BIOSANTE PHARMACEUTICALS INC
Form 10KSB
March 31, 2003

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark one)

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

For the fiscal year ended December 31, 2002

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: **None**

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

Common Stock, $0.0001 par value

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 ý 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. ý

The issuer s revenues for the fiscal year ended December 31, 2002 were $2,833,851.

As of March 3, 2003, 8,571,169 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 Over-the-Counter Bulletin Board), excluding outstanding shares beneficially owned by directors and executive officers, was $13,813,928.

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 2003 Annual Meeting of Stockholders to be held May 30, 2003.

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

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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, plans, projected, predicts, potential or continue or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the heading Item 1. Description of Business Certain Important Factors. 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 otherwise 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 .

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

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, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants or immune system boosters, drug delivery systems and the purification of the milk of transgenic animals.

To enhance the value of our company, we are pursuing the following corporate growth strategies:

pursuing the development of our hormone therapy products;

continuing to develop our nanoparticle-based platform technology, or CAP, and seeking assistance in such development through corporate partner sub-licenses;

implementing business collaborations or joint ventures with other pharmaceutical and biotechnology companies; and

licensing or otherwise acquiring other drugs that will add value to our current product portfolio.

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 required 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).

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, most 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;

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.

CAP-Oral a delivery system using proprietary CAP technology for oral administration of proteins and other therapies that currently must be injected.

BioAir proprietary technology using CAP as a delivery system 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 extracting therapeutic proteins from the milk of transgenic animals.

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.

Business Strategy

Our goal is to develop and commercialize our hormone therapy products and 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. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis. Human clinical trials have begun on four of our proposed hormone therapy products, a necessary step in the process of obtaining FDA approval to market the products.

Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses. We are seeking opportunities to enter into business collaborations, joint ventures or sub-licenses with companies that have businesses or technologies complementary to our CAP technology business, such as vaccine and drug delivery pharmaceutical companies and transgenic milk companies. 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. We are particularly interested in entering into product licenses, co-development or co-marketing arrangements. We are also in the process of exploring strategic alternatives, which could include selling some of our assets or entering into a business combination.

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 the U.S. Food and Drug Administration, or 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 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 required 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 our hormone therapy 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).

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.

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 in the over age 40 male population group, 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 dermal, or skin, patches. Delivery of testosterone through dermal patches was developed primarily to promote the therapeutic effects of

testosterone therapy without the often painful side effects associated with testosterone injections. Dermal 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, the physical presence and skin irritation and discomfort associated with dermal patches. We are aware of two gel testosterone products for men currently on the market in the United States and several in development.

Estrogen deficiency in women can result in hot flashes and flushes, vaginal atrophy, decreased libido and osteoporosis. Hormone therapy in women decreases the chance that women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately 15 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, gallstones and blood clots. Although dermal patches have been shown to avoid some of these problems, delivery of estrogen through dermal 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, dermal patches. Also, Bio-E-Gel contains bioidentical estradiol versus conjugated equine estrogen contained in the most commonly prescribed oral estrogen.

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product, Bio-E/P-Gel. 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 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-progestin 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 progestin components of Prempro are different chemical entities than those used in our proposed gel formulated 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 formulated delivery system containing estradiol, which is identical to the estrogen produced naturally by a woman s ovaries, and progestin, different than the type of progestin in Prempro. The WHI study results do not necessarily apply to estrogen and progestin administered through the transdermal route and to different hormones which may provide a different risk-benefit profile. In addition, the intended use for our proposed gel-formulated Bio-E/P-Gel is no more than two years.

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

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 absorbed evenly, 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 will keep our costs, time and risks associated with the FDA approval process at a comparatively lower level.

