BIOSANTE PHARMACEUTICALS INC
Form 10KSB
March 26, 2004

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

FORM 10-KSB

(Mark one)

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

For the fiscal year ended December 31, 2003

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 000-28637

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

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has

been subject to such filing requirements for the past 90 days. YES x NO o

Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. o

The issuer s revenues for the fiscal year ended December 31, 2003 were $65,494.

As of March 15, 2004, 14,309,786 shares of common stock of the registrant were outstanding, and the aggregate market value of the common stock of the registrant as of that date (based upon the last reported sale price of the common stock on that date as reported by the American Stock Exchange), excluding outstanding shares beneficially owned by directors and executive officers, was $51,276,768.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-KSB incorporates by reference information (to the extent specific sections are referred to herein) from the registrant s Proxy Statement for its 2004 Annual Meeting of Stockholders to be held June 22, 2004.

Transitional Small Business Disclosure Format (check one): YES o NO x

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PART I

This Form 10-KSB contains forward-looking statements. For this purpose, any statements contained in this Form 10-KSB 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, pred 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 Form 10-KSB, references to BioSante, the company, we, our or us, unless the context otherwi requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

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, for vaccine adjuvants or immune system boosters, drug delivery systems and the purification of the milk of transgenic animals.

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., 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 we in-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), combinations of estradiol and testosterone and estradiol and progestogen (another female hormone). 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 in development:

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

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

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

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

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

Our CAP technology, a portion of which 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 adjuvants or immune system boosters, for drug delivery and to purify the milk of transgenic animals. We have identified three 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 and allow for delivery of the vaccine via non-injectable routes of administration;

the creation of oral and inhaled forms of drugs that currently must be given by injection (*e.g.*, insulin); and

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

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, viral and bacterial infections and autoimmune diseases, among others including biodefense vaccines such as anthrax and ricin.

CAP-Oral a delivery system using CAP technology for oral 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.

CAP biotechnology production use of CAP technology in a new patented process for purifying the milk of transgenic animals in order to extract therapeutic proteins.

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.

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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. Human clinical trials have begun on four of our proposed hormone therapy products, a necessary step in the process of obtaining approval from the U.S. Food and Drug Administration, or FDA, to market the products. Our proposed Bio-E-Gel product is currently in a pivotal Phase III clinical trial. Our proposed LibiGel product is in a Phase II clinical trial. Our proposed Bio-T-Gel is also currently in a clinical trial.

Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sublicenses. We are seeking opportunities to enter into 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, transgenic milk 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 which we otherwise would be able. In addition, these collaborations have and will significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology.

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies. We intend to seek 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 a full portfolio in development.

Description of Our Hormone Therapy Products

We are focused on building a pipeline of hormone therapy products to treat hormone deficiencies in men and women. Our hormone therapy products are gel formulations of bioidentical testosterone (the natural

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male hormone), bioidentical estradiol (the natural female hormone), a combination of bioidentical estradiol and bioidentical testosterone and a combination of bioidentical estradiol and a progestogen (another female hormone). 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, 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 hormone dermal 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;

- adding progestogen to estrogen may reduce the potential risks of endometrial cancer and endometrial hyperplasia of estrogen therapy alone when the uterus is intact;

- 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 dermal patches or oral tablets or capsules; and

- clinical trials involving the hormone products are expected to be relatively small requiring fewer patients than most drug development projects, which should keep our costs, time and risks associated with the FDA approval process at a comparatively lower level.

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The following table provides an overview of the status of our hormone therapy products in development:

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.

Prior to 2000, testosterone often was delivered through injections or transdermal, or skin, patches. 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, have a physical presence and have been associated with skin irritation. Our testosterone formulated gel product for men, Bio-T-Gel, is 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 several in development.

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 most common physical symptoms of natural or surgical menopause and the resultant estrogen deficiency, are hot flashes, vaginal atrophy, decreased libido and osteoporosis. Hormone therapy in women decreases the chance that women will experience the symptoms of menopause due to estrogen deficiency. According to industry estimates, approximately

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10 million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy.

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 and blood clots. Although transdermal patches have been shown to avoid some of these problems, delivery of estrogen through transdermal patches, similar to testosterone patches have a physical presence and can result in skin irritation. Our estrogen formulated gel product, Bio-E-Gel, is designed to deliver estrogen without the skin irritation associated with, and the physical presence of, transdermal patches. Also, Bio-E-Gel contains bioidentical estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen.

We also are developing a testosterone formulated gel product for women, LibiGel. 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 (about 40 million) experience some degree of impaired sexual function. Among the more than 1,400 women surveyed, 32 percent lacked interest in sex and 26 percent could not experience orgasm. The majority of women with FSD are postmenopausal, experiencing FSD due to hormonal changes following menopause, whether natural or surgical.

In addition to LibiGel, we are developing a combination gel product of testosterone and estradiol, LibiGel-E/T, for the treatment of FSD in menopausal women.

Through a sublicense agreement with Solvay Pharmaceuticals, B.V., Bio-E/P-Gel, a combined estrogen/progestogen gel product, is in development. Women whose uteri are intact often use a combined hormone therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial cancer and endometrial hyperplasia associated with estrogen-alone therapy in 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 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. Both the estrogen and progestogen components of Prempro are different chemical entities than those used in our proposed gel, Bio-E/P-Gel, and the means of delivery into the system are significantly different. Prempro is an oral tablet formulation consisting of conjugated equine estrogen and medroxyprogesterone acetate as active ingredients. Our proposed Bio-E/P-Gel is a gel delivery system containing estradiol, which is identical to the estrogen produced naturally by a woman s ovaries, and progestogen, different than the type of progestogen in Prempro. The WHI study results do not necessarily apply to estrogen and progestogen administered through the transdermal route and to different hormones that may provide a different risk-benefit profile. In addition, the intended use for Bio-E/P-Gel is no more than two years.

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., under which we collaborate with Teva USA on the development of one of our hormone therapy products for the U.S. market. Teva USA also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

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Our strategy with respect to our hormone therapy products is to conduct human clinical trials, which are required to obtain approval from the U.S. Food and Drug Administration and to market the products in the United States. Human clinical trials have begun on four of our hormone therapy products.

We have completed a Phase II/III clinical trial of Bio-E-Gel. The trial, conducted in the United States and Canada, was a double-blind placebo-controlled study of 161 patients. The data from the Phase II/III Bio-E-Gel clinical trial have been analyzed. The objective of the Phase II/III clinical trial was to identify an effective dose of Bio-E-Gel to study in Phase III development. The Phase II/III trial demonstrated that Bio-E-Gel successfully delivers therapeutic doses of bioidentical estradiol and statistically significantly reduces the frequency and severity of moderate-to-severe hot flashes in menopausal women.

Current FDA requirements for approval of new estradiol products include one 12-week Phase III clinical trial. In October 2003, we initiated the Phase III Bio-E-Gel clinical trial for the treatment of moderate-to-severe hot flashes and vaginal atrophy in menopausal women. The Bio-E-Gel Phase III clinical trial tests two doses of Bio-E-Gel to maximize the safety profile by identifying the lowest effective dose. The Phase III trial is being conducted in the United States and Canada and is a randomized, double-blind, placebo-controlled study of symptomatic menopausal women. The clinical endpoints of the required Phase III trial include a significant reduction in the severity and frequency of hot flashes at week 4 and week 12 of treatment as compared to placebo.

