but not yet introduced and several still in development. According to IMS Health, the U.S. market for transdermal testosterone therapies grew approximately 10% in 2005 to $439 million from $400 million in 2004.

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 arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

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.

Our strategy with respect to our hormone therapy products is to conduct human clinical trials, which are required to obtain FDA approval, and to market the products in the United States. We have completed conducting human clinical trials on several of our hormone therapy products. In February 2006, we submitted a New Drug Application with the FDA for our Bio-E-Gel product.

Bio-E-Gel. Our estrogen formulated gel product, Bio-E-Gel, is a once daily gel designed to deliver estrogen without the skin irritation associated with, and the physical presence of, transdermal patches. Bio-E-Gel contains bioidentical estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted an NDA with the FDA in February 2006. We hope to commercially launch our Bio-E-Gel product after receipt of FDA approval, which we currently expect by late 2006 or early 2007.

The NDA we submitted in February 2006 includes data from one pivotal Phase III clinical trial of Bio-E-Gel and data from three additional clinical trials required by the FDA, including a transfer study, a sunscreen study and a pharmacokinetic study. Current FDA requirements for approval of new estradiol products include one 12-week Phase III clinical trial. In March 2005, we completed our Phase III

Bio-E-Gel clinical trial for the treatment of moderate-to-severe hot flashes and vaginal atrophy in menopausal women. This trial was a 12-week, randomized, double-blind, placebo-controlled study of 484 symptomatic menopausal women. Following FDA recommendations, the Phase III trial tested three doses of Bio-E-Gel in order to establish the lowest effective dose and maximize the safety profile. The four co-primary endpoints, as defined by the FDA, are a significant decrease over placebo in both the number and severity of hot flashes at Week 4 and Week 12 of treatment. Across the low, mid, and high Bio-E-Gel doses tested in the Phase III trial, there was a clear dose response in the reduction in the number and severity of hot flashes. By Week 4 of treatment, the mid and high doses of Bio-E-Gel showed highly significant decreases in the number and severity of hot flashes versus placebo ($p<0.0001$), and this significant response was maintained from Week 4 to Week 12 of treatment ($p<0.0001$). Beginning at Week 5, the low dose of Bio-E-Gel showed a highly significant decrease in the number ($p<0.001$) and severity ($p<0.01$) of hot flashes versus placebo, therefore suggesting identification of the lowest effective dose. This significant response for both number and severity of hot flashes was maintained through Week 12 ($p<0.0001$). Importantly, over 80 percent of women who used Bio-E-Gel reported moderate or great results with Bio-E-Gel ($p<0.0001$). Our recently filed NDA is seeking approval for all three doses. Additionally, there were no significant differences in the safety profile of any dose of Bio-E-Gel compared to placebo other than for predictable estrogen effects such as breast tenderness.

LibiGel. Our LibiGel product is a once daily transdermal testosterone gel designed to treat female sexual dysfunction, specifically HSDD. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes due to aging or following surgical menopause. We have successfully completed a Phase II clinical trial of our LibiGel. We currently are working on our Phase III development plan in order to begin Phase III clinical trials, which we anticipate initiating in 2006.

The Phase II trial was a double-blind, placebo-controlled study to determine the effect of LibiGel on a women s sexual activity. 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.

Our Other Hormone Therapy Products. In addition to Bio-E-Gel 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. 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.

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

Description of Our CaP Technology and Products

We believe our CaP technology will 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 280 nanometers (nm). For comparison, a polio virus particle is about 27 nm in diameter, a herpes virus particle has a central core measuring 100 nm in diameter, contained in an envelope measuring 150-200 nm, while a tuberculosis bacterium is rod-shaped, about 1,200 nm long by 300 nm across. Because the size of these particles is measured in nanometers, we use the term nanoparticles to describe them.

We use the nanoparticles as the basis of a delivery system. The critical property of these coated nanoparticles is that biologically active molecules, proteins, peptides or pharmacological agents, for example, vaccine components like bacterial or viral antigens or proteins like insulin, attached to them retain their activity and can be protected from natural alterations to their molecular structure by adverse

environmental conditions. It has been shown in studies conducted by us and confirmed by others that when these combinations are injected into animals, the attachment can enhance the biological activity as compared to injection of the molecule alone.

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

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

it is biodegradable (capable of being decomposed by natural biological processes) and non-toxic and therefore potentially safe to use and introduce into the human body;

it is fast, easy and inexpensive to manufacture, which should keep costs down and potentially lead to higher profit margins compared to other delivery systems;

the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays, through inhalation or intranasally, instead of using often painful and inconvenient injections; and

it has excellent loading capacity the amount of molecules that can bond with the nanoparticles thereby potentially decreasing the dose needed to be taken by patients while enhancing the release capabilities.

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

injected and non-injected vaccines using CaP as a delivery system and vaccine adjuvant; and

drug delivery systems, including a method of delivering proteins (e.g., insulin) orally or buccally, or through intranasal and subcutaneous routes of administration.

Our pre-clinical research team in our laboratory in Smyrna, Georgia is currently pursuing the development of our CaP technology in these areas as well as exploring other areas, such as allergy 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. 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 in July 2000 to commence a Phase I human clinical trial. We completed our Phase I human clinical trial in October 2000. As discussed in more detail under the heading Government Regulation, the purpose of a Phase I trial is to evaluate the metabolism and safety of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. The Phase I trial of our CaP specifically looked at safety parameters, including local irritation and blood chemistry changes. The trial was completed and there was no apparent difference in the side effects profile between CaP and placebo.

Drug Delivery Systems. The second field of use in which we are exploring applying our CaP technology involves creating novel and improved forms of delivery of drugs, especially proteins (e.g., insulin). The attachment of drugs to CaP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. Pizer has received FDA approval of their 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 cancer, allergies, viral and bacterial infections and autoimmune diseases, among others including, biodefense vaccines such as anthrax, and ricin. 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.

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 outlicensing 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 12 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

In December 2005, we were awarded a subcontract by the University of Nebraska-Lincoln for the development of recombinant Factor IX formulations for delivery via alternative routes of administration. The subcontract was awarded to us as part of the University s five year $10 million grant entitled GMP Recombinant FIX for IV and Oral Hemophilia B Therapy from the National Institutes of Health. Our subcontract is for the first year of the grant, and if warranted, we can apply to renew the subcontract in subsequent years. The first year of the subcontract is valued at approximately $250,000. 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 the first year of this contract which should conclude in the second half of 2006.

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.

In June 2003, we announced the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Army s Medical Research Institute of Infectious Disease (USAMRIID) for the development of non-injected biodefense vaccines, including anthrax, staph and ricin. The USAMRIID has agreed to grant us an exclusive license to any U.S. patent application or issued patent as a result of the work under the CRADA. The work under this CRADA has been completed and we are seeking funding to move to the next phase of vaccine development, including challenge studies.

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 other company s and the government s expertise 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 proposed products. Under our sub-license agreements, our sub-licensees have agreed to market the products covered by the agreements in certain countries. If and when we are ready to commercially launch a product not covered by our sub-license agreements, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner or licensee to assist us with this function. In addition, we retain co-promotion rights for Bio-E/P-Gel, the product covered under the Solvay sub-license agreement.

Research and Product Development

We expect to spend a significant amount of our financial resources on product development activities, with the largest portion being spent on clinical trials of our hormone therapy products. We spent

approximately $6,409,000 in 2005 and $9,162,000 in 2004 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues from the sale of our products, these research and development costs must be financed by us. We spent an average of approximately $500,000 to $600,000 per month on our research and development activities in 2005. We expect our research and development expenses to be significantly lower in 2006 until the commencement of our LibiGel Phase III trial, which we expect to commence sometime during 2006. Upon initiation of our Phase III LibiGel clinical trials, we expect our research and development fees to go up to $800,000 to $900,000 per month for the remainder of 2006. 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 licensees 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 proposed 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 proposed 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.

Patents, Licenses and Proprietary Rights

Our success depends and will continue to depend in part upon our ability to maintain our exclusive licenses, to maintain patent protection for our products and processes, to preserve our proprietary information and trade secrets and to operate without infringing the proprietary rights of third parties. Our policy is to attempt to protect our technology by, among other things, filing patent applications or obtaining license rights for technology that we consider important to the development of our business.

Hormone Therapy Products. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares granted us an exclusive license to four 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 our inventors) for this licensed technology in the U.S. and several foreign jurisdictions, including those licensed to us.

In a series of amendments executed during 2001 between us and Antares, we returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, it was agreed that we are the owner of Bio-T-Gel, our testosterone gel for men with no milestone or royalty obligations to Antares. We also returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the single entity estradiol and testosterone gel products in Malaysia and Australia, Antares granted us a credit for approximately $600,000 of manufacturing and formulation services and a license for a transdermal hormone therapy gel combination of testosterone and estradiol. In August 2002 and December 2002, BioSante and Antares further amended the license agreement to clarify interpretations of the license agreement, including products covered by the license agreement, and to terminate a supply agreement with Antares.

The license agreement with Antares required us to pay a $1,000,000 up-front license fee to Antares, which we paid in June 2000. Also pursuant to the terms of the Antares license agreement, we expect to:

pay royalties to Antares based on a percentage of the net sales of any products we or our sublicensees sell incorporating the licensed technology;

develop the hormone product portfolio, including:

testing proposed products;

conducting clinical trials;

obtaining government approvals;

introducing products incorporating the licensed technology into the market; and

enter into sublicense arrangements or agreements with other entities regarding development and commercialization of the products covered by the license.

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. During the third quarter ended September 30, 2002, we received a $950,000 milestone payment pursuant to the Solvay sublicense agreement. 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 will 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. Upon execution of the sublicense agreement, Paladin made an initial investment of $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $10.50 per share. In August 2001, we exercised our right and declared the debenture converted in full. Accordingly, 47,619 shares of our common stock were issued to Paladin in August 2001. During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in issuing an additional 18,940 shares of our common stock to Paladin.

In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, e.g. testosterone) and obtained an option to license the patents for triple hormone contraception. The financial terms of the license include an upfront payment by 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.

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. 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.

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 nine United States patents owned by the University, including rights to sublicense such patents, in fields of use initially pertaining to: (1) vaccine adjuvants; (2) vaccine constructs or combinations for use in immunization against herpes virus; (3) drug delivery systems and (4) red blood cell surrogates. 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 with the University of California requires us to undertake various obligations, including:

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;

payment of minimum annual royalties on February 28 of each year beginning for the year 2004 to be credited against earned royalties, for the life of the agreement;

maintaining an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market;

payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which amounted to $13,491 in 2005;

meeting performance milestones relating to:

hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;

testing proposed products;

conducting clinical trials;

obtaining government approvals;

introducing products incorporating the licensed technology into the market; and

entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.

The license agreement further provides that we have the right to abandon any project in any field of use without abandoning our license to pursue other projects in that or other fields of use covered by the agreement. In May 1999, we notified the University that we would not pursue the red blood cell

surrogate use because we did not believe it would be proven an effective use of CaP. In October 1999, we signed an amendment to our license agreement with the University, which removed the red-blood cell surrogate use from the agreement. In addition, under the terms of the amendment, the University agreed to make other changes we suggested to the license agreement, including delaying minimum royalty payments until 2004 and limiting the University s rights to terminate the agreement in cases where we do not perform under the agreement. If we violate or fail to perform any term or covenant of the license agreement and fail to cure this default within 60 days after written notice from the University, the University may terminate some projects included in the agreement. In May 2001, we signed a second amendment to our license agreement with the University to amend certain provisions of the license agreement for sublicensing arrangements with third parties. In June 2004, we signed a third amendment to our license agreement with the University to further amend certain provisions of the license agreement.