Human clinical trials have begun on four of our hormone therapy products, which are required to obtain FDA approval to market the products.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, 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 sub-licenses, 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 and 2002 between us 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, 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 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 sub-license 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 sub-licensed 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 sub-license agreement. Solvay will be responsible for all costs of development and marketing of the product. We have retained co-promotion rights to the product and are 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 sub-licensed to Paladin as part of that sub-license 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 sub-licensed the marketing rights to our portfolio of female hormone therapy products in Canada to Paladin Labs Inc. In exchange for the sub-license, 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 sub-license 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 will 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, future development and sales related milestone payments and royalties on sales of the commercialized product upon approval in exchange for rights to develop and market a hormone therapy product. Teva USA will also be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

Our strategy with respect to our hormone therapy product portfolio is to conduct human clinical trials of our proposed hormone therapy products, which are required to obtain approval from the FDA and to market the products in the United States. We have initiated a Phase II clinical trial of our LibiGel for the treatment of female sexual dysfunction. The Phase II trial, being conducted in the United States and Canada, is a double-blind, placebo-controlled study that will enroll approximately 120 patients to determine the effect of LibiGel on a women s sexual desire and activity.

We have completed a Phase II/III clinical trial of Bio-E-Gel, a topical gel for the treatment of menopausal symptoms, including hot flushes. The trial, conducted in the United States and Canada, was a double-blind placebo-controlled study of 161 patients. The data are being analyzed and an end-of-Phase II/III meeting is planned with the FDA. We hope to initiate the one required pivotal Phase III clinical trial in 2003.

Description of Our CAP Technology and CAP Technology Products

We believe our CAP technology will serve as an effective vehicle for delivering drugs and vaccines and enhancing the effects of vaccines. Our nanoparticles have successfully passed the first stage of toxicity studies for administration orally, into muscles, under the skin, and into the lungs by inhalation. Also, we have successfully completed a Phase I human clinical safety trial of CAP.

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.

CAP-Oral a delivery system using proprietary CAP technology for oral administration of proteins and other therapies that currently must be injected.

BioAir proprietary technology using CAP as a delivery system 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 extracting therapeutic proteins from the milk of transgenic animals.

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.

These ultra fine particles are made from inert, biologically acceptable materials, such as ceramics, pure crystalline carbon or biodegradable calcium phosphate. 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 will 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.

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.

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 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 (1) vaccine adjuvants, (2) drug delivery systems, including a method of delivering proteins (*e.g.*, insulin) orally, through inhalation and subcutaneous routes of administration, and (3) the purification of the milk of transgenic animals. Our pre-clinical research team in our laboratory in Smyrna, Georgia is currently pursuing the development of our CAP technology.

Vaccine adjuvants. 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.

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, 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.

In addition to continuing our own research and development in this area, we intend 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 nanoparticles for use as a vaccine adjuvant. We intend to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in vaccine development, co-development and co-marketing arrangements. We believe these collaborations may enable us to accelerate the development of potential improved vaccines. These arrangements also could include out-licenses of our CAP technology to vaccine companies and others for further development in their on-going vaccine development.

Our outlicensing activities with respect to our 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 which 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 negotiate an out-license agreement with the target company.

In October 2001, we announced a non-exclusive license agreement with Corixa Corporation to use our BioVant vaccine adjuvant in several potential vaccines to be developed by Corixa. Under the license 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 sub-licenses 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 auto immune disease vaccines.

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.

Drug delivery systems. The third field of use in which we are exploring applying our CAP technology involves creating novel and improved forms of delivery of drugs, 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 product, which we call CAP-Oral, has shown an 80% reduction of glucose levels within the first hour of treatment. These

reduced glucose levels were maintained for 12 hours versus 20-25% glucose reduction for three hours for free insulin. In fed mouse models, our oral formulation reduced glucose levels by 50% 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.

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 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% 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.

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.

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately $4,787,000 in 2002 and $2,142,000 in 2001 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 estimate that we are currently 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-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 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.

Currently, our gel hormone products are manufactured through a U.S.-based GMP approved manufacturer.

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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.

Antares Pharma, Inc. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares has 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 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 the 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;

accelerate the human clinical development of the hormone product portfolio, including:

- testing proposed products;
- conducting clinical trials;
- obtaining government approvals;
- introducing products incorporating the licensed technology into the market; and

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

University of California. 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 in 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 $12,241 in fiscal 2002;

meeting performance milestones relating to:

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

testing proposed products;

conducting clinical trials;

obtaining government approvals;

introducing products incorporating the licensed technology into the market; and

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

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

Patents and patent applications. We own two United States patents and no foreign patents. In June 1999, we filed a patent 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 will be our property.