We have initiated a Phase II clinical trial of our LibiGel. The Phase II trial, being conducted in the United States, is a double-blind, placebo-controlled study to determine the effect of LibiGel on a women s sexual desire and activity. In October 2003, we announced that the ongoing Phase II trial of LibiGel (topical testosterone gel) for the treatment of female sexual dysfunction (FSD) showed statistically significant results for the primary endpoints of the study. In the U.S.-based, double-blind, placebo-controlled study to determine the effect of LibiGel on women s sexual activity and desire, after three months of treatment there was a 130 percent increase from baseline ($p<0.01$) in the frequency of satisfying sexual events as measured by individual patient diaries. In addition, there was a 136 percent increase from baseline ($p<0.01$) in sexual desire as measured by the Brief Index of Sexual Functioning for Women (BISF-W). The interim analysis reports on the first 28 patients who have completed the study, without breaking the blind as to dose of LibiGel or placebo. The data indicate an effective LibiGel dose for the treatment of hypoactive sexual desire disorder (HSDD) in women, and that LibiGel was well tolerated during the course of the trial.

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 set up under an agreement dated April 6, 1989 between the University of California and one of our predecessor companies, Structured Biologicals, relating to viral protein surface absorption studies. The discovery research was funded by Structured Biologicals 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 has resulted in the issuance of a number of patents, which we either license from the University of California or own.

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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 1,000 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 by applying a layer of a bonding coating of cellobiose or another carbohydrate derivative. 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;
- the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays or through inhalation, 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 the development of:

- vaccine adjuvants and non-injected vaccines;
- drug delivery systems, including a method of delivering proteins (*e.g.*, insulin) orally, through inhalation and subcutaneous routes of administration; and
- the purification of the milk of transgenic animals.

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Our pre-clinical research team in our laboratory in Smyrna, Georgia is currently pursuing the development of our CAP technology in all three of these areas.

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 orally or 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. 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, including proteins (*e.g.*, insulin). The attachment of drugs to CAP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We have shown pre-clinical efficacy in the oral delivery of insulin in normal and diabetic mouse models. In the oral insulin mouse models in fasted mice, our proposed product, which we call CAP-Oral, 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 CAP-Oral and BioAir. Our research and development efforts in these areas are ongoing testing insulin and other drugs that must now be given by injection.

Transgenic Milk Purification. The third field of use in which we are exploring applying our CAP technology is in the purification of the milk of transgenic animals in which protein drugs are grown. This

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is achieved by selectively isolating biologically active therapeutic proteins from the milk of transgenic animals. This method uses our CAP technology to recover greater than 90 percent of drug protein from the milk in a way that may require less downstream processing and may produce higher overall yields at lower cost than currently used methods. Our method dissolves casein clusters, thereby freeing the drug proteins, and then reforms the casein clusters using CAP as the core. Caseins are then removed from the milk, leaving high concentrations of the drug protein in the remaining crystal clear whey fraction.

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, viral and bacterial infections and autoimmune diseases, among others including biodefense vaccines such as anthrax and ricin.

CAP-Oral a delivery system using CAP technology for oral 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.

CAP biotechnology production use of CAP technology in a new patented process for purifying the milk of transgenic animals in order to extract therapeutic proteins.

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.

We also have conducted preclinical studies of our BioAir CAP 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 three 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 co-development and co-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.

Our outlicensing activities with respect to our vaccine adjuvant, 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 adjuvant 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 hope to negotiate an out-license agreement with the target company.

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

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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 Alhydrogel as the vaccine adjuvant. The subcontract is in support of the U.S. Department of Defense Joint Vaccine Acquisition Program.

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.

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.

In January 2003, we announced the signing of a CRADA with the U.S. Navy s Naval Medical Research Center s (NMRC) Malaria Program for the development of a malaria vaccine. The development agreement leverages our expertise with NMRC s expertise to develop an enhanced vaccine for malaria. Under the agreement, we provide the NMRC with BioVant, our proprietary vaccine adjuvant and delivery system, and the NMRC provides DNA plasmids or proteins encoding antigens for *Plasmodium spp*., the parasite that causes malaria. It is hoped that the resulting DNA vaccine will improve the effectiveness of the ensuing humoral and cell-mediated immunity against malaria and therefore be more effective as it activates both arms of the immune system.

In October 2001, we licensed BioVant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay us milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sublicenses vaccines that include BioVant, we will share in milestone payments and royalties received by Corixa. The license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

Sales and Marketing

We currently have no sales and marketing personnel to sell on a commercial basis any of our proposed products. Under our agreements with Solvay and Teva, Solvay and Teva 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 agreements with Solvay and Teva, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner to assist us with this function. In addition, we retain co-promotion rights for Bio-E/P-Gel, the product in the Solvay agreement.

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately $3,691,000 in 2003 and $4,787,000 in 2002 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 have been spending approximately $300,000 to $400,000 per month on research and development activities. These expenditures, however, may fluctuate from quarter-to-quarter and year-to-

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year depending upon the resources available and our development schedule. Results of preclinical studies, clinical trials, regulatory decisions and competitive developments may significantly influence the amount of our research and development expenditures. In addition, we expect that our spending on product development will increase if we are successful at in-licensing or otherwise acquiring other late-stage development products, which in-licensing or acquisitions are currently a low priority.

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 Good Manufacturing Practices, or GMP, 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 through a U.S.-based GMP 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 for the treatment of testosterone deficiency in men and women and estrogen deficiency in women, 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 patent applications for this licensed technology in the U.S. and several foreign jurisdictions, including Argentina, Australia, Canada, Europe, Italy, Japan, Korea, New Zealand, South Africa, and Taiwan.

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 sell incorporating the licensed technology;

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develop the hormone product portfolio, including:

- Ø testing proposed products;
- Ø conducting clinical trials;
- Ø obtaining government approvals;
- Ø 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 is responsible for all costs of development and marketing of the product. We have retained co-promotion rights to the product and will be compensated for sales generated by us over and above those attributable to Solvay s marketing efforts. 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 female 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 an option for triple hormone contraception. The financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if the product 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., under which we collaborate with Teva USA on the development of a hormone therapy 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 also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the

product.

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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 University of California has 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 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 $15,371 in fiscal 2003;

meeting performance milestones relating to:

- Ø hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;
- Ø testing proposed products;
- Ø conducting clinical trials;
- Ø obtaining government approvals;
- Ø 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.

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Patents and patent applications. We own two United States patents and no foreign patents. In June 1999, we filed a patent application for our advanced method of selectively isolating biologically active therapeutic proteins from transgenic milk. This patent issued in February 2001. In February 2000, we filed a patent application with the U.S. Patent and Trademark Office relating to our development work with CAP, including its applications as a vaccine adjuvant, as a carrier for biologically active material and as part of a controlled release matrices for biologically active material. A patent directed to methods of formulating the CAP particles issued in March 2002. In addition, we have other patent applications pending in the U.S. and internationally for products in development.