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. 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 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 if warranted, we can apply to renew the subcontract in subsequent years. The first year of the subcontract is valued at approximately $250,000. 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 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 12 months, MATC has the exclusive right to exercise an option to secure a license to this technology in the field of aesthetic medicine upon payment to us of a license fee. We have the right to receive additional milestone payments upon approval by the FDA or first commercial sale of each product containing CaP, a royalty on net sales of any such products, and a share of any milestones and license fees from third party sublicenses.

Patents and patent applications. We have licensed a patent portfolio relating to hormone therapy from Antares Pharma Inc. (Antares). The expiration dates of these patents range from 2011 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 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. We have filed trademark applications in the U.S. and certain foreign jurisdictions for the mark BIOSANTE and for other trademarks relating to vaccines and vaccine adjuvants, drug delivery platforms, and for our proposed hormone therapy products. In addition to the BIOSANTE mark, trademark protection has been obtained or is sought for the following marks: BIO-E-GEL, BIO-T-GEL, BIOVANT, BIOAIR, NANOVANT and LIBIGEL. Registrations have issued for some of these trademarks in certain jurisdictions and some are currently in the 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.

We expect our 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.

There are several firms currently marketing or developing hormone therapy products similar to ours. They include The Procter & Gamble Company, Noven Pharmaceuticals, Inc., Novavax, Inc., Auxilium Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and Solvay Pharmaceuticals, Inc. Competitor hormone therapy products include oral tablets, transdermal patches, creams and gels.

With regard to our CaP technology, the international vaccine industry is dominated by three companies: GlaxoSmithKline, Aventis (through its subsidiaries, including Institut Merieux International, Pasteur Merieux Serums et Vaccins, 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), 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; and

FDA approval of the NDA prior to any commercial sale or shipment of the product.

Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a proposed product s uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information.

The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

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

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

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

Upon the successful completion of clinical testing, an NDA is submitted to the FDA for approval. This application requires detailed data on the results of preclinical testing, clinical testing and the composition of the product, specimen labeling to be used with the drug, information on manufacturing methods and samples of the product. The FDA typically takes from 10 to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further, there is no assurance that the FDA will ultimately approve an NDA. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

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

Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. We intend to seek and utilize foreign partners to apply for foreign approvals of our products.

Employees

We had 14 full-time employees as of December 31, 2005, including nine in product development and four in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We also engage independent contractors from time to time. For example, in December 2005, we engaged Michael C. Snabes, M.D., Ph.D. as an independent consultant to work with our product development team in completion of our Bio-E-Gel NDA activities, as well as work on LibiGel development. Also in December 2005, we engaged Eugene V. DeFelice as an independent consultant to assist us with corporate and business development activities.

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 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, wil expect, intend, plan, predict, anticipate, estimate, approximate, contemplate or continue and other words and terms of similar me 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;

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 company, which was initially formed as a corporation organized under the laws of the Province of Ontario on August 29, 1996, was continued as a corporation under the laws of the State of Wyoming on December 19, 1996 and pursuant to stockholder approval was reincorporated in Delaware on June 26, 2001. Our company is the continuing corporation resulting from an amalgamation, or consolidation, of three companies our company, which was previously named Ben-Abraham Technologies Inc., Structured Biologicals Inc., a corporation organized under the laws of the Province of Ontario, and 923934 Ontario Inc., a corporation organized under the laws of the Province of Ontario and a wholly owned subsidiary of Structured Biologicals. The amalgamation was approved by our stockholders on November 27, 1996 and the articles of arrangement were filed and became effective as of December 6, 1996. In November 1999, our stockholders approved the change of our corporate name from Ben-Abraham Technologies Inc. to BioSante Pharmaceuticals, Inc.

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

We make available, free of charge and through our Internet web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as 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 x120.

Item 1A. # RISK FACTORS

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

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

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of $9,651,036 for the year ended December 31, 2005, and as of December 31, 2005, our accumulated deficit was $49,688,320.

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. 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. 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 costs of licensure or acquisition of new products;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of obtaining third party reimbursement;
- the timing and cost of sales and marketing activities for future products; and
- the costs of pending and any future litigation of which we may be subject.

In order to generate new and significant revenues, we must successfully develop and commercialize our own proposed products or enter into collaborative agreements with others who can successfully develop and 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 never generate significant revenues or achieve profitability.

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 complete the commercialization of any of our proposed products. Therefore, we will need to raise substantial additional capital to fund our operations sometime in the future. Based on our current rate of cash outflows, we believe that our cash and short-term investments of $9,101,531 at December 31, 2005, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months. We have based this estimate on assumptions, however, that may prove to be wrong. As a result, we may need 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 rate of technological advances;

ongoing determinations of the potential commercial success of our proposed products;

our general and administrative expenses, including legal expenses incurred in connection with pending any and future litigation of which we may be subject;

if we receive FDA approval of any of our proposed products and choose to commercialize them ourselves, the amount of resources we devote to sales and marketing capabilities;

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, facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

We are a development stage company, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

the absence of an operating history;

the lack of commercialized products;

insufficient capital;

expected substantial and continual losses for the foreseeable future;

limited experience in dealing with regulatory issues;

limited marketing and manufacturing experience;

an expected reliance on third parties for the development and commercialization of some of our proposed products;

a competitive environment characterized by numerous, well-established and well-capitalized competitors;

uncertain market acceptance of our proposed products; and

reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

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. We have not commercially introduced any products and do not expect to do so until early 2007 at the earliest depending upon the timing of the FDA s decision on our New Drug Application for our Bio-E-Gel product which was submitted in February 2006 and the approval of such application. We cannot assure you that any of our proposed products will:

be successfully developed;

prove to be safe and efficacious in clinical trials;

meet applicable regulatory standards or obtain required regulatory approvals;

demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;

be capable of being produced in commercial quantities at reasonable costs;

obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or

be successfully marketed or achieve market acceptance by physicians and patients.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed or withdrawn, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each product or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management s credibility, the value of our company and our operating results and liquidity would be adversely affected. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. Even after obtaining regulatory approval, we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture are subsequently discovered. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would

have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition.

To obtain regulatory approval to market our products, costly and lengthy pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct, at our own expense or the expense of current or potential licensees, clinical trials on humans on each of our proposed products. Pre-clinical studies on animals must be conducted on some of our proposed products. We expect the number of pre-clinical studies and human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results would prevent us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

slow patient enrollment;

timely completion of clinical site protocol approval and obtaining informed consent from subjects;

longer treatment time required to demonstrate efficacy or safety;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

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

A request by an FDA advisory committee for additional safety data which may require Procter & Gamble to conduct additional studies to learn more about the long-term safety of testosterone treatment in women for FSD prior to granting approval of Procter & Gamble s Intrinsa testosterone patch could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to abandon the product depending on the extent of the additional time and cost to develop LibiGel.

In December 2004, the FDA s Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of Procter & Gamble 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. This FDA action with respect to Intrinsa or testosterone products in general may affect the regulatory pathway for our LibiGel product, as well as other similarly competitive products to treat HSDD with testosterone therapy. The FDA s final decision could increase the time, cost and expense of obtaining regulatory approval for our LibiGel product, which might cause us to delay or abandon further development of the product depending on the extent of the additional time and cost to develop LibiGel.

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. has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, these withdrawals have resulted and may continue to result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilence after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the market for hormone therapy products and the trading price of our common stock.

The market for hormone therapy products has been negatively affected by the Women s Health Initiative study and other studies that have found that the overall health risks from the use of certain hormone therapy products exceed the benefits from the use of those products among healthy postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed 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 proposed 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 proposed products, would also adversely affect our business.

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.

We license the technology underlying most of our proposed 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 proposed hormone therapy products from Antares Pharma, Inc. and a portion of our CaP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California s license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees 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 outlicense agreement with a third party under which we agree to outlicense our hormone therapy technology or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc. or the University of California could either, depending upon the terms of the outlicense agreement, cause us to breach our obligations under the outlicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the outlicense fees.

We have licensed two of our proposed 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 two of our proposed hormone therapy product to third parties, Solvay Pharmaceuticals, B.V. and Teva Pharmaceuticals USA, Inc., which 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. 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 cannot assure you that Solvay 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 Solvay 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.

We do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions and may remain dependent upon others for these functions.

We do not have a manufacturing facility that can be used for production of our products. In addition, at this time, we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions. In the course of our development program, we may be required to enter into additional arrangements with other companies, universities or clinical investigators for our animal testing, human clinical testing, manufacturing and sales and marketing activities. Alternatively, we may decide to add additional personnel and perform some of these functions ourselves, such as sales and marketing activities. If our licensees or other third parties in which we have entered into agreements breach their obligations under our agreements to perform these functions or if we are otherwise unable to retain third parties for these purposes on acceptable terms or perform such functions successfully ourselves, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by our licensees or other third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise impair our competitive position. Our dependence on our licensees and other third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

Even if our proposed products receive FDA approval, they 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.

Even if we are able to obtain required regulatory approvals for our proposed products, the success of those products is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our new 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 our market entry; and

the ability to market our products effectively.

Some of these factors are not within our control. 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 the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply we could experience material adverse effects on our business, financial position and results of operations, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, we must comply with FDA requirements with respect to the development of our proposed products and our clinical trials, and if any of our proposed products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of our products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA s review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties.

Where appropriate, we seek patent protection for certain aspects of our technology. However, our owned and licensed patents and patent applications may not ensure the protection of our intellectual property for a number of other reasons:

We do not know whether our licensor s patent applications will result in issued patents.

Competitors may interfere with our patents and patent process in a variety of ways. Competitors may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore we cannot use our technology as claimed under our patent. Competitors may also have our patents reexamined by showing the patent examiner that the invention was not original or novel or was obvious.

We are in the development stage and are in the process of developing proposed products. Even if we receive a patent, it may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our proposed products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

Enforcing patents is expensive and may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose protection on products covered by those patents.

We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

It also is unclear whether efforts to secure our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors resulting in a loss of protection. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

Claims by others that our products infringe their patents or other intellectual property rights could adversely affect our financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States and also are maintained in secrecy outside the United States until the application is published. Accordingly, we can conduct only limited searches to determine whether our technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties would be time-consuming and could likely:

result in costly litigation;

divert the time and attention of our technical personnel and management;

cause product development delays;

require us to develop non-infringing technology; or

require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

We have very limited staffing and will continue to be dependent upon key employees.

Our success is dependent upon the efforts of a small management team and staff. We have employment arrangements in place with all of our executive officers, but none 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 any of our other executive officers or employees. If key individuals leave BioSante, we could be adversely affected if suitable replacement personnel are not quickly recruited.

On November 30, 2005, we sent written notice to Leah M. Lehman, Ph.D., our former Vice President, Product Development, that we were exercising our contractual right not to renew her employment agreement. As a result of this notice, Dr. Lehman s employment agreement expired by its terms on December 31, 2005. Although we immediately engaged Michael C. Snabes, M.D., Ph.D. as an independent consultant to work with our product development team in completion of our Bio-E-Gel NDA activities, as well as work on LibiGel development, it is possible that the departure of Dr. Lehman and the transition of her duties to Mr. Simes and Dr. Snabes may have an adverse effect on our business.

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.