Competition

There is intense competition in the biopharmaceutical industry, including in the hormone therapy market, the market for prevention and/or treatment of the same infectious diseases we target and in the acquisition of products in the late-stage development phase or already on the market. Potential competitors in the United States are numerous and include major pharmaceutical and specialized biotechnology companies, universities and other institutions. In general, competition in the pharmaceutical industry can be divided into four categories: (1) corporations with large research and developmental departments that develop and market products in many therapeutic areas; (2) companies that have moderate research and development capabilities and focus their product strategy on a small number of therapeutic areas; (3) small companies with limited development capabilities and only a few product offerings; and (4) university and other research institutions.

All of our competitors in categories (1) and (2) and some of our competitors in category (3) have longer operating histories, greater name recognition, substantially greater financial resources and larger research and development staffs than we do, as well as substantially greater experience than us in developing products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products.

A significant amount of research in the field is being carried out at academic and government institutions. These institutions are becoming increasingly aware of the commercial value of their findings and are becoming more aggressive in pursuing patent protection and negotiating licensing arrangements to collect royalties for use of technology that they have developed.

We expect our products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. In addition, the first product to reach the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market.

We are aware of certain programs and products under development by others which 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 A2, 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.

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 six to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further, there is no assurance that the FDA will ultimately approve an NDA. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with current good manufacturing practice regulations, commonly referred to as 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 twelve full-time employees and one part-time employee as of December 31, 2002, including nine in research and development and four in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We believe we have an excellent relationship with our employees.

Certain Important Factors

There are several important factors that could cause our actual results to differ materially from those anticipated by us or which are reflected in any of the forward-looking statements we have made in this annual report. These factors, and their impact on the success of our operations and our ability to achieve our goals, include the following:

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 $3,810,690 for the year ended December 31, 2002, and as of December 31, 2002, our accumulated deficit was 22,061,723.

All of our revenue to date has been derived from interest earned on invested funds and up-front and milestone payments earned on licensing and 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 and continue. 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 products in the late-stage human clinical development phase or already on the market that we may in-license or otherwise acquire, 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 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, 2002 was $4,883,697. We believe this cash will be sufficient to fund our operations through December 2003. 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. Any additional equity financings may be dilutive to our existing stockholders and involve the issuance of securities that may have rights, preferences or privileges senior to those possessed by our current stockholders. A debt financing, if available, may involve restrictive covenants on our business which could limit our operational and financial flexibility, and the amount of debt incurred could make us more vulnerable to economic downturns and limit our ability to compete. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. In addition, 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 with a short operating history, 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.

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.

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 released data from its Women s Health Initiative study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The National Institutes of Health 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. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

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 preclinical studies and clinical trials may be required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct preclinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of preclinical studies and 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 preclinical studies using various doses and formulations before we can begin clinical trials, which could result in delays in our ability to obtain any regulatory approvals or to market any of our products. Furthermore, even if we obtain favorable results in preclinical studies on animals, the results in humans may be different.

After we have conducted preclinical studies in animals, we must demonstrate that our products are safe and effective for use on human patients in order to receive regulatory approval for commercial sale. The data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. Adverse or inconclusive clinical results would prevent us from filing for regulatory approval of our products. Additional factors that could cause delay or termination of our clinical trials include:

slow patient enrollment;

longer treatment time required to demonstrate efficacy;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

We license the technology underlying most of our proposed hormone therapy products and most 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 most 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 do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We may, therefore, be dependent upon others for our clinical testing, manufacturing, sales and marketing.

Our current facilities do not include accommodation for the testing of our proposed products in animals or in humans for the clinical testing required by the FDA. We do not have a manufacturing facility that can be used for full-scale production of our products. In addition, at this time, we have very limited sales and marketing personnel. In the course of our development program, we will therefore be required to enter into arrangements with other companies or universities for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If we are 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.

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 may not definitively ensure the protection of our intellectual property for a number of other reasons that are beyond our control. For example:

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 or manufacturing a product 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.