Trademarks and trademark applications. We have filed trademark applications in the U.S. for the mark BIOSANTE for vaccines and vaccine adjuvants and for our proposed hormone therapy products. The BIOSANTE mark is registered for the hormone preparations. The application for vaccines and vaccine adjuvants has been allowed for registration and will register upon submission of proof of use. We have also filed U.S. trademark applications and received Notices of Allowance for the marks BIOVANT, BIOAIR, NANOVANT and LIBIGEL. Two other U.S. trademark applications are pending for BIO-E-GEL and BIO-T-GEL for products in development. The BIOSANTE mark is also registered in the European Union and Israel, BIOAIR is registered in the European Union and Israel, BIOVANT is registered in Israel and Mexico, NANOVANT is registered in the European Union, Israel and Mexico, and BIO-E-GEL and BIO-T-GEL are registered in Mexico. There are 10 other applications pending in the European Union, Canada and Mexico for these marks. We do not have any other registered trademarks.

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.

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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.

We are aware of certain programs and products under development by others that may compete with our proposed hormone therapy products and products we may develop that incorporate our CAP technology. Several competing companies, including Wyeth Pharmaceuticals, Novartis AG, Solvay Pharmaceuticals, Inc., Noven Pharmaceuticals, Inc. and Berlex Laboratories, Inc., dominate the international hormone therapy industry. 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.

There are several firms currently marketing or developing transdermal hormone therapy products. They include The Proctor & Gamble Company, Noven Pharmaceuticals, Inc., Novavax, Inc., Cellegy Pharmaceuticals, Inc., Auxilium, Inc., Watson Pharmaceuticals Inc. and Solvay Pharmaceuticals, Inc.

With regard to our CAP technology, 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. Competitive or comparable companies to us include Corixa Corporation, generally regarded as a leader in vaccine adjuvant development and ID Biomedical Corporation, which both develop sub-unit vaccines from mycobacteria and other organisms.

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.

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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 usually include from 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 12 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,

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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 GMP regulations, which govern the production of pharmaceutical products. We currently do not have 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 GMP 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 thirteen full-time employees and one part-time employee as of December 31, 2003, including ten in research and development and four in management or administrative positions. None of our employees is covered by a collective bargaining agreement.

Forward-Looking Statements

This Annual Report on Form 10-KSB 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. 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. Statements that are not historical are forward-looking and reflect expectations and assumptions. We try to identify forward-looking statements in this report and elsewhere by using words such as may, will, should, expects, anticipates, contemplates, estimates, believes, plans, predicts, potential or continue or the negative of these or similar terms. Our forward-looking statements generally relate to:

- our substantial and continuing losses;
- 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;
- our existing cash and whether and how long these funds will be sufficient to fund our operations; and
- our need to raise additional capital through future equity and other financings.

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Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to BioSante. Below are 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.

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 above, as well as others that we may consider immaterial or do not anticipate at this time. The foregoing risks and uncertainties are not exclusive and further information concerning the company 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-QSB and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

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 $5,959,354 for the year ended December 31, 2003, and as of December 31, 2003, our accumulated deficit was $28,021,077.

All of our revenue to date has been derived from up front and milestone payments earned on sub-licensing transactions. 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; and

the timing and cost of obtaining third party reimbursement.

In order to generate 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 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

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in the future. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our own product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business.

Our cash on hand as of December 31, 2003 was $9,134,327. We believe this cash will be sufficient to fund our operations through December 2004. We have based this estimate on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. We currently do not have sufficient resources to complete the commercialization of any of our proposed products. 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 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;

the lack of manufacturing experience and limited marketing 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; 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.

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

Our proposed products are in the research and development stages and will require further research and development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. 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;

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; or

be successfully marketed.

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed, 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.

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, pre-clinical studies on animals and clinical trials on humans on each 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. Adverse or inconclusive human clinical results

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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;

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.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the trading price of our shares.

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. At the same time, estrogen alone did not appear to increase the risk of breast cancer. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture. Preliminary data from the memory study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

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 will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we currently are developing or will develop.

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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.

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 our business.

We have licensed two of our proposed hormone therapy product to third parties that have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. 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 our business if we are unable to license the proposed products to another party on substantially the same or better terms or continue the work 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 will likely 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 and in the course of our development program, we will likely be required to enter into additional arrangements with other companies or universities or clinical investigators for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If our licensees breach their obligations under our license agreements to perform these functions or we are otherwise unable to retain third parties for these purposes on acceptable terms, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by 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 third parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

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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. In February 2000, we filed a patent application relating to our CAP technology. However, our owned and licensed patents and patent applications will not ensure the protection of our intellectual property for a number of other reasons:

We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease before others have developed similar methods.

Competitors may interfere with our 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 contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

We are in the research and 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 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 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. 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.

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

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States until the patents are issued and also are maintained in secrecy for a period of time outside the United States. Accordingly, we can conduct only limited searches to determine whether our technology infringes any patents or patent applications of others. Any claims of patent infringement 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.

Item 2. DESCRIPTION OF PROPERTY

Our principal executive office is 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. This lease, as amended, will expire in March 2005. Our CAP research and 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 2004. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

Item 3. LEGAL PROCEEDINGS

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

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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, 2003.

Item 4A. EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers, their ages and the offices held, as of March 20, 2004, are as follows:

Name	Age	Title
Stephen M. Simes	52	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	43	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	42	Vice President, Clinical and Regulatory Affairs
Steven J. Bell, Ph.D.	44	Vice President, Research and Pre-Clinical Development

Information regarding the business experience of the 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., 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.

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. from January 1995 to July 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc., Applied NeuroSolutions, Inc. (formerly Molecular Geriatrics Corporation) and Xtramedics, Inc.

Leah M. Lehman, Ph.D. has served as our Vice President, Clinical and Regulatory Affairs since March 2004 and was our Vice President, Clinical Development from January 2001 to March 2004. Prior to joining our company, Dr. Lehman was Director of Clinical Research with Scientific Research Development Corp., a research consulting company, from April 1995 to December 2000. From 1993 to 1995, Dr. Lehman was a clinical statistician at Abbott Laboratories.

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.

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PART II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Price

Our common stock is listed for trading on the American Stock Exchange, under the symbol BPA. From June 1, 2002 to September 30, 2003, our common stock was quoted on the Over-the-Counter Bulletin Board under the symbol BISP and under the symbol BTPH from May 5, 2000 to May 31, 2002. From December 20, 1996 to July 20, 2001, our common stock traded in Canada on the Canadian Venture Exchange, formerly known as the Alberta Stock Exchange, under the symbol BAI.

The following table sets forth, in dollars and cents (in lieu of fractions), the high and low sales prices for our common stock, as reported by the American Stock Exchange, for the one calendar quarter on which our common stock was listed for trading during 2003.

American Stock Exchange

2003	High	Low
Fourth Quarter	$4.50	$3.20

The following table sets forth, in dollars and cents (in lieu of fractions), the high and low sales prices, as reported by the Over-the-Counter Bulletin Board, for each of the calendar quarters indicated on which our common stock was quoted during 2003 and 2002. The prices in the table may not represent actual transactions. These quotations reflect inter-dealer prices, without retail mark up, mark down or commissions and may not represent actual transactions. On May 31, 2002, we effected a one-for-ten reverse split of our issued and outstanding shares of common stock and class C special stock. All per share numbers in the following tables have been adjusted to reflect the reverse split.

OTC Bulletin Board

2003	High	Low
First Quarter	$3.60	$1.65
Second Quarter	$3.10	$1.85
Third Quarter	$3.10	$2.45
2002	**High**	**Low**
First Quarter	$7.90	$5.10
Second Quarter	$7.00	$3.60
Third Quarter	$5.25	$3.35
Fourth Quarter	$3.75	$1.91

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Number of Record Holders; Dividends

As of March 3, 2004, there were 207 record holders of our common stock and nine 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.