We are engaged in pending legal proceedings with two former employees which have caused and will continue to cause us to incur significant legal fees and expenses and may distract our management from the operation of our business.

On November 30, 2005, we sent written notice to Leah M. Lehman, Ph.D., our former Vice President, Product Development, that we were exercising our contractual right not to renew her employment agreement. As a result of this notice, Dr. Lehman s employment agreement expired by its terms on December 31, 2005. On February 15, 2006, we received notice that on February 10, 2006, Dr. Lehman had filed a complaint against us, our Chief Executive Officer, our Chief Financial Officer and one of our directors, with the Occupational Safety and Health Administration under the Sarbanes-Oxley Act of 2002 seeking reinstatement of her employment with back pay, interest and attorney s fees and claiming, among

other things, wrongful termination. On February 17, 2006, we filed a complaint against Dr. Lehman in the Circuit Court of Cook County, Illinois alleging breach of fiduciary duty, breach of contract in regard to her employment agreement, tortious interference with prospective economic advantage and abuse of process. We are seeking an unspecified amount of damages, punitive damages, declaratory judgment regarding a breach by Dr. Lehman of her employment agreement and the amount of severance pay, if any, to be owed to Dr. Lehman, reimbursement of our legal fees and costs and such other relief as the Court may deem proper. In March 2006, Dr. Lehman filed a charge with the Equal Employment Opportunity Commission claiming sex discrimination and retaliation in violation of Title VII of the Civil Rights Act of 1964. We also believe that Dr. Lehman s charges with the EEOC are wholly without merit and intend to vigorously defend our position. In addition, in January 2006, a former employee filed charges of sexual harassment, gender discrimination and retaliation against us and our Chief Executive Officer with the Illinois Department of Human Rights. We believe that Dr. Lehman s allegations of wrongful termination, violations of the Sarbanes-Oxley Act, the EEOC claim and the other former employee s employment related claims are wholly without merit and intend to vigorously defend our position. Such defenses, however, have caused us to incur and will likely cause us to continue to incur significant legal fees and expenses and may distract our management from the operation of our business.

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 2005, our common stock traded in a range from a low of $2.72 to a high of $5.94, and our daily trading volume ranged from 8,900 shares to 405,300 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;

developments in pending and any future litigation of which we may be subject; and

economic conditions in the United States and abroad.

In addition, the occurrence of any of the risks described above or elsewhere in this report or otherwise in reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our common stock. For example, in December 2004, primarily as a result of the unanimous vote by the FDA s Reproductive Health Drugs Advisory Committee panel against recommendation for approval of Procter & Gamble s Intrinsa testosterone patch for hypoactive sexual desire disorder, the price of our common stock decreased over 35% in one trading day and over 50% over the course of three trading days. In addition, on the day of and first two trading days after the public announcement of FDA advisory panel s recommendation, the daily trading volume of our common stock went from an average of approximately 166,000 shares per day to an average of over approximately 3 million shares per day for those same three days and then back down to an average of approximately 140,000 shares per day. Our current trading volume is approximately 80,000 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, which will become applicable to BioSante beginning with our fiscal year ended December 31, 2007 (or earlier, if BioSante becomes an accelerated filer under the Exchange Act). Section 404 of the Sarbanes-Oxley Act requires annual management assessment of the effectiveness of our internal controls over financial reporting (ICFR) a report by our registered independent public accounting firm addressing 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, under the new standard issued by the Public Company Accounting Oversight Board.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effects on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the American Stock Exchange. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in ICFR, we will be unable to assert that our ICFR is effective. If we are unable to assert that our ICFR is effective (or if

our auditors are unable to attest that management s report is fairly stated, they are unable to express an opinion on our management s evaluation or on the effectiveness of the internal controls or they issue an adverse opinion on ICFR), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective ICFR in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective ICFR could have an adverse effect on our common stock price.

Item 1B. # UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. # PROPERTIES

Our principal executive office is a leased facility located in Lincolnshire, Illinois. In December 2003, we entered into a lease agreement for approximately 4,000 square feet of office space for approximately $7,400 per month. In March 2004, we signed an amendment to this lease effective April 1, 2004. 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 January 2006 to continue the term for one additional year, with the financial terms remaining unchanged. This lease will expire in March 2007. Our CaP development operations are located in Smyrna, Georgia where we lease approximately 11,840 square feet of laboratory space for approximately $7,400 per month. This lease expires in October 2006. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

Item 3. # LEGAL PROCEEDINGS

On November 30, 2005, we sent written notice to Leah M. Lehman, Ph.D., our former Vice President, Product Development, that we were exercising our contractual right not to renew her employment agreement. As a result of this notice, Dr. Lehman s employment agreement expired by its terms on December 31, 2005. On February 15, 2006 we received notice that on February 10, 2006, Dr. Lehman had filed a complaint against us, our President and Chief Executive Officer, our Chief Financial Officer and one of our directors, with the Occupational Safety and Health Administration under the Sarbanes-Oxley Act of 2002 seeking reinstatement of her employment with back pay, interest and attorney s fees and claiming, among other things, wrongful termination. We believe that Dr. Lehman s allegations of wrongful termination and violations of the Sarbanes-Oxley Act are wholly without merit and intend to vigorously defend our position. On February 17, 2006, we filed a complaint against Dr. Lehman in the Circuit Court of Cook County, Illinois alleging breach of fiduciary duty, breach of contract in regard to her employment agreement with us, tortious interference with prospective economic advantage and abuse of process. We are seeking an unspecified amount of damages, punitive damages, declaratory judgment regarding a breach by Dr. Lehman of her employment agreement and the amount of severance pay, if any, to be owed to Dr. Lehman, reimbursement of our legal fees and costs and such other relief as the Court may deem proper. In March 2006, Dr. Lehman filed a charge with the Equal Employment Opportunity Commission claiming sex discrimination and retaliation in violation of Title VII of the Civil Rights Act of 1964. We also believe that Dr. Lehman s charges with the EEOC are wholly without merit and intend to vigorously defend our position.

We have accrued $750,000 in connection with this matter. Although we believe that a portion of any liability resulting from this matter may be covered under our employment practices liability insurance policy, we cannot assure you that it will be so covered or that the ultimate resolution of this matter will

not exceed the amount of our accrual or will not otherwise result in a material adverse effect on our business, financial condition or results of operations.

We are not a party to any other material threatened or pending legal proceedings.

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, 2005.

Item 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and the offices held, as of March 15, 2006, are as follows:

Name	Age	Title
Stephen M. Simes	54	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	45	Chief Financial Officer, Treasurer and Secretary
Steven J. Bell, Ph.D.	46	Vice President, Research and Pre-Clinical Development

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

Information regarding the business experience of our executive officers is set forth below.

Stephen M. Simes has served as our Vice Chairman, President and a director of our company since January 1998 and Chief Executive Officer since March 1998. From October 1994 to January 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., (currently a wholly owned subsidiary of Solvay Pharmaceuticals, Inc.) a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Savient Pharmaceuticals Inc. (formerly Bio-Technology General Corp.), and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Savient Pharmaceuticals Inc. Mr. Simes career in the pharmaceutical industry started in 1974 with G.D. Searle & Co. (now a part of Pfizer Inc.).

Phillip B. Donenberg, CPA has served as our Chief Financial Officer, Treasurer and Secretary since July 1998. Before joining our company, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. (currently a wholly owned subsidiary of Solvay Pharmaceuticals, Inc.) from January 1995 to July 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc. (currently Savient Pharmaceuticals, Inc.), Applied NeuroSolutions, Inc. (formerly Molecular Geriatrics Corporation) and Xtramedics, Inc.

Steven J. Bell, Ph.D. has served as our Vice President, Research and Pre-Clinical Development since October 2000 and served as a Director of Research and Development of BioSante from July 1997 to October 2000. Prior to joining our company, Dr. Bell held various positions with Boehringer Mannheim, Hoffman-LaRoche, The Upjohn Company and Boehringer Ingelheim.

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 prices for our common stock, as reported by the American Stock Exchange (AMEX), for each calendar quarter on which our common stock was listed for trading during on the AMEX.

American Stock Exchange

2004	**High**	**Low**
First Quarter	$ 6.40	$ 4.08
Second Quarter	$ 8.38	$ 4.61
Third Quarter	$ 9.89	$ 4.75
Fourth Quarter	$ 10.44	$ 4.54

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

Number of Record Holders; Dividends

As of March 15, 2006, there were 605 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, 2005, we did not issue or sell any equity securities 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, 2005. 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.

Item 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data sets forth the results of operations and balance sheet data of our company:

	Year Ended December 31,				
	2001	2002	2003	2004	2005
	(in thousands, except per share data)				
Statement of Operations Data:					
Licensing income	$ 1,747	$ 2,770	$ 65	$ 10	$ 45
Interest income	175	64	87	250	401
Grant income				68	181
Other income					32
Total income	1,922	2,834	152	328	659
Expenses					
Research and development	2,142	4,787	3,691	9,162	6,409
General and administration	2,299	1,766	2,327	3,080	3,050
Provision for contingencies					750
Depreciation and amortization	92	92	93	102	101
Total expenses	4,533	6,645	6,111	12,344	10,310
Loss before other expenses	(2,611)	(3,811)	(5,959)	(12,016)	(9,651)
Net loss	$ (2,611)	$ (3,811)	$ (5,959)	$ (12,016)	$ (9,651)
Basic and diluted net loss per share	$ (0.40)	$ (0.51)	$ (0.54)	$ (0.70)	$ (0.50)
Weighted average number of shares outstanding	6,485	7,503	11,039	17,145	19,392

	As of December 31,				
	2001	2002	2003	2004	2005
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short term investments	$ 4,502	$ 4,884	$ 9,134	$ 17,269	$ 9,102
Working capital	3,666	4,292	8,436	15,659	6,681
Total assets	4,979	5,880	9,565	17,827	9,575
Stockholders equity	4,051	4,624	8,684	15,921	6,819

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

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 caption Forward-Looking Statements in Item 1 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.

Overview

We are a development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, for primarily vaccine adjuvants or immune system boosters and drug delivery systems.

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 until early 2007 at the earliest depending upon the timing of the FDA s decision on our New Drug Application for our Bio-E-Gel product which we submitted in February 2006 and the potential approval of such application.

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 2005, we received approximately $200,000 from warrant and option exercises. Our cash, cash equivalents and short-term investments were $9,101,531 as of December 31, 2005. We currently do not have sufficient resources on a long-term basis to complete the commercialization of any of our proposed products. Based on our current cash resources and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be made that we will not need additional cash prior to such time.

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 Bio-E-Gel or other proposed products receive FDA approval, we may begin to incur other expenses, including sales and marketing related expenses if we choose to market the product ourselves.

We spent an average of approximately $500,000 to $600,000 per month on research and development activities in 2005. Our research and development expenses decreased $2,753,359 or 30 percent, to $6,409,080 for the year ended December 31, 2005 from $9,162,439 for the year ended December 31, 2004, primarily as a result of the completion of the Phase III clinical trial of our Bio-E-Gel product in March 2005, partially offset by the costs associated with the preparation of the Bio-E-Gel NDA. We expect our research and development expenses to be significantly lower in 2006 until the commencement of our LibiGel Phase III trial, which we expect to commence sometime during 2006. 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. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds for research and development activities.

Our general and administrative expenses for the year ended December 31, 2005 decreased one percent, compared to general and administrative expenses for the year ended December 31, 2004. 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.