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.

Because we are developing new products, we may fail to gain market acceptance for our products and our business could suffer.

None of the products we propose to develop or are developing have yet been approved for marketing by regulatory authorities in the United States or elsewhere. Even if our proposed products ultimately are approved for sale, there can be no assurance that they will be commercially successful.

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 are numerous and include pharmaceutical 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 also are 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.

We are dependent upon key personnel, many of whom would be difficult to replace.

Our success will be largely dependent upon the efforts of Stephen M. Simes, our Vice Chairman, President and Chief Executive Officer, and other key employees. Our future success also will depend in large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, could make it more difficult for us to manage our business and meet key objectives, such as the timely introduction of our proposed products, which would harm our business, financial condition and operating results.

Item 2. DESCRIPTION OF PROPERTY

Our principal executive office is located in Lincolnshire, Illinois. In September 2001, we entered into a new lease agreement for approximately 4,034 square feet of office space for approximately $6,200 per month, which lease expires in December 2003. Our CAP research and development operations are located in Smyrna, Georgia where we lease approximately 11,840 square feet of laboratory space for approximately $5,400 per month. This lease expires in October 2003. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

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Item 3. LEGAL PROCEEDINGS

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

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

No matter was submitted to a vote of our security holders during the fourth quarter ended December 31, 2002.

Item 4A. EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers, their ages and the offices held, as of March 1, 2003, are as follows:

Name	Age	Title
Stephen M. Simes	51	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	42	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	40	Vice President, Clinical Development
Steven J. Bell, Ph.D.	43	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 Bio-Technology General Corp., and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Bio-Technology General Corp. 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., Molecular Geriatrics Corporation and Xtramedics, Inc.

Leah M. Lehman, Ph.D. has served as our Vice President, Clinical Development since January 2001. 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.

PART II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Price

Our common stock is currently trading in the United States on the over-the-counter market on the OTC Bulletin Board, under the symbol BISP, and traded on the OTC Bulletin Board under the symbol BTPH from May 5, 2000 to May 31, 2002. Our common stock traded in Canada on the Canadian Venture Exchange, formerly known as the Alberta Stock Exchange, under the symbol BAI, from December 20, 1996 to July 20, 2001.

The following table sets forth, in U.S. dollars and in dollars and cents (in lieu of fractions), the high and low sales prices for each of the calendar quarters indicated, as reported by the OTC Bulletin Board. 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

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

2001	**High**	**Low**
First Quarter	$ 7.50	$ 3.80
Second Quarter	$ 10.70	$ 3.90
Third Quarter	$ 10.00	$ 4.60
Fourth Quarter	$ 10.50	$ 4.80

The following table sets forth, in U.S. dollars and in dollars and cents (in lieu of fractions), the high and low sales prices for each of the calendar quarters indicated, as reported by the Canadian Venture Exchange.

Canadian Venture Exchange

	High	Low
2001		
First Quarter	$ 7.20	$ 4.60
Second Quarter	$ 10.70	$ 3.50

Number of Record Holders; Dividends

As of March 3, 2003, there were approximately 735 record holders of our common stock and 10 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 quarter ended December 31, 2002, we did not issue any securities without registration under the Securities Act.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes outstanding options under our Amended and Restated 1998 Stock Option Plan as of December 31, 2002. Options granted in the future under the plan are within the discretion of our Compensation Committee 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	997,300	$ 3.74	2,700
Equity compensation plans not approved by security holders	0	N/A	0
Total	997,300	$ 3.74	2,700

Our only equity compensation plan is the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan. One of the matters to be submitted to our stockholders at our 2003 Annual Meeting of Stockholders is to (i) approve an increase in the number of shares of our common stock available for issuance under the plan by 1,000,000 shares of common stock and (ii) approve certain amendments to the plan, including an amendment adding a stock compensation feature. We do not have any other equity compensation plans.

Item 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This Form 10-KSB contains forward-looking statements relating to our financial condition, results of operations and business, including statements pertaining to:

our substantial and continuing losses;

our need to raise additional capital through future equity and other financings;

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; and

our existing cash and whether and how long these funds will be sufficient to fund our operations.