Previous Sales of Unregistered Securities

During the fourth quarter ended December 31, 2003, we did not issue any securities without registration under the Securities Act.

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Item 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN 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-KSB. 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 nano technology, or CAP, for vaccine adjuvants, drug delivery systems and the purification of the milk of transgenic animals.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions. We have not commercially introduced any products and do not expect to do in the near future.

Our business operations consist mostly of research and development activities. We spent approximately $300,000 to $400,000 per month on research and development activities in 2003 and expect our research and development expenses to increase in 2004 based on our planned clinical development schedule. 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; (3) results of studies, clinical trials and regulatory decisions; and (4) 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.

Since our inception, we have experienced significant operating losses. We incurred a net loss of $5,959,354 for the year ended December 31, 2003, resulting in an accumulated deficit of $28,021,077. 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; and
- the timing and cost of obtaining third party reimbursement.

Hormone Therapy Products. Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. The products we in-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), a combination of estradiol and testosterone and a combination of estradiol and progestogen (another female hormone). Human clinical

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trials have begun on four of our hormone therapy products, which are required to obtain FDA approval to market the products. Our proposed Bio-E-Gel product is currently in a pivotal Phase III clinical trial. Our proposed LibiGel product is in a Phase II clinical trial. Our proposed Bio-T-Gel product also is currently in a clinical trial.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sublicenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Indonesia, Malaysia, Australia, New Zealand, China and South Africa. 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 the 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, after all necessary regulatory approvals are received, pay royalties to Antares on sales of the products.

In a series of amendments executed during 2001 between BioSante and Antares, we returned to Antares the license rights to one of four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, we 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 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 for all countries described above.

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 is responsible for all costs of development and marketing of the product. We have retained co-promotion rights to the product and will be compensated for sales generated by us over and above those attributable to Solvay s marketing efforts. As described 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 female 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 us 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.

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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 an option for triple hormone contraception. The financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if the product 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., under which we collaborate with Teva USA on the development of a hormone therapy 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 in exchange for rights to develop and market a hormone therapy product. Teva USA also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

CAP Technology and Proposed Products. Our CAP technology, which 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. We have identified three 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 and allow for delivery of the vaccine via non-injectable routes of administration;

- the creation of inhaled and oral forms of drugs that currently must be given by injection (*e.g.*, insulin); and

- the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

Our strategy with respect to CAP is to continue development of our nanoparticle technology and actively seek collaborators and licensees to accelerate the development and commercialization of products incorporating the technology.

In addition to continuing our own research and development in the three 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 co-development and co-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.

In October 2001, we licensed BioVant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay us milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sublicenses vaccines that include BioVant, we will share in milestone payments and royalties received by Corixa. The license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

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In January 2003, we announced the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Navy s Naval Medical Research Center s (NMRC) Malaria Program for the development of a malaria vaccine. The development agreement leverages our expertise with NMRC s expertise to develop an enhanced vaccine for malaria. Under the agreement, we will provide the NMRC with BioVant our proprietary vaccine adjuvant and delivery system, and the NMRC will provide DNA plasmids or proteins encoding antigens for *Plasmodium spp*., the parasite that causes malaria. It is hoped that the resulting DNA vaccine will improve the effectiveness of the ensuing humoral and cell-mediated immunity against malaria and therefore be more effective as it activates both arms of the immune system. The NMRC will cover all costs associated with the CRADA.

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 did not recognize any revenue for this grant in our December 31, 2003 financial statements as the grant funds had not yet been received. We receive the funds as reimbursement of research and development expenses.

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 Alhydrogel 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 $658,000 per the terms of the contract.

Critical Accounting Policies

Our significant accounting policies are described in Note 1 to our financial statements included in Item 8 of this Form 10-KSB. 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. Revenue is recognized when cash is received and we have completed

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all of our obligations under our licensing arrangement which are required for the payment to be non-refundable. Revenue 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 payment 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 costs are charged to expenses as incurred. Costs associated with production of products are capitalized only when FDA approval has occurred. 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,		
	2003	**2002**	**2001**
Revenue	$ 65,494	$ 2,770,063	$ 1,747,386
Expenses	6,111,437	6,644,541	4,533,163
Research and development	3,691,420	4,786,818	2,141,944
General and administrative	2,327,090	1,765,624	2,298,659
Interest income	86,589	63,788	174,416
Net loss	$(5,959,354)	$(3,810,690)	$(2,611,361)

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Revenue for the year ended December 31, 2003 decreased 97 percent compared to revenue during 2002 primarily due to minimal net licensing income received in 2003. We earned licensing income of $65,494 for the year ended December 31, 2003 due to the reimbursement revenue from a licensee for certain clinical development expenses. We earned net licensing income of $2,770,063 for the year ended December 31, 2002 due to the receipt of a $750,000 milestone payment (net) pursuant to our sublicense agreement with Solvay Pharmaceuticals, Inc. and a $1.5 million up front licensing payment from Teva Pharmaceuticals USA, Inc.

Research and development expenses for the year ended December 31, 2003 decreased 23 percent compared to research and development expenses during 2002 primarily as a result of decreased expenses during 2003 associated with the clinical development of certain of our hormone therapy products.

General and administrative expenses for the year ended December 31, 2003 increased 32 percent compared to general and administrative expenses for 2002 primarily as a result of recognition on payment of board compensation expenses under a newly approved board stock compensation program for 2003 and 2002 and filing fees and legal expenses related to our common stock being accepted for listing on the American Stock Exchange during 2003.

Interest income for the year ended December 31, 2003 increased 36 percent compared to interest income during 2002 primarily as a result of higher invested cash balances during 2003. We expect interest income to decline in future periods as we use our cash balances for operations.

The overall increase in the net loss for the year ended December 31, 2003 compared to 2002 was primarily the result of lower licensing income and higher board stock compensation, filing and legal expenses as described above.

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Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Revenue for the year ended December 31, 2002 increased 59 percent compared to revenue for 2001 primarily due to a $1.5 million upfront payment by Teva USA and a $950,000 ($750,000 net of a related payment due to Antares) milestone payment by Solvay in 2002.

Research and development expenses for the year ended December 31, 2002 increased 123 percent compared to research and development expenses for the year ended December 31, 2001 as a result of increased expenses during 2002 associated with the clinical development of certain of our hormone therapy products.

General and administrative expenses for the year ended December 31, 2002 decreased 23 percent compared to general and administrative expenses for 2001. This decrease was due primarily to a decrease in legal and personnel-related expenses during 2002 compared to 2001.

Interest income for the year ended December 31, 2002 decreased 63 percent compared to interest income for 2001 as a result of lower average cash balances and lower interest rates on invested cash balances in 2002.

The overall increase in the net loss for the year ended December 31, 2002 compared to 2001 was largely the result of increased expenses associated with the clinical development of our hormone therapy product portfolio during 2002 compared to 2001.

Liquidity and Capital Resources

Sources of Cash

To date, we have raised equity financing and received licensing income to fund our operations, and we expect to continue this practice to fund our ongoing operations. Since inception, we have raised net proceeds of approximately $31.0 million from equity financings, class A and class C stock conversions, warrant 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 and cash equivalents were $9,134,327 and $4,883,697 at December 31, 2003 and 2002, respectively. The increase in our cash balance was primarily due to our $10.3 million ($9.6 million net) private placement of 4.8 million common shares and warrants to purchase 2.8 million shares that closed in August 2003.