Since our inception, we have experienced significant operating losses. We incurred a net loss of $9,651,036 for the year ended December 31, 2005, resulting in an accumulated deficit of $49,688,320. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs expand and various preclinical and clinical trials commence and continue. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

the timing and cost of product development;

the progress and cost of preclinical and clinical development programs;

the costs of licensure or acquisition of new products;

the timing and cost of making necessary regulatory filings and obtaining approvals;

the timing and cost of obtaining third party reimbursement;

the cost of sales and marketing activities; and

the costs of pending and any future litigation of which we may be subject.

Hormone Therapy Products. Our hormone therapy products address a variety of hormone therapies for symptoms that affect both men and women. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen. Our hormone therapy products include Bio-E-Gel, LibiGel, Bio-E/P-Gel, Bio-E/T-Gel and Bio-T-Gel. We have completed human clinical trials on several of our hormone therapy products, which are required to obtain FDA approval to market the products. We completed our pivotal Phase III clinical trial of Bio-E-Gel in March 2005 and submitted an NDA with the FDA in February 2006. We hope to commercially launch our Bio-E-Gel product after obtaining FDA approval, which we hope to receive in late 2006 or early 2007. Our proposed LibiGel product successfully completed a Phase II clinical trial, and we are currently in the planning stage for our Phase III clinical trials which we hope to begin during 2006. We have not received FDA or ay other government approval for any of our products and thus have not commercialized any of them

in the United States or elsewhere.

Under the terms of our license agreement with Antares Pharma, Inc., we acquired exclusive marketing rights, with the right to grant sublicenses, to the single active ingredient products containing testosterone and estradiol for all therapeutic indications in the U.S. and several foreign countries. We acquired exclusive marketing rights, with the right to grant sublicenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of these hormone therapy products, we paid Antares an upfront license fee of $1.0 million in June 2000. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, pay royalties to Antares on sales of the products if and when the products are brought to market. In a series of amendments executed during 2001 between BioSante and Antares, we returned to Antares the license rights to an estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, and Antares granted us a credit for approximately

$600,000 of manufacturing and formulation services, which have been fully utilized, and a license for the combination estradiol plus testosterone gel product in the U.S and several foreign countries.

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), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, we received a $950,000 milestone payment pursuant to the Solvay sublicense agreement. Solvay has been responsible for all costs of development to date.

We have sublicensed the marketing rights to our portfolio of hormone therapy products (other than the estrogen/progestogen combination product) 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 will 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 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.

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. 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.

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

CaP Technology and Proposed Products. Our CaP technology, several of whose issued patents we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call nanoparticles, as immune system boosters, for drug delivery and to purify the milk of transgenic animals, among other uses. 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. 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.

In June 2003, we announced the signing of another CRADA with the U.S. Army s Medical Research Institute of Infectious Disease (USAMRIID) for the development of non-injected biodefense vaccines, including anthrax, staph and ricin. The USAMRIID has agreed to grant us an exclusive license to any U.S. patent application or issued patent as a result of the work under the CRADA. The USAMRIID will cover all costs associated with the CRADA.

In September 2003, we announced that we were awarded a $100,000 Small Business Innovation Research grant from the National Institutes of Health to support our development of formulations for the oral delivery of insulin using our CaP technology. We recognized $10,000 as a contra-expense for this grant in our December 31, 2005 financial statements. We receive the funds as reimbursement of research and development expenses. We have completed the work outlined under this grant and are currently investigating our options with respect to a Phase II SBIR grant.

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. The subcontract is valued at approximately up to $658,000. We have successfully completed the first year of this contract which should conclude in the second half of 2006. Revenue related to this contract of $157,780 was recorded in 2005.

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. Revenue related to this contract of $45,455 was recorded in 2005.

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 if warranted, we can apply to renew the subcontract in subsequent years. The first year of the subcontract is valued at approximately $250,000. 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. Revenue related to this subcontract of $23,116 was recorded in 2005.

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

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 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. Any ancillary payments related to the products being licensed, such as royalties to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized.

Research and Development Costs

Research and development (R&D) costs are charged to expense as incurred. Costs associated with production of 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. To date, none of our products has received FDA approval.

Results of Operations

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

	Year Ended December 31,		
	2005	**2004**	**2003**
Revenue	$ 258,351	$ 77,886	$ 65,494
Expenses	9,857,613	12,344,517	6,111,437
Research and development	6,409,080	9,162,439	3,691,420
General and administrative	3,050,555	3,080,135	2,327,090
Provision for contingencies	750,000		
Interest income	401,186	250,424	86,589
Net loss	$ (9,651,036)	$ (12,016,207)	$ (5,959,354)
Net loss per share (basic and diluted)	(0.50)	(0.70)	(0.54)
Weighted average number of shares outstanding	19,392,116	17,145,387	11,038,595

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 Bio-E-Gel product in March 2005, partially offset by the costs associated with the preparation of the Bio-E-Gel NDA.

Our general and administrative expenses for the year ended December 31, 2005 decreased one percent compared to general and administrative expenses for 2004.

Interest income for the year ended December 31, 2005 increased 60 percent compared to interest income during 2004 primarily as a result of a significantly higher interest rate on our invested funds, partially offset by lower invested cash and short term investment balances during 2005. We expect interest income to decline in future periods as we use our cash and short term investment balances for operations.

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 provision for contingencies.

Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

Revenue for the year ended December 31, 2004 increased 19 percent compared to revenue during 2003 primarily due to $67,886 received from our Dynport subcontract in 2004, offset by a reduction of $55,494 in licensing revenue for 2004 compared to licensing revenue during 2003.

Research and development expenses for the year ended December 31, 2004 increased 148 percent compared to research and development expenses during 2003 primarily as a result of increased expenses during 2004 associated with the Phase III clinical trial of our Bio-E-Gel product and the completion of our Phase II trial of our LibiGel product.

General and administrative expenses for the year ended December 31, 2004 increased 32 percent compared to general and administrative expenses for 2003 primarily as a result of an increase in non-cash stock-based compensation related to $572,541 associated with changing the life of previously issued options to officers and compensation paid in common stock to board members. The majority of this non-cash stock-based compensation expense was a result of an amendment to certain options to purchase an aggregate of 285,000 shares of common stock at an exercise price of $2.10 per share that were granted in the second quarter 2003 and were amended in first quarter 2004 to change the vesting periods from milestone-based vesting schedules to time-based vesting schedules. The amended stock options now vest in three equal annual installments over a three-year period from the date of the amendment as opposed to upon a change in control of the company. As a result of the stock option amendments, we will recognize $1,054,500 in compensation expense over a three-year period which began in the first quarter 2004.

Interest income for the year ended December 31, 2004 increased 189 percent compared to interest income during 2003 primarily as a result of higher invested cash and short term investment balances during 2004. We expect interest income to decline in future periods as we use our cash and short term investment balances for operations.

The overall increase in the net loss for the year ended December 31, 2004 compared to 2003 was primarily the result of increased clinical trial costs as well as the non-cash stock-based compensation expense as described above.

Liquidity and Capital Resources

Working Capital

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and from subcontracts. To date, we have used primarily equity financing and received licensing income to fund our ongoing business operations and short-term liquidity needs, and we expect to continue this practice for the foreseeable future. Since inception, we have raised net proceeds of approximately $50.5 million from equity financings, class A and class C stock conversions, warrant and option exercises and the issuance of a $500,000 convertible debenture, and have received $4.6 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash, cash equivalents and short-term investments available to fund current operations were $9,101,531 and $17,268,688 at December 31, 2005 and 2004, respectively. Our accounts payable were $1,139,566 and $1,169,037 at December 31, 2005 and 2004, respectively, and our other accrued expenses were $147,125 and $202,086 at December 31, 2005 and 2004, respectively. Our provision for contingencies was $750,000 and $0 at December 31, 2005 and 2004, respectively, and our accrued compensation was $492,980 and $531,882 at December 31, 2005 and 2004, respectively. Our deferred revenue was $204,545 and $0 at December 31, 2005 and 2004, 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. The decrease in our cash and short term investment balances was primarily due to our use of cash to fund operations. We expect our cash balance to decrease as we continue to use cash to fund our operations. We do not have any outstanding debt.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash balance and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through at least the next twelve months, although no assurance can be given that we will not need additional cash prior to such 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 rate of technological advances;

ongoing determinations of the potential commercial success of our proposed products;

our general and administrative expenses, including legal expenses incurred in connection with pending and any future litigation of which we may be subject;

if we receive FDA approval of any of our proposed products, the amount of resources we devote to sales and marketing capabilities;

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, 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 $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 reflects the decreased net loss partially offset by a decrease in non-cash stock-based compensation expense. 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 $16.4 million private placement offering in May 2004. Redemption of auction rate securities provided $7,700,150 in cash during 2005, and we used $392,375 to

purchase auction rate securities and $67,416 to purchase computer equipment during 2005. We used $16,098,663 to purchase auction rate securities 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.

Our cash used in operating activities was $10,442,443 for the year ended December 31, 2004 versus cash used in operating activities of $5,521,992 for the year ended December 31, 2003. The increase in cash used in operating activities largely reflects our ongoing research and development expenditures, offset by the increase in accounts payable and accrued expenses as well as payments received from grants related to reimbursement of development costs of products within our CAP product portfolio and non-cash stock-based compensation expense described above. We used cash in investing activities of $16,201,867 for the year ended December 31, 2004, $103,204 of which was used for the purchase of computer equipment, office furniture and equipment and new lab equipment as well as $16,098,663 used to purchase auction rate securities, versus $8,865 for the year ended December 31, 2003, which was used for the purchase of computer and office equipment. 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. Net cash provided by financing activities during the year ended December 31, 2003 was $9,781,487 and was primarily the result of our $10.3 million private placement, which closed in August 2003.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2005. We have, however, several potential financial commitments, including product development milestone payments to the licensors of our hormone therapy products, payments under our license agreements with the University of California and Wake Forest University, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of December 31, 2005:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating Leases	$ 244,843	$ 208,866	$ 35,977	$	$
Commitments Under License Agreement with UCLA	3,375,000	50,000	375,000	700,000	2,250,000
Commitments Under License Agreement with Wake Forest	720,000	10,000	120,000	150,000	440,000
Total Contractual Cash Obligations	$ 4,339,843	$ 268,866	$ 530,977	$ 850,000	$ 2,690,000

We expect to continue to spend capital on:

research and development programs;

pre-clinical studies and clinical trials;

regulatory processes;

general administrative expenses, involving investor relations, legal and accounting fees and expenses;

establishment of our own marketing capabilities or a search for third party sales and marketing partners to sell and market our products for us; and

the licensure or acquisition of new products.

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 establish our own sales and marketing capabilities or 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;

new collaborative, licensing and other commercial relationships that we may establish; and

costs incurred in connection with pending and any future litigation of which we may be subject.

In addition, our license agreement with the licensor of our hormone therapy products requires us to make certain payments as development milestones are achieved, and our license agreement with the University of California requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve research and development milestones. 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by generally accepted accounting principles, 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

On December 16, 2004, the FASB issued SFAS 123(R), Share-Based Payment, which is a revision of SFAS 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion 25, Accounting for Stock Issued to Employees. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be valued at fair value on the date of grant, and to be expensed over the applicable vesting period and is effective for us on January 1, 2006. We expect the adoption of SFAS 123(R) will have a material impact on our results of operations and financial position resulting from the requirement to recognize this additional component of compensation expense.