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. Without limiting the foregoing, words such as may, will, expect, believe, anticipate, estimate or continue or the negative or variations thereof or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, including those described under this section and the section entitled Certain Important Factors. We are not obligated to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as otherwise required by law. For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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, nanoparticulate-based platform technology, 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), a combination of estradiol and testosterone and a combination of estradiol and progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required 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.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, 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 sub-licenses, 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 us 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, 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 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 sub-license 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 sub-licensed 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 sub-license 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 sub-licensed to Paladin as part of that sub-license 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 sub-licensed the marketing rights to our portfolio of female hormone therapy products in Canada to Paladin Labs Inc. In exchange for the sub-license, 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 sub-license 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.

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 will 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, future development and sales related milestone payments and royalties on sales of the commercialized product in exchange for rights to develop and market a hormone therapy product. Teva USA will also be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

Our strategy with respect to our hormone therapy product portfolio is to conduct human clinical trials of our proposed hormone therapy products, which are required to obtain approval from the FDA and to market the products in the United States.

We have initiated a Phase II clinical trial of our LibiGel for the treatment of female sexual dysfunction. The Phase II trial, being conducted in the United States, is a double-blind, placebo-controlled study that will enroll approximately 120 patients to determine the effect of LibiGel on a women s sexual desire and activity.

We have completed a Phase II/III clinical trial of Bio-E-Gel, a topical gel for the treatment of menopausal symptoms, including hot flushes. The trial, conducted in the United States and Canada, was a double-blind placebo-controlled study of 161 patients. The data are being analyzed and an end of Phase II/III meeting is planned with the FDA.

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;

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 over the next 12 months is to continue development of our nanoparticle technology and actively to seek collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the FDA to initiate a Phase I clinical trial of our CAP as a vaccine adjuvant and delivery system based on an

Investigational New Drug Application that we filed in July 2000. 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 was completed in October 2000. The results showed that there was no apparent difference in side effect profile between CAP and placebo.

In October 2001, we licensed our 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 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 sub-licenses 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.

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. 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.

Our goal is to develop and commercialize our portfolio of hormone therapy products and CAP technology into a wide range of pharmaceutical products and to expand this product portfolio as appropriate. Our strategy to obtain this goal is to:

Continue the development of our hormone therapy products;

Continue the development of our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses;

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies; and

License or otherwise acquire other drugs that will add value to our current product portfolio and consider the sub-license of certain hormone therapy products.

We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $3,810,690 for the year ended December 31, 2002, resulting in an accumulated deficit of $22,061,723. In order to generate revenues, we must successfully develop and commercialize our 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.

Critical Accounting Policies

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 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. Interest income on invested cash balances is recognized on the accrual basis as earned.

Research and Development

Research and development costs are charged to expenses as incurred. Research and development costs are capitalized only when FDA approval has occurred. To date, no research and development expenses have been capitalized.

Results of Operations

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

Revenues increased from $1,921,802 during the year ended December 31, 2001 to $2,833,851 during the year ended December 31, 2002, 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. All of our revenue to date has been derived from interest earned on invested funds and upfront and milestone payments earned on licensing and sub-licensing transactions.

Research and development expenses increased from $2,141,944 during the year ended December 31, 2001 to $4,786,818 during the year ended December 31, 2002. This overall increase is the result of increased expenses during 2002 associated with the clinical development of certain of our hormone therapy products. We expect that our research and development expenses will continue to be significant in future periods as a result of human clinical trials of our hormone therapy products. Management estimates that its 2002 spending of approximately $300,000 to $400,000 per month on research and development activities and approximately $500,000 to $600,000 per month in total expenses, including research and development activities will decline slightly in 2003 based on our planned clinical development schedule. These expenses are planned to increase if we are able to raise additional funds. 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. The amount of our actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

General and administrative expenses decreased from $2,298,659 during the year ended December 31, 2001 to $1,765,624 during the year ended December 31, 2002. This decrease of approximately 23% is due primarily to a decrease in legal and personnel-related expenses compared to the same one-year period last year.