Uses of Cash and Cash Flow

We used cash in operating activities of $5,521,992 for the year ended December 31, 2003 versus cash used in operating activities of $3,962,493 for the year ended December 31, 2002. The increase in cash used in operating activities largely reflects the increased net loss and associated decrease in accounts payable and accrued expenses, offset by payments received from a license related to reimbursement of clinical development costs of a product within our hormone therapy product portfolio. The increase in cash used in operating activities also reflects the decrease in cash received for licensing income and an increase in cash expenditures related to filing fees and legal expenses related to our common stock being accepted for listing on the American Stock Exchange. The $217,438 reduction in Due to Antares during the year ended December 31, 2003 represents expenses related to a development milestone paid to, and manufacturing and formulation services provided by, Antares Pharma. There was $8,865 net cash used in investing activities for the year ended December 31, 2003 which was used for the purchase of computer

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equipment versus $38,922 used in investing activities for the year ended December 31, 2002 which was used for the purchase of computer equipment and filing cabinets. Net cash provided by financing activities during the year ended December 31, 2003 was $9,781,487 and was primarily the result of our private placement which closed in August 2003. Net cash provided by financing activities during the year ended December 31, 2002 was $4,382,795 and was primarily the result of a financing which closed in September 2002.

We used cash in operating activities of $3,962,493 for the year ended December 31, 2002 versus cash used in operating activities of $1,823,820 for the year ended December 31, 2001. The increase in cash used in operating activities reflects an increase in cash expenditures in: (1) research and development and associated personnel-related expenses, and (2) expenses related to the clinical development of our hormone therapy products. Net cash used in investing activities for capital expenditures for computer equipment and filing cabinets was $38,992 for the year ended December 31, 2002 versus $86,735 for computer equipment for the year ended December 31, 2001. Net cash provided by financing activities was $4,382,795 for the year ended December 31, 2002 compared to $3,801,187 for the year ended December 31, 2001. Net cash provided by financing activities during 2002 was primarily the result of $4.4 million net cash proceeds pursuant to our equity offering that closed in September 2002.

Commitments and Contractual Obligations

We did not have any material commitments for capital expenditures as of December 31, 2003. 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, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 159,359	$159,359	$	$	$
Commitments Under License Agreement with UCLA	6,800,000		150,000	350,000	6,300,000
Commitments Under License Agreement with Wake Forest	1,740,000	10,000	125,000	155,000	1,450,000
Total Contractual Cash Obligations	$8,699,359	$169,359	$275,000	$505,000	$7,750,000

We expect to continue to spend capital on:

research and development programs;

pre-clinical studies and clinical trials;

regulatory processes;

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

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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; and

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

In addition, our license agreement with the licensor of our hormone therapy products requires us to make certain payments as development milestones are achieved, 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

Except for operating leases entered in the ordinary course of business, we do not have any material off-balance sheet arrangements.

Outlook

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 through December 2004, 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 need additional financing prior to December 2004.

We are in the process of exploring financing and strategic alternatives, which could include selling shares of our common stock or other equity securities in a public or private offering, entering into an equity line of credit, selling some or all of our assets or entering into a business combination. If we are successful at raising additional capital, our expenses may increase as we accelerate product development. We currently have no commitments for additional funding or a strategic alternative and so our ability to meet our

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liquidity needs beyond December 2004 is uncertain. If we raise additional funds through the issuance of equity securities, our stockholders may experience significant dilution. 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 commercial introduction of our proposed products, prevented from commercial introduction of our products altogether or restricted from acquiring new products that we believe may be beneficial to our business. We are required under the terms of our license agreement with the University of California, however, to have available certain amounts of funds for research and development activities.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to interest rate risk on the investments of our excess cash, 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.

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Item 7. FINANCIAL STATEMENTS

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Independent Auditors Report

Board of Directors and Stockholders
BioSante Pharmaceuticals, Inc.
Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (a development stage company) as of December 31, 2003 and 2002 and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2003, and for the period from August 29, 1996 (date of incorporation) through December 31, 2003. 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 auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, and for the period from August 29, 1996 (date of incorporation) through December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

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

/s/ Deloitte & Touche LLP

March 18, 2004
Chicago, Illinois

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
December 31, 2003 and 2002

	2003	2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 9,134,327**	**$ 4,883,697**
Due from Teva Pharmaceuticals USA, Inc. (Note 4)		**520,063**
Prepaid expenses and other sundry assets	**183,316**	**144,155**
	9,317,643	**5,547,915**
PROPERTY AND EQUIPMENT, NET (Note 5)	**247,827**	**331,889**
	$ 9,565,470	**$ 5,879,804**
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 12)	**$ 238,743**	**$ 470,871**
Accrued compensation	**514,130**	**313,287**
Other accrued expenses	**110,467**	**236,758**
Due to Antares (Note 4)	**17,865**	**235,303**
	881,205	**1,256,219**
COMMITMENTS (Notes 11 and 13)		
STOCKHOLDERS EQUITY (Note 8)		
Capital stock		
Issued and Outstanding		
2003 - 404,102; 2002 - 466,602 Class C special stock	**404**	**467**
2003 - 13,548,875; 2002 - 8,571,169 Common stock	**36,704,938**	**26,684,841**
	36,705,342	**26,685,308**
Deficit accumulated during the development stage	**(28,021,077)**	**(22,061,723)**
	8,684,265	**4,623,585**
	$ 9,565,470	**$ 5,879,804**

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Years ended December 31, 2003, 2002 and 2001
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003
REVENUE	$ 65,494	$ 2,770,063	$ 1,747,386	$ 4,582,943
EXPENSES				
Research and development	3,691,420	4,786,818	2,141,944	14,904,554
General and administration	2,327,090	1,765,624	2,298,659	12,201,611
Depreciation and amortization	92,927	92,099	92,560	659,420
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
	6,111,437	6,644,541	4,533,163	33,675,349
OTHER - Interest income	86,589	63,788	174,416	1,071,329
NET LOSS	$ (5,959,354)	$(3,810,690)	$(2,611,361)	$(28,021,077)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.54)	$ (0.51)	$ (0.40)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	11,038,595	7,503,134	6,485,349	

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Stockholders Equity
Years ended December 31, 2003, 2002 and 2001
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

	Class A Special Shares		Class C Special Shares		Common Stock		Deferred Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
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 September 23, 1996					410,000	4,100,000			4,100,000
Financing fees accrued						(410,000)			(410,000)
November 27, 1996 - issued as consideration upon acquisition of SBI (Note 3)					743,432	4,545,563			4,545,563
Exercise of Series X warrants					21,571	275,387			275,387
Exercise of Series Z warrants					143	2,553			2,553
Net loss								(6,246,710)	(6,246,710)