In March 2005, the FASB issued Interpretation No. (FIN) 47, *Accounting for Conditional Asset Retirement Obligations*. This is an interpretation of SFAS 143, *Accounting for Asset Retirement Obligations* which applies to all entities and addresses the legal obligations with the retirement of tangible long-lived assets that result from the acquisition, construction, development or normal operation of a long-lived asset. The SFAS requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. FIN 47 further clarifies what the term conditional asset retirement obligation means with respect to recording the asset retirement obligation discussed in SFAS No. 143. The provisions of FIN 47 are effective no later than December 31, 2005. We do not expect the adoption of FIN 47 to have a material impact on our results of operations, financial position or cash flows. We adopted the provisions of FIN 47 on December 31, 2005. As a result of the adoption of FIN 47, we recorded an asset and corresponding liability of $21,500 related to the Smyrna, Georgia laboratory lease.

In May 2005, the Financial Accounting Standards Board (FASB) issued SFAS No. 154, Accounting Changes and Error Corrections. This statement generally requires retrospective application to prior periods financial statements of voluntary changes in accounting principles. Under the prior rules, changes in accounting principles were generally recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This statement does not change the previous requirements for reporting the correction of an error in previously issued financial statements, change in accounting estimate or justification of a change in accounting principle on the basis of preferability. This statement is effective for accounting changes made in fiscal years beginning after December 15, 2005. Adoption of the provisions of the statement is not expected to have a material effect on the results of operations or financial position of our company.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Description

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2005 and 2004

Statements of Operations for the years ended December 31, 2005, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

Statements of Stockholders Equity for the years ended December 31, 2005, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

Notes to the Financial Statements for the years ended December 31, 2005, 2004 and 2003 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

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) (a development stage company) as of December 31, 2005 and 2004, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2005 and for the period from August 29, 1996 (date of incorporation) through December 31, 2005. 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, 2005 and 2004, and the related statements operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2005 and for the period from August 29, 1996 (date of incorporation) through December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1, the Company is in the development stage.

/s/ DELOITTE & TOUCHE LLP

Chicago, Illinois
March 30, 2006

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Balance Sheets

December 31, 2005 and 2004

	2005	2004
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 310,643	$ 1,170,025
Short-term investments	8,790,888	16,098,663
Prepaid expenses and other sundry assets	245,465	297,593
	9,346,996	17,566,281
PROPERTY AND EQUIPMENT, NET (Note 5)	215,566	249,088
OTHER ASSETS		
Security Deposits	11,992	11,992
	$ 9,574,554	$ 17,827,361
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 12)	$ 1,139,566	$ 1,169,037
Provision for contingencies (Note 14)	750,000	
Accrued compensation	492,980	531,882
Other accrued expenses	147,125	202,086
Deferred revenue	136,363	
Due to Antares (Note 4)		3,750
TOTAL CURRENT LIABILITIES	2,666,034	1,906,755
LONG TERM LIABILITIES		
Leasehold retirement liability	21,500	
Deferred Revenue	68,182	
TOTAL LONG TERM LIABILITIES	89,682	
TOTAL LIABILITIES	$ 2,755,716	$ 1,906,755
STOCKHOLDERS EQUITY (Note 8)		
Capital stock		
Issued and Outstanding		
2005 - 391,286; 2004 - 391,286 Class C special stock	398	398
2005 - 19,007,800; 2004 - 18,955,181 Common stock	56,653,219	56,455,451
	56,653,617	56,455,849
Deferred unearned compensation	(146,459)	(497,959)
Deficit accumulated during the development stage	(49,688,320)	(40,037,284)
	6,818,838	15,920,606
	$ 9,574,554	$ 17,827,361

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Operations

Years ended December 31, 2005, 2004 and 2003

and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

	Year ended December 31, 2005	Year ended December 31, 2004	Year ended December 31, 2003	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005
REVENUE				
Licensing income	$ 45,455	$ 10,000	$ 65,494	$ 4,638,398
Grant income	180,896	67,886		248,782
Other Income	32,000			32,000
	258,351	77,886	65,494	4,919,180
EXPENSES				
Research and development	6,409,080	9,162,439	3,691,420	30,476,073
General and administration	3,050,555	3,080,135	2,327,090	18,332,301
Provision for contingencies	750,000			750,000
Depreciation and amortization	100,938	101,943	92,927	862,301
Loss on disposal of capital assets				157,545
Costs of acquisition of Structured Biologicals Inc.				375,219
Purchased in-process research and development				5,377,000
	10,310,573	12,344,517	6,111,437	56,330,439
OTHER - Interest income	401,186	250,424	86,589	1,722,939
NET LOSS	$ (9,651,036)	$ (12,016,207)	$ (5,959,354)	$ (49,688,320)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.50)	$ (0.70)	$ (0.54)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	19,392,116	17,145,387	11,038,595	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Stockholders Equity

Years ended December 31, 2005, 2004 and 2003

and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

	Class A Special Shares		Class C Special Shares		Common Stock		Deferred Unearned	Deficit Accumulated During the Development	
	Shares	Amount	Shares	Amount	Shares	Amount	Compensation	Stage	Total
Balance, August 29, 1996, Date of incorporation		$		$		$	$	$	$
Issuance of Class C shares August 29, 1996 ($0.0001 per share)			415,000	415					415
Issuance of Class A shares September 23, 1996 ($0.0001 per share)	2,000,000	2,000							2,000
Issuance of common shares					535,427	5,037,364			5,037,364
November 27, 1996 - issued as consideration upon acquisition of SBI (Note 3)					743,432	4,545,563			4,545,563
Exercise of warrants					28,971	376,462			376,462
Conversion of shares			(76,537)	(76)	76,537	191,416			191,340
Adjustment for partial shares issuedupon amalgamation					13				
Conversion of shares	(1,700,000)	(1,700)			1,700,000	4,251,700			4,250,000
Return of shares to treasury	(146,861)	(147)	(25,000)	(25)					(172)
Private placements of common shares, net					5,487,500	12,243,096			12,243,096
Issuance of Warrants for services received						42,290			42,290
Share redesignation	(153,139)	(153)	153,139	153					
May 31, 2002 - Fractional share adjustment					(711)	(3,050)			(3,050)
Net loss								(22,061,723)	(22,061,723)
Balance, December 31, 2002			466,602	467	8,571,169	26,684,841		(22,061,723)	4,623,585
Conversion of shares October 30, 2003			(62,500)	(63)	62,500	156,313			156,250
Private placement of common shares, net August 6, 2003					4,791,982	9,593,237			9,593,237
Issuance of common shares Board Compensation - Various					89,686	193,000			193,000
2002 bonus paid to executives in May 2003					33,538	77,547			77,547
Net loss								(5,959,354)	(5,959,354)
Balance, December 31, 2003			404,102	404	13,548,875	36,704,938		(28,021,077)	8,684,265
Conversion of shares									
October 1, 2004			(1,816)	(1)	1,816	4,541			4,540
October 8, 2004			(10,000)	(4)	10,000	25,004			25,000

December 16, 2004	(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net							
May 14, 2004			2,949,000	16,370,247			16,370,247
Issuance of common shares							
Option exercises - Various			142,670	234,495			234,495
Warrant exercises - Various			2,317,670	1,990,120			1,990,120
Board Compensation - Various			2,988	16,000			16,000
Treasury Shares Cancellation - December 15, 2004			(18,838)				
Stock Option Compensation - Executive Officers				1,054,500	(497,959)		556,541
Section 16B Short Swing Profit				53,105			53,105
Net loss						(12,016,207)	(12,016,207)
Balance, December 31, 2004	391,286	398	18,955,181	56,455,451	(497,959)	(40,037,284)	15,920,606
Issuance of common shares							
Option exercises - Various			14,270	41,518			41,518
Warrant exercises - Various			37,825	156,250			156,250
Stock Option Compensation - Executive Officers					351,500		351,500
Share redesignation			524				
Net loss						(9,651,036)	(9,651,036)
Balance, December 31, 2005	**$ 391,286**	**$ 398**	**19,007,800**	**$ 56,653,219**	**$ (146,459)**	**$ (49,688,320)**	**$ 6,818,838**

See accompanying noters to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Years ended December 31, 2005, 2004 and 2003

and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005

	Year ended December 31, 2005	Year ended December 31, 2004	Year ended December 31, 2003	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2005
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	$ (9,651,036)	$ (12,016,207)	$ (5,959,354)	$ (49,688,320)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	100,938	101,943	92,927	862,301
Amortization of deferred unearned compensation				42,290
Repurchase of licensing rights				125,000
Employee & director compensation - noncash	351,500	572,541	193,000	1,268,041
Purchased in-process research and development				5,377,000
Loss on disposal of equipment				157,545
Changes in other assets and liabilities affecting cash flows from operations				
Prepaid expenses and other sundry assets	52,128	(126,269)	(39,161)	(254,489)
Due from licensee (Teva Pharmaceuticals USA, Inc.)			520,063	
Accounts payable and accrued liabilities	(101,834)	1,039,664	(112,029)	1,106,530
Provision for contingencies	750,000			750,000
Due to licensor (Antares/Regents)	(3,750)	(14,115)	(217,438)	
Deferred revenue	204,545			204,545
Due from SBI				(128,328)
Net cash used in operating activities	(8,297,509)	(10,442,443)	(5,521,992)	(40,177,885)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES				
Redemption of short term investments	7,700,150			7,700,150
Purchase of short term investments	(392,375)	(16,098,663)		(16,491,038)
Purchase of capital assets	(67,416)	(103,204)	(8,865)	(1,201,302)
Net cash provided by (used in) investing activities	7,240,359	(16,201,867)	(8,865)	(9,992,190)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture				500,000
Proceeds from sale or conversion of shares	197,768	18,680,008	9,781,487	49,983,768
Fractional share payout				(3,050)
Net cash provided by financing activities	197,768	18,680,008	9,781,487	50,480,718
	(859,382)	(7,964,302)	4,250,630	310,643

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS				
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**1,170,025**	**9,134,327**	**4,883,697**	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 310,643**	**$ 1,170,025**	**$ 9,134,327**	**$ 310,643**
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION				
Acquisition of SBI				
Purchased in-process research and development	**$**	**$**	**$**	**$ 5,377,000**
Other net liabilities assumed				**(831,437)**
				4,545,563
Less: subordinate voting shares issued therefor				**4,545,563**
	$	**$**	**$**	**$**
Income tax paid	**$**	**$**	**$**	**$**
Interest paid	**$**	**$ 1,426**	**$ 1,995**	**$ 3,421**
SIGNIFICANT NON-CASH TRANSACTIONS				
Fair value of common stock warrants issued in connection with the sale of capital stock	**$**	**$ 513,551**	**$ 539,872**	**$ 1,053,423**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Notes to the Financial Statements

For the years ended December 31, 2005, 2004, and 2003, and the cumulative period

From August 19, 1996 (date of incorporation) to December 31, 2005

1. ORGANIZATION

On December 19, 1996, Ben-Abraham Technologies, Inc. (BAT) was continued under the laws of the State of Wyoming, U.S.A. Previously, BAT had been incorporated under the laws of the Province of Ontario, Canada, effective August 29, 1996. Pursuant to the shareholders meeting to approve the arrangement on November 27, 1996 and subsequent filing of the articles of arrangement on December 6, 1996, BAT acquired Structured Biologicals Inc. and its wholly-owned subsidiary 923934 Ontario Inc. (SBI), a Canadian public company listed on the Alberta Stock Exchange. The acquisition was effected by a statutory amalgamation wherein the stockholders of BAT were allotted a significant majority of the shares of the amalgamated entity. Upon amalgamation, the then existing stockholders of SBI received 743,432 subordinate voting shares of BAT (1 such share for every 35 shares held in SBI) which was subsequently adjusted for a one-for-ten reverse split of its issued and outstanding shares of common stock and class C common stock in 2002. On November 10, 1999, BAT changed its name to BioSante Pharmaceuticals, Inc. (the Company).