Interest income decreased from $174,416 during the year ended December 31, 2001 to $63,788 during the year ended December 31, 2002 as a result of lower average cash balances in 2002 and as a result of lower interest rates on invested cash balances in 2002. We expect interest income to decline in future periods as we use our cash balances for operations.

We incurred a net loss of $3,810,690 for the year ended December 31, 2002, compared to a net loss of $2,611,361 for the year ended December 31, 2001. The overall increase in the net loss is largely the result of increased expenses associated with the clinical development of our hormone therapy product portfolio during the year ended December 31, 2002 compared to December 31, 2001. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs 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 obtaining necessary regulatory filings and approvals; and

the timing and cost of obtaining third party reimbursement.

Year Ended December 31, 2001 Compared to Year Ended December 31, 2000

Research and development expenses increased from $1,887,832 during the year ended December 31, 2000 to $2,141,944 during the year ended December 31, 2001. This overall increase was the result of increased expenses during the year ended December 31, 2001 associated with the clinical development of our hormone therapy product portfolio and payment to Antares for certain manufacturing and formulation services, offset by a $1.0 million upfront license fee paid to Antares during the year ended December 31, 2000. 2001 also included recognition of a $250,000 credit from Antares, which represented the portion of the initial $1.0 million upfront license fee paid in 2000 which was creditable against future payments.

On August 7, 2001, we entered into a sub-license 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 in June 2000. Under the terms of the agreement, Solvay paid us an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin) and has agreed to make future milestone payments and pay escalating sales-based royalties. Solvay is responsible for all costs of development and marketing of the estrogen/progestogen combination transdermal hormone therapy gel product. We have retained co-promotion rights to the product and will be compensated for sales we generate 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 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.

General and administrative expenses increased from $1,678,581 during the year ended December 31, 2000 to $2,298,659 during the year ended December 31, 2001. This increase of approximately 37% was due primarily to expenses related to personnel-related expenses and the higher legal expenses related to the increase in our patent, collaboration and licensing activities.

Interest income decreased from $227,718 during the year ended December 31, 2000 to $174,416 during the year ended December 31, 2001 as a result of lower average cash balances in 2001 and as a result of lower interest rates on invested cash balances in 2001.

We incurred a net loss of $2,611,361 for the year ended December 31, 2001, compared to a net loss of $3,437,195 for the year ended December 31, 2000. The overall decrease in the net loss was the result of a $1.0 million upfront license fee paid to Antares during the year ended December 31, 2000, offset by the combination of $1.7 million, net, in revenue from a sub-license upfront payment received by us and increased expenses during the year ended December 31, 2001 associated with (1) personnel-related expenses, (2) legal expenses related to increased patent, collaboration and licensing activities, and

(3) increased expenses associated with the clinical development of our hormone therapy product portfolio and payment to Antares for certain manufacturing and formulation services.

Liquidity and Capital Resources

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 $17.3 million from equity financings, class A and class C stock conversions, warrant exercises and the issuance of a $500,000 convertible debenture, which was subsequently converted into 47,619 shares of common stock. Since inception, we have received $4.5 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

Our cash and cash equivalents were $4,883,697 and $4,502,387 at December 31, 2002 and 2001, respectively. The increase in our cash balance is due to our $4.5 million equity offering that closed in September 2002, as well as upfront and milestone payments received from licensing and sub-licensing transactions offset against our expenses during the period.

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 was $38,992 for the year ended December 31, 2002 versus $86,735 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.