Balance, December 31, 1996	2,000,000	2,000	415,000	415	1,175,146	8,513,503		(6,246,710)	2,269,208
Conversion of shares January 13, 1997			(28,285)	(28)	28,285	70,741			70,713
January 13, 1997			(9,428)	(9)	9,429	23,580			23,571
December 2, 1997			(10,639)	(11)	10,639	26,607			26,596
December 2, 1997			(10,000)	(10)	10,000	25,010			25,000
Exercise of Series V warrants					2,400	36,767			36,767
Exercise of Series X warrants					2,857	36,200			36,200
Exercise of Series W warrants					2,000	25,555			25,555
Adjustment for partial shares issued upon amalgamation					13				
Financing fees reversed						410,000			410,000
Net loss								(1,890,093)	(1,890,093)
Balance, December 31, 1997	2,000,000	2,000	356,648	357	1,240,769	9,167,963		(8,136,803)	1,033,517
Conversion of shares March 4, 1998			(2,000)	(2)	2,000	5,002			5,000
March 16, 1998			(1,000)	(1)	1,000	2,501			2,500
May 8, 1998	(1,500,000)	(1,500)			1,500,000	3,751,500			3,750,000
June 1, 1998	(100,000)	(100)			100,000	250,100			250,000
June 1, 1998	(100,000)	(100)			100,000	250,100			250,000
Return of shares to treasury May 8, 1998	(146,861)	(147)							(147)
May 8, 1998			(25,000)	(25)					(25)
Net loss								(2,659,415)	(2,659,415)
Balance, December 31, 1998	153,139	153	328,648	329	2,943,769	13,427,166		(10,796,218)	2,631,430

Conversion of shares February 2, 1999			(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net May 6, 1999					2,312,500	4,197,843			4,197,843
Share redesignation July 13, 1999	(153,139)	(153)	153,139	153					
Issuance of common shares August 15, 1999					7,000	25,000			25,000
Net loss								(1,406,259)	(1,406,259)
Balance, December 31, 1999			480,787	481	5,264,269	17,652,510		(12,202,477)	5,450,514
Conversion of shares March 17, 2000			(1,000)	(1)	1,000	2,501			2,500
March 24, 2000			(3,184)	(3)	3,184	7,963			7,960
June 12, 2000			(5,000)	(5)	5,000	12,505			12,500
July 13, 2000			(2,835)	(3)	2,834	7,088			7,085
Issuance of common shares July 18, 2000					19,007	58,000			58,000
Issuance of warrants for services received						42,290	(42,290)		
Amortization of deferred unearned compensation							24,290		24,290
Net loss								(3,437,195)	(3,437,195)
Balance, December 31, 2000			468,768	469	5,295,294	17,782,857	(18,000)	(15,639,672)	2,125,654
Conversion of shares September 15, 2001			(1,166)	(1)	1,166	2,916			2,915

December 15, 2001			(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net April 4, 2001					925,000	3,659,408			3,659,408
Issuance of common shares August 15, 2001					15,500	93,000			93,000
August 15, 2001					47,619	500,000			500,000
September 15, 2001					17,361	125,000			125,000
September 15, 2001					18,940	136,364			136,364
Amortization of deferred unearned compensation							18,000		18,000
Net loss								(2,611,361)	(2,611,361)
Balance, December 31, 2001			466,602	467	6,321,880	22,302,046		(18,251,033)	4,051,480
Reverse stock stock split May 31, 2002 - Fractional share adjustment					(711)	(3,050)			(3,050)
Issuance of registered common shares, net September 6, 2002					2,250,000	4,385,845			4,385,845
Net loss								(3,810,690)	(3,810,690)

Statements of Stockholders Equity continued on the next page

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Stockholders Equity
Years ended December 31, 2003, 2002 and 2001
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

Continued from previous page

	Class A Special Shares		Class C Special Shares		Common Stock		Deferred Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
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									
May 30, 2003					82,348	180,047			180,047
June 2, 2003					37,265	79,000			79,000
September 10, 2003					2,641	7,500			7,500
November 7, 2003					226	1,000			1,000
December 19, 2003					744	3,000			3,000
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

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Years ended December 31, 2003, 2002 and 2001
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	**$(5,959,354)**	**$(3,810,690)**	**$(2,611,361)**	**$(28,021,077)**
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	**92,927**	**92,099**	**92,560**	**659,420**
Amortization of deferred unearned compensation			**18,000**	**42,290**
Repurchase of licensing rights			**125,000**	**125,000**
Compensation paid in shares of common stock	**193,000**			**344,000**
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	**(39,161)**	**(52,296)**	**(27,518)**	**(180,348)**
Due from licensee (Teva Pharmaceuticals USA, Inc.)	**520,063**	**(520,063)**		
Accounts payable and accrued expenses	**(112,029)**	**526,473**	**146,180**	**168,700**
Due to licensor (Antares/Regents)	**(217,438)**	**(198,016)**	**433,319**	**17,865**
Due from SBI				**(128,328)**
Net cash used in operating activities	**(5,521,992)**	**(3,962,493)**	**(1,823,820)**	**(21,437,933)**
CASH FLOWS USED IN INVESTING ACTIVITIES				
Purchase of capital assets	**(8,865)**	**(38,992)**	**(86,735)**	**(1,030,682)**
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				

Issuance of convertible debenture				**500,000**
Proceeds from sale or conversion of shares	**9,781,487**	**4,385,845**	**3,801,187**	**31,105,992**
Fractional share payout		**(3,050)**		**(3,050)**
Net cash provided by financing activities	**9,781,487**	**4,382,795**	**3,801,187**	**31,602,942**
NET INCREASE IN CASH AND CASH EQUIVALENTS	**4,250,630**	**381,310**	**1,890,632**	**9,134,327**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**4,883,697**	**4,502,387**	**2,611,755**	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 9,134,327**	**$ 4,883,697**	**$ 4,502,387**	**$ 9,134,327**
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**
	$	**$**	**$**	**$**
Income tax paid	**$**	**$**	**$**	**$**
Interest paid	**$ 1,995**	**$**	**$**	**$ 1,995**
SIGNIFICANT NON-CASH TRANSACTIONS				
Fair value of common stock warrants issued in connection with the sale of capital stock	**$ 539,872**	**$**	**$**	**$ 539,872**

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

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 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). On November 10, 1999, BAT changed its name to BioSante Pharmaceuticals, Inc. (the Company).

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 these financial statements have been adjusted to reflect the reverse stock split.

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 through December 2004, 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 need additional financing prior to December 2004.

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

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.

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 option renewals.

Long-Lived Assets

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

Research and Development

Research and development (R&D) costs are charged to expense as incurred. Costs associated with production of products are capitalized only when FDA approval has occurred.

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 earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted earnings (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 earnings (loss) per share does not include the Company s stock options,

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

warrants or convertible debt with dilutive potential because of their antidilutive effect on earnings (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. 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 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 following table illustrates the effect on net loss and loss per share if the Company had applied the fair value based method.

	2003	2002	2001
Net loss			
As reported	**$ (5,959,354)**	$(3,810,690)	$(2,611,361)
Stock-based compensation included in net loss as reported	**193,000**		
Total stock-based employee compensation determined under fair value based method for all awards	**(685,932)**	(374,866)	(890,461)
Net loss, pro forma	**$ (6,452,286)**	$(4,185,556)	$(3,501,822)
Basic and diluted net loss per share			
As reported	**$ (0.54)**	$ (0.51)	$ (0.40)
Pro forma	**$ (0.58)**	$ (0.56)	$ (0.54)
Cumulative net loss			
As reported	**$(28,021,077)**		
Stock-based compensation included in net loss as reported	**344,000**		
Total stock-based employee compensation determined under fair value based method for all awards	**(3,503,987)**		
Pro forma	**$(31,181,064)**		

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The weighted average fair value of the options at the date of grant for options granted during 2003, 2002 and 2001 was $1.57, $2.44 and $5.00, 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:

	2003	2002	2001
Expected option life (years)	**10**	10	10
Risk free interest rate	**3.98%**	4.61%	5.39%
Expected stock price volatility	**64.17%**	45.47%	118.79%
Dividend yield			

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue.