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 laboratory facility. In addition to its nanoparticle technology, the Company also is 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 has been in the development stage since its inception. The Company s successful completion of its development program and its transition to profitable operations is dependent upon obtaining regulatory approval from the United States (the U.S.) Food and Drug Administration (FDA) prior to selling its products within the U.S., and foreign regulatory approval must be obtained to sell its products internationally. There can be no assurance that the Company s products will receive regulatory approvals, and a substantial amount of time may pass before the achievement of a level of sales adequate to support the Company s cost structure. The Company will also incur substantial expenditures to achieve regulatory approvals and will need to raise additional capital during its developmental period. Obtaining marketing approval will be directly dependent on the Company s ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. It is not possible at this time to predict with assurance the outcome of these activities.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash resources and commitments, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures for at least the next 12 months, although no assurance can be given that we will not need additional cash prior to such time. Unexpected increases in general and administrative expenses and research and development expenses may cause us to seek additional financing prior to such time.

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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) and Statement of Financial Accounting Standards (SFAS) No. 7 Accounting and Reporting by Development Stage Enterprises. 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.

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 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.

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

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Research and Development

Research and development (R&D) costs are charged to expense as incurred. Costs associated with production of products are capitalized only when FDA approval has occurred. Direct Government grants are recorded as an offset to the related research and development costs when the Company has complied with the conditions attached to the grant and there is reasonable assurance that the funds will be received.

Legal Costs

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

Basic and Diluted Net Loss Per Share

The basic and diluted net 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 loss per share is computed by dividing loss available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted 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 loss per share does not include the Company s stock options, warrants or convertible debt with dilutive potential because of their antidilutive effect on loss per share.

Stock-based Compensation

The Company follows the provisions of APB Opinion No. 25, Accounting For Stock-Based Compensation (APB No. 25) which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the measurement date (generally the date of grant) and the amount the employee must pay to acquire the stock. On December 16, 2004, the FASB issued SFAS 123(R), Share-Based Payment, which is a revision of SFAS 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion 25, Accounting for Stock Issued to Employees. SFAS 123(R) requires that the expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected term of the option,

the current price of the underlying stock, its expected volatility, expected dividends on the stock and the expected risk-free rate of return during the term of the option. The compensation cost is recognized over the service period, usually the period from the grant date to the vesting date. The Company expects to adopt the provisions of SFAS 123(R) on January 1, 2006. In addition, as a result of the Company s application of APB No. 25, SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 148), requires certain additional disclosures of the pro forma compensation expense arising from the Company s fixed and performance stock compensation plans. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value based method.

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	2005	2004	2003
Net loss			
As reported	**$ (9,651,036)**	$ (12,016,207)	$ (5,959,354)
Stock-based compensation included in net loss as reported	**351,500**	572,541	193,000
Total stock-based employee compensation determined under fair value based method for all awards	**(784,329)**	(1,042,589)	(685,932)
Net loss, pro forma	**$ (10,083,865)**	$ (12,486,255)	$ (6,452,286)
Basic and diluted net loss per share			
As reported	**$ (0.50)**	$ (0.70)	$ (0.54)
Pro forma	**$ (0.52)**	$ (0.73)	$ (0.58)
Cumulative net loss			
As reported	**$ (49,688,320)**		
Stock-based compensation included in net loss as reported	**1,268,041**		
Total stock-based employee compensation determined under fair value based method for all awards	**(5,330,905)**		
Pro forma	**$ (53,751,184)**		

The weighted average fair value of the options at the date of grant for options granted during 2005, 2004 and 2003 was $3.79, $4.32, and $1.57, 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:

	2005	2004	2003
Expected option life (years)	**10**	10	10
Risk free interest rate	**3.96%**	4.75%	3.98%
Expected stock price volatility	**73.91%**	100.28%	64.17%
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 2005.

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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 to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized.

Reclassifications

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

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard 123 (Revised), Share-Based Payment (SFAS 123R). Among other changes, SFAS 123R requires companies to record share-based compensation using the fair value method, versus the intrinsic value method allowed by APB No. 25. The adoption of SFAS 123(R) is expected to have a material impact on the Company s financial position and results of operations.

In March 2005, the FASB issued Interpretation No. (FIN) 47, Accounting for Conditional Asset Retirement Obligations. This is an interpretation of SFAS 143, Accounting for Asset Retirement Obligations which applies to all entities and addresses the legal obligations with the retirement of tangible long-lived assets that result from the acquisition, construction, development or normal operation of a long-lived asset. The SFAS requires that the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. FIN 47 further clarifies what the term conditional asset retirement obligation means with respect to recording the asset retirement obligation discussed in SFAS No. 143. The Company adopted the provisions of FIN 47 on December 31, 2005. As a result of the adoption of FIN 47, the Company recorded an asset and corresponding liability of $21,500 related to the Smyrna, Georgia laboratory lease.

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In May 2005, the Financial Accounting Standards Board (FASB) issued SFAS No. 154, Accounting Changes and Error Corrections. This statement generally requires retrospective application to prior periods financial statements of voluntary changes in accounting principles. Under the prior rules, changes in accounting principles were generally recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. This statement does not change the previous requirements for reporting the correction of an error in previously issued financial statements, change in accounting estimate or justification of a change in accounting principle on the basis of preferability. This statement is effective for accounting changes made in fiscal years beginning after December 15, 2005. Adoption of the provisions of the statement is not expected to have a material effect on the results of operations or financial position of the Company.

3. ACQUISITION

Pursuant to the shareholders meeting to approve the arrangement held on November 27, 1996 and the subsequent filing of the articles of arrangement December 6, 1996, the Company completed the acquisition of 100% of the outstanding shares of SBI. The acquisition was effected by a statutory amalgamation wherein the stockholders of the Company were allotted a significant majority of the shares of the amalgamated entity. Upon amalgamation, the then existing shareholders of SBI received 743,432 shares of common stock of the Company (1 such share for every 35 shares they held in SBI). SBI s results of operations have been included in these financial statements from the date of acquisition. The acquisition was accounted for by using the purchase method of accounting, as follows:

Assets		
In-process research and development	**$**	**5,377,000**
Other		**37,078**
		5,414,078
Liabilities		
Current liabilities		**679,498**
Due to directors		**60,689**
Due to the Company		**128,328**
		868,515
Net assets acquired	**$**	**4,545,563**
Consideration		
Common stock	**$**	**4,545,563**

In connection with the acquisition of SBI, accounted for under the purchase method, the Company acquired the rights to negotiate with the Regents of the University of California for licenses of specific CaP-related technologies and products. The specific technologies and products relate to investigative research funded by SBI. At the time of acquisition, the technologies and products had not yet been approved for human clinical research. The value ascribed to the rights, based on an independent evaluation, was $5,377,000. This amount was immediately expensed as the technologies and products did not have their technological feasibility established and had no identified future alternative use.

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As of the date of acquisition, the technology related to the development of products for six indications (i.e. applications of the technology). The Company determined the value of the in process research and development related to the acquired rights based on an independent valuation using discounted expected cash flows.

4. 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 license agreement requires the Company to undertake various obligations as described in Note 13.

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 an additional 18,940 shares of its common stock to Paladin at a 10 percent premium to the Company s market price. The dollar value of the premium, $39,394, was recorded as licensing income in the statements of operations.

In a series of amendments executed during 2001 and 2002 between the Company and Antares, the Company returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. It was agreed, that the Company is the owner of Bio-T-Gel, its testosterone gel for men with no milestone or royalty obligations to Antares.

Additionally, the Company returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted the Company a credit for approximately $600,000 of manufacturing and formulation services and a license for LibiGel E/T, a transdermal combination gel of bioidentical estrogen and bioidentical testosterone. During the third quarter of 2001, Antares informed the Company that the total costs for manufacturing and formulation services had exceeded the $600,000 credit. Accordingly, beginning in third quarter of 2001 and

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going forward, the Company is required to reimburse Antares for such services. At December 31, 2005 and 2004, the amount owed to Antares for such services was $0 and $3,750, respectively.

On August 7, 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay sub-licenses the Company s estrogen/progestogen combination transdermal hormone gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. During 2002, the Company received a $950,000 ($750,000 net of the related payment due to Antares as a result of a series of amendments executed during 2002 between the Company and Antares) milestone payment pursuant to the Solvay sub-license agreement. Solvay has been responsible for all costs of development of the product to date.

The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of the Company s common stock with a market value of $125,000 at the date of the transaction.

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

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

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the decision by Teva to discontinue the development of Bio-T-Gel is based on strategic decisions by Teva.

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.

5. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2005 and 2004 comprise:

		2005		**2004**
Computer equipment	**$**	**194,905**	$	164,036
Office equipment		**155,191**		145,700
Laboratory equipment		**129,433**		123,878
Leasehold improvements Laboratory		**498,840**		477,339
		978,367		910,953
Accumulated depreciation and amortization		**(762,803)**		(661,865)
	$	**215,566**	$	249,088

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6. INCOME TAXES

The components of the Company s net deferred tax asset at December 31, 2005, 2004 and 2003 were as follows:

	2005	2004	2003
Net operating loss carryforwards	**$ 15,916,677**	$ 12,918,553	$ 8,484,151
Amortization of intangibles	**809,462**	944,783	1,032,968
Research & development credits	**2,115,222**	1,711,000	1,375,959
Stock option expense	**342,785**	210,094	
Other	**426,157**	123,398	96,347
	19,610,303	15,907,827	10,989,425
Valuation allowance	**(19,610,303)**	(15,907,827)	(10,989,425)
	$	$	$

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2005, the Company had approximately $42,163,382 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2011-2024. 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 $2,115,222 of research and development credits, which are available to reduce future income taxes, if any, through the year 2024.

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:

	2005	2004	2003
Tax at U.S. federal statutory rate	**$ (3,329,607)**	$ (4,145,591)	$ (2,085,774)
State taxes, net of federal benefit	**(313,659)**	(393,531)	(193,679)
Research and development credits	**(255,723)**	(208,454)	(232,559)
Change in valuation allowance	**3,702,476**	4,918,402	2,448,894

Other, net	**196,513**	(170,826)	63,118
	$	$	$

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7. CONVERTIBLE DEBENTURE

In September 2000, in connection with entering into a sub-license agreement, the Company issued a convertible debenture to Paladin Labs Inc. (Paladin) in the face amount of $500,000. The debenture did not bear interest and was due September 1, 2001, unless converted into shares of the Company s common stock. On August 13, 2001, the Company exercised its right and declared the debenture converted in full at a price of $10.50 per share. Accordingly, 47,619 shares of the Company s common stock were issued to Paladin. This was a non-cash financing transaction.

8. STOCKHOLDERS EQUITY

By articles of amendment dated July 20, 1999 (effective as of July 13, 1999), the subordinate voting shares of the Company were redesignated as common stock, the Class A special shares were reclassified as Class C special shares and the Class B special shares were eliminated. There were no changes in the number of shares outstanding.

On May 31, 2002, the Company effected a one-for-ten reverse split of its issued and outstanding shares of common stock and class C stock. All share and per share stock numbers in this Form 10-K have been adjusted to reflect the reverse stock split.

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, 2005.