We used cash in operating activities of $1,823,820 for the year ended December 31, 2001 versus cash used in operating activities of $3,149,604 for the year ended December 31, 2000. This decrease reflects the combination of the upfront payment received from Solvay in 2001, offset by cash expenditures associated with: (1) increased general and administrative and research and development personnel-related expenses, (2) legal fees associated with the increase in patent, licensing and collaboration activities; and (3) increased expenses related to the clinical development of our hormone therapy products and expenses related to manufacturing and formulation services provided by Antares. Offsetting these increased expenses for the year ended December 31, 2001 is the recognition of $1.7 million of licensing revenues pursuant to the Solvay sub-license agreement versus the year ended December 31, 2000 and the $1.0 million upfront license fee payment to Antares paid in June 2000. Net cash used in investing activities was $86,735 for the year ended December 31, 2001 versus $43,238 for the year ended December 31, 2000. The significant uses of cash in investing activities for the year ended December 31, 2001 and 2000 included capital expenditures for computer equipment. Additionally, during the year ended December 31, 2001, we relocated our business office thus incurring the capital expenditures of used office equipment and furniture. Net cash provided by financing activities was $3,801,187 for the year ended December 31, 2001 compared to $530,045 for the year ended December 31, 2000. Net cash provided during 2001 was primarily the result of $3.7 million cash proceeds pursuant to our private placement of common stock and warrants which closed in April 2001 and licensing milestone payments received while net cash provided during 2000 was primarily the result of a $500,000 convertible debenture issued to Paladin Labs Inc. pursuant to a sub-license agreement related to our female hormone therapy products.

We currently project that we have adequate cash resources to meet our planned expenditures through December 2003; however, we 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. 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. If we are successful at raising additional capital, our expenses will increase as we accelerate product development.

Commitments

The following table summarizes the timing of these future contractual obligations and commitments:

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 131,784	$ 131,784			
Commitments Under License Agreement with UCLA	6,800,000		150,000	$ 350,000	$ 6,300,000
Commitments Under License Agreement with Wake Forest	1,140,000		55,000	$ 145,000	$ 940,000
Total Contractual Cash Obligations	$ 8,071,784	$ 131,784	$ 205,000	$ 495,000	$ 7,240,000

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 marketing partners to market our products for us; and

the licensure or acquisition of new products.

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

progress, timing and scope of our research and development programs;

progress, timing and scope of our pre-clinical studies and clinical trials;

time and cost necessary to obtain regulatory approvals;

time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;

time and cost necessary to respond to technological and market developments;

changes made or new developments in our existing collaborative, licensing and other commercial relationships; and

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

In addition, our license agreement with Antares, 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.

In addition to the commitments to the University of California and Wake Forest University, we also have minimum annual lease payments.

Outlook

Based on our current cash resources, we believe we should be able to maintain our current planned development activities and the corresponding level of expenditures through December 2003, 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 2003. We are in the process of exploring alternatives for raising additional financing and strategic alternatives, which could include selling some or all of our assets or entering into a business combination. If we are successful at raising additional capital, our expenses will increase as we accelerate product development. We currently have no commitments for additional funding or such a strategic alternative and so our ability to meet our liquidity needs beyond December 2003 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 unable to develop our products or take advantage of business opportunities. If necessary, we can conserve cash by delaying aspects of our clinical development schedule. 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.

Recently Issued Accounting Statements

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, Accounting for Stock Based Compensation Transition and Disclosure, (SFAS 148), which amends SFAS No. 123, Accounting for Stock-Based Compensation to provide alternative methods of transition for an entity that voluntarily changes to the fair value method of accounting for stock-based compensation. This standard also amends disclosure provisions to require prominent disclosures, in both annual and interim financial statements, about the method of accounting for stock-based compensation and the effects of the method used on reporting results. SFAS 148 became effective for financial statements for fiscal years ending after December 15, 2002. We have chosen not to convert to the fair value method of accounting for stock-based compensation and do not believe that adoption of SFAS 148 will have an impact on our financial position or results of operations.

Quantitative and Qualitative Disclosure About Market Risk

We are exposed to interest rate risk on the investments of our excess cash. 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. Due to the nature of our short-term investments, we have concluded that we do not have a material market risk of interest

rate exposure.