Revenue Recognition

The Company recognizes revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees. Revenue is recognized when cash is received and the Company has completed all of its obligations under the licensing arrangement which are required for the payment to be non-refundable. Revenue 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.

New Financial Accounting Standards Board (FASB) Interpretation

In November 2002, the FASB Emerging Issues Task Force (EITF) issued FASB Interpretation (FIN) 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others (FIN45), which elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements of FIN 45 became effective for financial statements of interim and annual periods ending after December 15, 2002, while the initial recognition and measurement provisions of FIN 45 became effective for all for guarantees issued or modified after December 31, 2002. Under FIN 45, the Company recognizes these liabilities based on the estimated fair value of the related obligation. The impact of adopting FIN 45 was not material.

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BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

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.

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 cash flows. Principle assumptions used in the valuation were as follows:

FDA approval for the CAP-related six indications was expected to be received at various dates between 2002 and 2004, however, there are many competitive products in development. There are also many requirements that must be met before FDA approval is secured. There is no assurance that the products will be successfully developed, proved to be safe in clinical trials, meet applicable regulatory standards, or demonstrate substantial benefits in the treatment or prevention of any disease.

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3. ACQUISITION (continued)

The estimated additional research and development expenditures required before FDA approval was $26.5 million, to be incurred over 8 to 10 years.

Future cash flows were estimated based on estimated market size, with costs determined based on industry norms, an estimated annual growth rate of 3%.

The cash flows were discounted at 25%. The rate was preferred due to the high-risk nature of the biopharmaceutical business.

The Company is continuing to develop the technology related to five of the six indications.

In June 1997, the Company exercised its option and entered into a license agreement with UCLA for the technology that it had previously supported.

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 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, is 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

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4. LICENSE AGREEMENTS (continued)

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 going forward, the Company will be required to reimburse Antares for such services. At December 31, 2003 and 2002, the amount owed to Antares for such services was $17,865 and $235,303 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 the third quarter ended September 30, 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 is responsible for all costs of development and marketing of the product. The Company has retained co-promotion rights to the product and will be compensated for sales generated by the Company over and above those attributable to Solvay s marketing efforts. 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.

On October 1, 2001, the Company sub-licensed its BioVant calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay the Company milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sub-licenses vaccines that include BioVant , the Company will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

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 an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company,

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4. LICENSE AGREEMENTS (continued)

regulatory milestones, maintenance payments and royalty payments by the Company if the product 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 a hormone therapy 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 will pay the Company development and sales-related milestone payments plus 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 also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

5. PROPERTY AND EQUIPMENT

Property and equipment, net of accumulated depreciation at December 31, 2003 and 2002 comprise:

	2003	2002
Computer equipment	**$ 135,156**	$ 127,179
Office equipment	**87,024**	86,136
Laboratory equipment	**108,230**	108,230
Leasehold improvements Laboratory	**477,339**	477,339
	807,749	798,884
Accumulated depreciation and amortization	**(559,922)**	(466,995)
	$ 247,827	$ 331,889

6. INCOME TAXES

The components of the Company s net deferred tax asset at December 31, 2003, 2002 and 2001 were as follows:

	2003	2002	2001
Net operating loss carryforwards	**$ 8,484,151**	$ 6,264,525	$ 4,861,792
Amortization of intangibles	**1,032,968**	1,178,212	1,323,455
Research & development credits	**1,375,959**	1,006,817	580,141

Other	**96,347**	90,977	79,197
	10,989,425	8,540,531	6,844,585
Valuation allowance	**(10,989,425)**	(8,540,531)	(6,844,585)
	$	$	$

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6. INCOME TAXES (continued)

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2003, the Company had approximately $22,930,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2011-2023. 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 approximately $1,376,000 of research and development credits available to reduce future income taxes through the year 2023.

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate of 35% to pre-tax income as follows:

	2003	2002	2001
Tax at U.S. federal statutory rate	**$(2,085,774)**	$(1,333,742)	$ (887,863)
State taxes, net of federal benefit	**(367,844)**	(365,200)	(355,149)
Change in valuation allowance	**2,448,894**	1,695,946	1,237,040
Other, net	**4,724**	2,996	5,972
	$	$	$

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-KSB have been adjusted to reflect the reverse stock split.

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8. STOCKHOLDERS EQUITY (continued)

a) Authorized

Preference shares

Ten million preference shares, $0.0001 par value per share, issuable in series subject to limitation, rights, and privileges as determined by the directors. No preference shares have been issued as of December 31, 2003.

Special Shares

4,687,684 Class C special shares, $0.0001 par value per share, convertible to common stock 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.

Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share.

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.

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8. STOCKHOLDERS EQUITY (continued)

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.

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.

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8. STOCKHOLDERS EQUITY (continued)

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.

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 estimated 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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8. STOCKHOLDERS EQUITY (continued)

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).

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. These warrants remain outstanding and are all exercisable as of December 31, 2003.

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. As of December 31, 2003, all 25,000 of these shares were exercisable. The Company recognized expense of approximately $18,000 for this warrant grant during 2000 and 2001.

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. These warrants remain outstanding and are all exercisable as of December 31, 2003.

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. These warrants remain outstanding and are all exercisable as of December 31, 2003.

In January and February 2004, 307,762 common stock warrants were exercised for total proceeds of $661,688.

In February and March 2004, 863,751 common stock warrants were exercised in exchange for 410,776 common shares which had been issued as part of the warrant exercise, for a net issuance of 452,975 shares of common stock. These warrants were originally issued in connection with a private placement of common shares and this was a non-cash financing transaction.

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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 for 1,237,634 shares of common stock have been granted as of December 31, 2003 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:

	2003	Weighted Average Exercise Price	2002	Weighted Average Exercise Price	2001	Weighted Average Exercise Price
Options outstanding, Beginning of period	**997,300**	$ 3.74	699,467	$ 3.80	526,312	$ 3.30
Options granted	**307,000**	$ 2.10	327,167	$ 3.71	174,155	$ 5.20
Options cancelled/expired	**(66,666)**	$ 7.60	(29,334)	$ 3.44	(1,000)	$ 7.50
Options exercised		$		$		$
Options outstanding, End of period	**1,237,634**	$ 3.13	997,300	$ 3.74	699,467	$ 3.80
Options exercisable, End of year	**694,461**	$ 3.29	631,611	$ 3.55	542,483	$ 3.40

The following table summarizes information about stock options outstanding at December 31, 2003:

	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	307,000	4.3 years	$ 2.10		$ 2.10
$2.30	237,813	2.2 years	$ 2.30	237,813	$ 2.30

$2.80 - $2.90	212,000	1.6 years	$ 2.85	212,000	$ 2.85
$3.40 - $6.70	480,821	8.2 years	$ 4.32	244,648	$ 4.63
	1,237,634			694,461	

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9. STOCK OPTIONS (continued)

During the second quarter 2003, BioSante issued 285,000 options 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, $1,054,500 will be recognized as compensation expense over the 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 2003, 2002 and 2001 totaled $60,005, $44,605 and $30,743, respectively.

11. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space and laboratory facilities which expire in 2004. The future minimum lease payments during 2004 are $159,359.

Rent expense amounted to $147,088, $148,184 and $119,765 for the years ended December 31, 2003, 2002 and 2001, respectively. Effective September 16, 1999, the Company entered into a sublease agreement for its Atlanta office space under which the Company received approximately $3,400 per month from the sub-tenant through May 14, 2002.

12. RELATED PARTY TRANSACTIONS

Included in current liabilities are $16,184 and $2,179 which represent amounts due to directors and officers of the Company as of December 31, 2003 and 2002, 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.

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12. RELATED PARTY TRANSACTIONS (continued)

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.

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., an executive officer of BioSante. Under the agreement, Scientific Research Development Corporation provides the Company with database and statistical programming, database management, medical writing and project management services. In consideration for such services, $103,035, $199,229, and $64,172 are included in research and development expenses for the years ended December 31, 2003, 2002 and 2001, respectively.

13. COMMITMENTS

University of California License

The Company s license agreement with the University of California 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;

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13. COMMITMENTS (continued)

Payment of minimum annual royalties beginning for the year 2004 to be paid by February 28 of the following year in the amounts set forth below, to be credited against earned royalties, for the life of the agreement;

Year	Minimum Annual Royalty Due
2004	$ 50,000
2005	100,000
2006	150,000
2007	200,000
2008	400,000
2009	600,000
2010	800,000
2011	1,500,000
2012	1,500,000
2013	1,500,000
Total	$6,800,000

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, 2003, 2002 and 2001 amounted to $15,371, $12,240 and $11,358, 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.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to the Financial Statements
For the years ended December 31, 2003, 2002 and 2001, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2003

13. COMMITMENTS (continued)

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. 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.

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 an option 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 milestones, 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
2004	$ 10,000
2005	45,000
2006	80,000
2007	65,000
2008	90,000
2009	140,000
2010	90,000
2011	40,000
2012	140,000
2013	240,000
Thereafter	800,000

The Company has agreed to indemnify, hold harmless and defend Wake Forest University 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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Item 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 8A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) that are designed to 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. 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-KSB. 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. There was no change in our internal control over financial reporting that occurred during our fiscal fourth quarter ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART III

Item 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Directors, Executive Officers, Promoters and Control Persons

The information required under Item 9 of this Form 10-KSB is to be contained under the captions Election of Directors Information About Nominees, Election of Directors Other Information About Board Nominees and Election of Directors Information About the Board of Directors and its Committees 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB not later than the end of the 120-day period.

The information concerning our executive officers is included in this Form 10-KSB under Item 4a, Executive Officers of the Company and is incorporated herein by reference.

Section 16(a) Beneficial Ownership Reporting Compliance

The information required under Item 9 of this Form 10-KSB is to be contained under the caption 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB not later than the end of the 120-day period.

Code of Conduct and Ethics for Employees, Officers and Directors

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 Form 10-KSB. 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 within five business days following any such amendment or waiver.

Item 10. EXECUTIVE COMPENSATION

The information required under Item 10 of this Form 10-KSB 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB not later than the end of the 120-day period.

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Item 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under Item 11 of this Form 10-KSB 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB 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, 2003. 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	1,237,634	$ 3.13	762,366
Equity compensation plans not approved by security holders	0	N/A	0
Total	1,237,634	$ 3.13	762,366

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, 2003 and December 31, 2003. As of January 1, 2003, the number of securities to be issued upon exercise of outstanding options, warrants and rights were 997,300 shares at a weighted average exercise price of $3.74. 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 2,700 shares. This information as of December 31, 2003 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. We also have a deferred compensation plan which permits our executive officers to defer the receipt of the stock portion of their annual bonus and our non-employee directors to defer the receipt of their annual stock retainer and stock compensation for attending board and committee meetings. Any stock compensation deferred under this plan, however, will be paid out in shares of BioSante common stock under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan. We do not have any other equity compensation plans.

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Item 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under Item 12 of this Form 10-KSB 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB not later than the end of the 120-day period.

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Item 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

The exhibits to this Report are listed on the Exhibit Index on pages 70 76. 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-KSB pursuant to Item 13(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. 0-286637)).

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 (filed herewith electronically).

E. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s directors (filed herewith electronically).

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 (incorporated by reference to Exhibit 10.16 to BioSante s Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 0-28637)).

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)).

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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)).

(b) Reports on Form 8-K

None.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under Item 14 of this Form 10-KSB is to be contained under the captions Ratification of Selection of Independent Auditors Audit, Audit-Related, Tax and Other Fees and Ratification of Selection of Independent Auditors 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 Form 10-KSB, such information will be filed as part of an amendment to this Form 10-KSB not later than the end of the 120-day period.

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SIGNATURES

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

Dated: March 26, 2004 **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 26, 2004 by the following persons on behalf of the registrant and in the capacities indicated.

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

/s/ Ross Mangano	Director
Ross Mangano	
	Director
Angela Ho	
/s/ Peter Kjaer	Director
Peter Kjaer	

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BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-KSB
FOR THE YEAR ENDED DECEMBER 31, 2003

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, (File 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, (File No. 333-64218)
4.1	Form of Warrant issued in connection with May 1999 Private Placement	Incorporated by reference to Exhibit 4.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
4.2	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 (File No. 333-64218)

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Exhibit No.	Exhibit	Method of Filing
4.3	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	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 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.5	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s executive officers	Incorporated by reference to Exhibit 10.5 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)

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Exhibit No.	Exhibit	Method of Filing
10.6	Escrow Agreement, dated December 5, 1996, among BioSante Pharmaceuticals, Inc., Montreal Trust Company of Canada, as Escrow Agent, and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.9 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.7	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)
10.8	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)
10.9	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)
10.10	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Incorporated by reference to Exhibit 10.16 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637)

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Exhibit No.	Exhibit	Method of Filing
10.11	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)
10.12	License Agreement, dated June 13, 2000, between Permatec Technologie, AG 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)
10.14	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)
10.15	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)
10.17	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)
10.18	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)

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Exhibit No.	Exhibit	Method of Filing
10.19	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)
10.20	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)
10.21	Consulting Agreement, dated January 1, 2001, between BioSante Pharmaceuticals, Inc. and Scientific Research Development Corp.	Incorporated by reference to Exhibit 10.21 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.22	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)
10.23	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)
10.24	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)

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Exhibit No.	Exhibit	Method of Filing
10.25	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)
10.26	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)
10.27	Deferred Compensation Plan	Incorporated by reference to Exhibit 10.2 contained in BioSante s 10-QSB, filed on August 14, 2003 (File No. 0-28637)
10.28	First Amendment to Lease, dated September 18, 2003, between BioSante and Highlands Park Associates	Filed herewith electronically
10.29	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	Filed herewith electronically
10.30	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s executive officers	Filed herewith electronically
10.31	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s directors	Filed herewith electronically
14.1	Code of Conduct and Ethics	Filed herewith electronically
23.1	Consent of Deloitte & Touche LLP	Filed herewith electronically
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith electronically
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith electronically
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 electronically

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Exhibit No.	Exhibit	Method of Filing
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 electronically

(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.