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, 2005 and 2004.

Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share. There were 19,007,800 and 18,955,181 shares of common stock issued and outstanding as of December 31, 2005 and 2004, respectively.

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Significant Equity Transactions

Significant equity transactions since the date of the Company s incorporation are as follows:

Prior to the Amalgamation on December 6, 1996, the Company issued 2,000,000 shares of the Company s Class A stock for $0.001 per share, 415,000 shares of Class C stock for $0.001 per share and 410,000 shares of the Company s common stock for $10.00 per share.

Pursuant to the shareholders meeting to approve the arrangement held on November 27, 1996 and the subsequent filing of articles of arrangement on December 6, 1996, the Company completed the acquisition of 100% of the outstanding shares of SBI. Upon the effectiveness of this Amalgamation, the then existing stockholders of SBI received 743,432 shares of common stock of the Company (1 common share of the Company for every 35 shares of SBI). The deemed fair market value of this stock was $4,545,563.

In May 1998, the Company and Avi Ben-Abraham, M.D., a then director and a founder of the Company and the Company s then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. Effective May 21, 2002, Dr. Ben-Abraham chose not to stand for re-election as a director of the Company. Pursuant to the agreement, Dr. Ben-Abraham converted shares of the Company s Class A stock held by him into 1,500,000 shares of common stock at $2.50 per share for proceeds to the Company of $3,750,000. In addition, Dr. Ben-Abraham agreed to return to the Company 146,861 shares of Class A stock and 25,000 shares of Class C stock to the Company, and also agreed not to sell any of his shares of common stock or any other securities of the Company for a period of 15 months. The Company and Dr. Ben-Abraham agreed to cross-indemnify each other upon the occurrence of certain events.

In June 1998, the Company issued an aggregate of 200,000 shares of common stock pursuant to the conversion of Class A stock at a conversion price of $2.50 per share.

On May 6, 1999, the Company sold an aggregate of 2,312,500 common shares and warrants to purchase 1,156,250 shares of common stock at an exercise price of $3.00 per share to 31 accredited investors in a private placement, including several current members of the board of directors and one executive officer. Net proceeds to the Company from this private placement were approximately $4.2 million.

In August 1999, an outstanding liability of $25,000 was converted into 7,000 shares of common stock.

In July 2000, 19,007 shares of common stock were issued to certain corporate officers in lieu of a cash bonus.

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On April 4, 2001, the Company sold an aggregate of 925,000 common shares and warrants to purchase 462,500 shares of common stock at an exercise price of $5.00 per share to 48 accredited investors in a private placement, including several current members of the board of directors and five executive officers. Net proceeds to the Company from this private placement were approximately $3.7 million.

During the third quarter 2001, Paladin made a series of equity investments in the Company as result of certain sub-licensing transactions and the Company reaching certain milestones. These equity investments resulted in the Company issuing an additional 18,940 shares of its common stock to Paladin at a 10 percent premium to the Company s market price on the date of the transactions. The dollar value of the premium is recorded as licensing income in the statements of operations.

On August 7, 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of the Company s common stock with a market value of $125,000 at the date of the transaction.

In August 2001, 15,500 shares of common stock were issued to certain corporate officers in lieu of a cash bonus.

On August 13, 2001, the Company exercised its right and declared a convertible debenture in the face amount of $500,000 issued to Paladin Labs Inc. (Paladin) converted in full at a price of $10.50 per share. See Note 7. Accordingly, 47,619 shares of the Company s common stock were issued to Paladin.

On September 6, 2002, the Company sold an aggregate of 2,250,000 common shares in a best efforts self-underwritten offering to 39 accredited investors, including several current members of the board of directors and three executive officers. Net proceeds from this offering were approximately $4.4 million.

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(a development stage company)

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In June 2003, BioSante issued 119,613 shares of common stock to its officers and directors as partial payment of the officers 2002 annual bonus (approximately $79,000) and payment of fees to BioSante s directors for their significant involvement during 2002 and 2003 for director-related services rendered, including attendance at board and committee meetings (approximately $181,500). The 2002 officer bonuses of approximately $79,000 had been previously accrued at December 31, 2002. However, as BioSante had historically not paid fees to directors, the $181,500 of fees paid to directors was expensed in the three month period ended June 30, 2003. The number of shares issued was determined by dividing the dollar amount of bonus or director fees owed to the officer or director, respectively, by the closing market price of BioSante s common stock on the date of issuance. The share price used in computing the number of shares to issue was approximately $2.16. Shares were issued in lieu of cash in order to conserve the cash funds of BioSante.

On August 6, 2003, BioSante closed a private placement, raising approximately $10.3 million, ($9.6 million net of transaction costs) upon the issuance of units, which consisted of an aggregate of approximately 4.8 million shares of common stock and five-year warrants to purchase an aggregate of approximately 2.8 million shares of common stock (includes placement agent warrants issued in conjunction with the financing). The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $2.15. The exercise price of the warrants is $2.15 per share. The estimated fair value of the warrants issued to the placement agent represents a non cash financing activity.

In September 2003, BioSante issued 2,641 shares of common stock to its directors as payment of fees to BioSante s directors for their involvement during the third quarter ended September 30, 2003 for director-related services rendered, including attendance at board and committee meetings ($7,500). The number of shares issued was determined by dividing the dollar amount of director fees owed to the directors by the closing market price of BioSante s common stock on the date of issuance. The share price used in computing the number of shares issued was between $2.70 and $2.90. Shares were issued in lieu of cash in order to conserve the cash funds of BioSante.

In October 2003, 62,500 shares of common stock were issued pursuant to a conversion of class C special stock to common stock at a conversion price of $2.50 per share. Accordingly, BioSante raised $156,250 on the conversion.

In November 2003, BioSante issued 226 shares of common stock to certain directors as payment of fees to those certain BioSante directors for their involvement during the fourth quarter ended December 31, 2003 for director-related services rendered, including attendance at a committee meeting ($1,000).

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In December 2003, BioSante issued 744 shares of common stock to certain directors as payment of fees to BioSante s directors for their involvement during the fourth quarter ended December 31, 2003 for director-related services rendered, including attendance at a board meeting ($3,000).

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.

b) Warrants

The Company, upon the acquisition of SBI, assumed 257,713 exercisable warrants to purchase common stock, all of which expired prior to or as of December 31, 1998. Of this amount, 7,257 were exercised in 1997 prior to their expiration.

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 64,063 shares were exercised during 2004, warrants to purchase an aggregate of 31,250 shares were exercised during 2005 and warrants to purchase an aggregate of 367,187 shares remained outstanding and were exercisable as of December 31, 2005. These warrants will expire 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 2,038,694 shares were exercised during 2004, warrants to purchase an aggregate of 6,575 shares of common stock were exercised in 2005 and warrants to purchase an aggregate of 717,172 shares of common stock remained outstanding and were exercisable as of December 31, 2005.

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Pursuant to the Company s private placement financing in May 2004, warrants to purchase an aggregate of 92,646 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, 2005.

As described individually above, during 2005, warrants to purchase an aggregate of 31,250 shares of common stock were exercised for total cash proceeds of $156,250, and warrants to purchase an aggregate of 11,500 shares of common stock were exercised on a cashless basis resulting in the issuance of 6,575 shares of common stock, and the withholding of 4,925 shares of common stock to pay the exercise price of such warrants. The 4,925 shares of common stock withheld to pay the exercise price of the warrants were cancelled by the Company, and, as a result, reduced the number of outstanding shares of common stock on a fully diluted basis.

c) *Options*

In 2005, options to purchase an aggregate of 14,270 common stock were exercised for total cash proceeds of $41,518.

9. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 2,000,000 shares of common stock have been reserved for issuance. Options to purchase an aggregate of 1,425,530 shares of common stock have been granted as of December 31, 2005 under this plan at prices equal to either the ten-day weighted average closing price, or the closing bid price of the stock at the date of the grant, and are exercisable and vest in a range substantially over a three-year period. The options expire either in substantially five or ten years from the date of the grants.

The following table summarizes the Company s stock option activity:

2005	**Weighted Average Exercise Price**	**2004**	**Weighted Average Exercise Price**	**2003**	**Weighted Average Exercise Price**

Options outstanding, Beginning of period	**1,111,798**	$	3.25	1,237,634	$	3.13	997,300	$ 3.74
Options granted	**419,000**	$	3.79	61,000	$	5.63	307,000	$ 2.10
Options cancelled/expired	**(90,998)**	$	2.95	(44,166)	$	3.93	(66,666)	$ 7.60
Options exercised	**(14,270)**	$	2.91	(142,670)	$	3.01		$
Options outstanding, End of period	**1,425,530**	$	3.41	1,111,798	$	3.25	1,237,634	$ 3.13
Options exercisable, End of year	**881,530**	$	3.32	668,378	$	3.47	694,461	$ 3.29

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The following table summarizes information about stock options outstanding at December 31, 2005:

	Outstanding Options			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life	Weighted Avg. Exercise Price	Number Outstanding	Weighted Avg. Exercise Price
$2.10	285,000	7.4 years	$ 2.10	190,000	$ 2.10
$2.30 - $2.85	239,313	0.3 Years	$ 2.30	239,313	$ 2.30
$3.34 - $4.84	740,717	8.0 years	$ 3.72	309,717	$ 3.62
$5.30 - $7.60	160,500	6.0 years	$ 6.02	142,500	$ 6.03
	1,425,530			881,530	

During the second quarter 2003, BioSante issued option to purchase an aggregate of 285,000 shares of common stock to certain officers of BioSante which vested only upon the achievement of certain milestones in connection with BioSante s evaluation of strategic alternatives. In March 2004, the vesting period related to these options was amended whereby the options now vest over a three year period from the date of grant. As a result of the amended option terms, $351,500 and $556,541 was recognized as non-cash, stock-based compensation expense during 2005 and 2004 respectively, and $146,459 will be recognized over the remaining vesting period.

10. 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 2005, 2004 and 2003 totaled $71,188, $62,701, and $60,005 respectively.

11. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space and laboratory facilities which were extended in 2005 and expire in 2007. The future minimum lease payments during 2006 and 2007 are $208,866 and $35,977, respectively.

Rent expense amounted to $219,516, $218,545, and $147,088 for the years ended December 31, 2005, 2004 and 2003, respectively.

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12. RELATED PARTY TRANSACTIONS

Included in current liabilities are $29,398, $10,231 and $16,184, which represent amounts due to current directors and officers of the Company as of December 31, 2005, 2004 and 2003, respectively.

Prior to the Amalgamation on December 6, 1996, the Company issued 2,000,000 shares of class A stock and 415,000 shares of class C stock for $0.001 per share. 1,700,000 of the class A shares were sold to a director of the Company. 105,000 of the class C shares were sold to the same director of the Company to be held by him in trust for the benefit of others; 50,000 of the class C shares were sold to a separate company controlled by a then officer of the Company; and 200,000 of the class C shares were sold to other directors of the Company.

The 2,000,000 class A shares and 415,000 class C shares were founder s shares and the terms under the authorization of these shares, provided for their conversion to common stock at $2.50 per share.

In May 1998, the Company and Avi Ben-Abraham, M.D., a then director and a founder of the Company and the Company s then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. See Note 8.

In connection with the May 1999 private placement of 2,312,500 shares of common stock and warrants to purchase 1,156,250 shares of common stock, the Company s Chief Executive Officer purchased 25,000 shares of the common stock sold and warrants to purchase 12,500 shares of common stock. Three other individuals, who purchased either individually or through affiliated entities, an aggregate 1,025,000 shares of common stock and warrants to purchase 512,500 shares of common stock, became directors of the Company upon their acquisition of the shares or sometime later.

In connection with the April 2001 private placement of 925,000 shares of common stock and warrants to purchase 462,500 shares of common stock, the Company s Chief Executive Officer, Chief Financial Officer and other senior officers purchased an aggregate of 52,875 shares of the common stock sold and warrants to purchase 26,437 shares of common stock. Three directors, either individually or through affiliated entities, purchased an aggregate 312,500 shares of common stock and warrants to purchase 156,250 shares of common stock.

In connection with the September 2002 best-efforts, self-underwritten offering of 2,250,000 shares of common stock, the Company s Vice President of Clinical Development, Chief Executive Officer and Chief Financial Officer purchased an aggregate of 164,701 shares of the common stock sold. Three directors, either individually or through affiliated entities, purchased an aggregate 453,504 shares of common stock.

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In connection with the August 2003 best-efforts offering of 4,791,982 shares of common stock, the Company s Vice President of Clinical Development, Chief Executive Officer and Chief Financial Officer purchased an aggregate of 3,000 shares of the common stock sold. Three directors, either individually or through affiliated entities, purchased an aggregate 736,023 shares of common stock.

In January 2001, BioSante entered into a consulting agreement with Scientific Research Development Corporation, a company owned and operated by Ronald B. McCright, Ph.D., the husband of Leah M. Lehman, Ph.D., a former executive officer of BioSante. Under the agreement, Scientific Research Development Corporation provided the Company with database and statistical programming, database management, medical writing and project management services. In consideration for such services, $0, $12,870 and $103,035 are included in research and development expenses for the years ended December 31, 2005, 2004 and 2003, respectively.

13. COMMITMENTS AND CONTINGENCIES

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

University of California License

The Company s license agreement with the University of California as amended most recently in June 2004, requires the Company to undertake various obligations, including:

Payment of royalties to the University based on a percentage of the net sales of any products incorporating the licensed technology;

Payment of minimum annual royalties beginning for the year 2005 to be paid by February 28 of the following year in the amounts set forth below, to be credited against any earned royalties, for the life of the agreement;

Year		Minimum Annual Royalty Due	Due Date
2005	$	50,000	February 28, 2006
2006		75,000	February 28, 2007
2007		100,000	February 28, 2008
2008		200,000	February 28, 2009
2009		300,000	February 28, 2010
2010		400,000	February 28, 2011
2011		750,000	February 28, 2012
2012		750,000	February 28, 2013
2013		750,000	February 28, 2014
Total	$	3,375,000	

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Minimum royalties of $50,000 were accrued for the year ended December 31, 2005. Under the terms of the license agreement with the University of California, BioSante has the right to terminate the license at any time.

Development of products incorporating the licensed technology until a product is introduced to the market;

Payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which for the years ended December 31, 2005, 2004 and 2003 amounted to $13,491, $13,404, and$15,371, respectively;

Meeting performance milestones relating to:

Hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;

Testing proposed products and obtaining government approvals;

Conducting clinical trials; and

Introducing products incorporating the licensed technology into the market;

Indemnifying, holding harmless and defending the University of California and its affiliates, as designated in the license agreement, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from or arising out of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability related to this obligation as no events occurred that would require indemnification.

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.

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Wake Forest License

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

Future minimum payments due under this agreement are as follows:

Year	Minimum Amount Due
2006	10,000
2007	30,000
2008	30,000
2009	60,000
2010	70,000
2011	80,000
2012	80,000
2013	80,000
2014	80,000
Thereafter	200,000

$10,000 of the 2006 minimum payment and $3,125 of the 2007 minimum payment was accrued during 2005. 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.

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14. SUBSEQUENT EVENTS

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

Pending Claims

On November 30, 2005, the Company sent written notice to Leah M. Lehman, Ph.D., the Company s former Vice President, Product Development, that the Company was exercising its contractual right not to renew her employment agreement. As a result of this notice, Dr. Lehman s employment agreement expired by its terms on December 31, 2005. On February 15, 2006, the Company received notice that on February 10, 2006, Dr. Lehman had filed a complaint against the Company, the Company s President and Chief Executive Officer, the Company s Chief Financial Officer and one of the Company s directors, with the Occupational Safety and Health Administration under the Sarbanes-Oxley Act of 2002 seeking reinstatement of her employment with back pay, interest and attorney s fees and claiming, among other things, wrongful termination. The Company believes that Dr. Lehman s allegations of wrongful termination and violations of the Sarbanes-Oxley Act are wholly without merit and intends to vigorously defend its position. On February 17, 2006, the Company filed a complaint against Dr. Lehman in the Circuit Court of Cook County, Illinois alleging breach of fiduciary duty, breach of contract in regard to her employment agreement with the Company, tortious interference with prospective economic advantage and abuse of process. The Company is seeking an unspecified amount of damages, punitive damages, declaratory judgment regarding a breach by Dr. Lehman of her employment agreement and the amount of severance pay, if any, to be owed to Dr. Lehman, reimbursement of the Company s legal fees and costs and such other relief as the Court may deem proper. In March 2006, Dr. Lehman filed a charge with the Equal

Employment Opportunity Commission claiming sex discrimination and retaliation in violation of Title VII of the Civil Rights Act of 1964. The Company also believes that Dr. Lehman s charges with the EEOC are wholly without merit and intends to vigorously defend its position.

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The Company has accrued $750,000 in connection with this matter. Although the Company believes that a portion of any liability resulting from this matter may be covered under its employment practices liability insurance policy, there can be no assurance that it will be so covered or that the ultimate resolution of this matter will not exceed the amount of the Company s accrual or will not otherwise result in a material adverse effect on the Company s business, financial condition or results of operations.

15. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Selected quarterly data for 2005 and 2004 is as follows:

	2004			
	First	**Second**	**Third**	**Fourth**
Revenue	$ 7,316	$ 4,976	$ 10,762	$ 54,832
Research and development expenses	1,456,523	1,865,749	2,450,486	3,389,681
General and administrative expenses	1,000,011	743,244	488,298	848,582
Operating loss	(2,472,501)	(2,629,757)	(2,954,219)	(4,210,154)
Net loss available to common shareholders	(2,445,231)	(2,574,158)	(2,869,635)	(4,127,183)
Loss per share available to common shareholders				
Basic and Diluted	$ (0.17)	$ (0.15)	$ (0.16)	$ (0.22)

	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)

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, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required under Item 10 of this report is to be contained under the captions Election of Directors Information About Nominees, Election of Directors Other Information About Board Nominees, Election of Directors 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.

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

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

The information required under Item 12 of this report is to be contained under the caption Security Ownership of Principal Stockholders and Management in our definitive proxy statement to be filed with the SEC with respect to our next annual meeting of stockholders, which involves the election of directors and is incorporated herein by reference, or, if such proxy statement is not filed with the SEC within 120 days after the end of the fiscal year covered by this report, such information will be filed as part of an amendment to this report not later than the end of the 120-day period.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes outstanding options under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan as of December 31, 2005. 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	1,425,530	$	3.41	417,530
Equity compensation plans not approved by security holders	0		N/A	0
Total	1,425,530	$	3.41	417,530

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, 2005 and December 31, 2005. As of January 1, 2005, the number of securities to be issued upon exercise of outstanding options, warrants and rights were 1,111,798 shares at a weighted average exercise price of $3.25. 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 636,134 shares. This information as of December 31, 2005 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.

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

Item 15. **EXHIBITS, FINANCIAL STATEMENTS, SCHEDULES**

The exhibits to this report are listed on the Exhibit Index on pages 84-89. 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. BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan (incorporated by reference to Exhibit 10.1 to BioSante s Quarterly Report on Form 10-QSB (File No. 0 28637)).

B. 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. 0-28637)).

C. 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 as filed on March 28, 2002 (File No. 0-28637)).

D. 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 as filed on March 26, 2004 (File No. 1-31812)).

E. 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 as filed on March 26, 2004 (File No. 1-31812)).

F. 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. 0-28637)).

G. Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended (filed herewith).

H. Employment Agreement, dated December 15, 2000, between BioSante Pharmaceuticals, Inc. and Leah Lehman, Ph.D. (incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB as filed on March 30, 2001 (File No. 0-28637)).

I. Employment Agreement, dated October 1, 2000, between BioSante Pharmaceuticals, Inc. and Steven J. Bell, Ph.D. (incorporated by reference to Exhibit 10.22 to BioSante s Annual Report on Form 10-KSB as filed on March 28, 2002 (File No. 0-28637)).

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

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

SIGNATURES

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

Dated: March 31, 2006

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 31, 2006 by the following persons on behalf of the registrant and in the capacities indicated.

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

BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2005

Exhibit No.	Exhibit	Method of Filing
2.1	Arrangement Agreement, dated October 23, 1996, between Structured Biologicals Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 2.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
3.1	Amended and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 contained in BioSante s Registration Statement on Form SB-2, as amended, (Reg. No. 333-64218)
3.2	Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.2 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218)
4.1	Form of Warrant issued in connection with April 2001 Private Placement	Incorporated by reference to Exhibit 4.2 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218)
4.2	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, filed on August 6, 2003 (File No. 0-28637)
10.1	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)

10.2	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)
10.3	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 contained in BioSante s 10-QSB filed on August 14, 2003 (File 0-28637)
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	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)
10.6	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)
10.7	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	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Incorporated by reference to Exhibit 10.10 contained in BioSante s Annual Report on Form 10-KSB filed on March 25, 2005 (File No. 001-31812)

10.9	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)
10.10	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 on July 11, 2000 (File No. 0-28637)
10.11	Employment Agreement, dated December 15, 2000, between BioSante Pharmaceuticals, Inc. and Leah Lehman, Ph.D.	Incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB filed on March 30, 2001 (File No. 0-28637)
10.12	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)
10.13	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 10.18 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.14	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 10.19 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.15	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 10.20 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)

10.16	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma 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)
10.17	Employment Agreement, dated October 1, 2000, between BioSante Pharmaceuticals, Inc. and Steven J. Bell, Ph.D.	Incorporated by reference to Exhibit 10.22 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (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, filed on March 28, 2002 (File No. 0-28637)
10.19	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma and BioSante Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 10.25 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.20	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)
10.21	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-K, filed on August 6, 2003 (File No. 0-28637)
10.22	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 filed on March, 26 2004 (file No. 1-31812)

10.23	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 filed on March, 26 2004 (file No. 1-31812)
10.24	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 filed on March, 26 2004 (file No. 1-31812)
10.25	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 filed on March, 26 2004 (file No. 1-31812)
10.26	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 filed on May 17, 2004 (file No. 1-31812)
10.27	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 filed on August 16, 2004 (File No. 1-31812)
10.28	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 filed with the SEC on September 1, 2004 (File No. 1-31812)
10.29	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 filed with the SEC on May 12, 2004 (File No. 1-31812)

10.30	Form of Warrant issued by BioSante Pharmaceuticals, Inc. to each of the subscribers party to the Subscription Agreements and the placement agents	Incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on May 14, 2004 (File No. 1-31812)
10.31	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 filed on February 1, 2006 (File No. 1-31812)
10.32	Description of Non-Employee Director Compensation Arrangements	Filed herewith
10.33	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 filed on March, 26 2004 (file No. 1-31812)
23.1	Consent of Deloitte & Touche LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Furnished herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Furnished herewith
32.1	Certification of Chief Executive Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.2	Certification of Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith

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