Item 7. FINANCIAL STATEMENTS

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, 2002 and 2001 and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2002, and for the period from August 29, 1996 (date of incorporation) through December 31, 2002. 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, 2002 and 2001 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, and for the period from August 29, 1996 (date of incorporation) through December 31, 2002 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

February 14, 2003
Chicago, Illinois

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Balance Sheets

December 31, 2002, 2001

	2002	2001
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 4,883,697	$ 4,502,387
Due from Teva Pharmaceuticals USA, Inc. (Note 5)	520,063	
Prepaid expenses and other sundry assets	144,155	91,859
	5,547,915	4,594,246
PROPERTY AND EQUIPMENT, NET (Note 6)	331,889	384,996
	$ 5,879,804	$ 4,979,242
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 13)	$ 470,871	$ 90,653
Accrued compensation	313,287	379,346
Other accrued expenses	236,758	24,444
Due to Antares (Note 5)	235,303	433,319
	1,256,219	927,762
COMMITMENTS (Notes 12 and 14)		
STOCKHOLDERS' EQUITY (Note 9)		
Capital stock		
Issued and Outstanding		
2002 - 466,602; 2001 - 466,602 Class C special stock	467	467
2002 - 8,571,169; 2001 - 6,321,880 Common stock	26,684,841	22,302,046
	26,685,308	22,302,513
Deficit accumulated during the development stage	(22,061,723)	(18,251,033)
	4,623,585	4,051,480
	$ 5,879,804	$ 4,979,242

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Operations

Years ended December 31, 2002, 2001 and 2000

and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	Cumulative period form August 29, 1996 (date of incorporation) to December 31, 2002
REVENUE				
Licensing income, net (Note 5)	$ 2,770,063	$ 1,747,386	$	$ 4,517,449
Interest income	63,788	174,416	227,718	984,740
	2,833,851	1,921,802	227,718	5,502,189
EXPENSES				
Research and development	4,786,818	2,141,944	1,887,832	11,213,134
General and administration	1,765,624	2,298,659	1,678,581	9,874,521
Depreciation and amortization	92,099	92,560	98,500	566,493
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
	6,644,541	4,533,163	3,664,913	27,563,912
NET LOSS	$ (3,810,690)	$ (2,611,361)	$ (3,437,195)	$ (22,061,723)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.51)	$ (0.40)	$ (0.60)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	7,503,134	6,485,349	5,753,676	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Stockholders Equity

Years ended December 31, 2002, 2001 and 2000

and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002

	Class A Special Shares		Class C Special Shares		Common Stock		Deferred Unearned	Deficit Accumulated During the Development	
	Shares	Amount	Shares	Amount	Shares	Amount	Compensation	Stage	Total
Balance, August 29, 1996, Date of incorporation		$		$		$	$	$	$
Issuance of Class C shares August 29, 1996 ($0.0001 per share)			415,000	415					415
Issuance of Class A shares September 23, 1996 ($0.0001 per share)	2,000,000	2,000							2,000
Issuance of common shares 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)
Balance, December 31, 2002			**466,602**	**467**	**8,571,169**	**26,684,841**		**(22,061,723) 4,623,585**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Years ended December 31, 2002, 2001 and 2000

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	$ (3,810,690)	$ (2,611,361)	$ (3,437,195)	$ (22,061,723)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	92,099	92,560	98,500	566,493
Amortization of deferred unearned compensation		18,000	24,290	42,290
Repurchase of licensing rights		125,000		125,000
Employee compensation paid in shares of common stock			93,000	151,000
Purchased in-process research and development				5,377,000
Loss on disposal of equipment				157,545
Changes in other assets and liabilitiesaffecting cash flows from operations				
Prepaid expenses and other sundry assets	(52,296)	(27,518)	(5,347)	(141,187)
Due from licensee (Teva Pharmaceuticals USA, Inc.)	(520,063)			(520,063)
Accounts payable and accrued expenses	526,473	146,180	102,148	280,729
Due to licensor (Antares/Regents)	(198,016)	433,319	(25,000)	235,303
Due from SBI				(128,328)
Net cash used in operating activities	(3,962,493)	(1,823,820)	(3,149,604)	(15,915,941)
CASH FLOWS USED IN INVESTING ACTIVITIES				
Purchase of capital assets	(38,992)	(86,735)	(43,238)	(1,021,817)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture			500,000	500,000
Proceeds from sale or conversion of shares	4,385,845	3,801,187	30,045	21,324,505
Fractional Share Payout	(3,050)			(3,050)
Net cash provided by financing activities	4,382,795	3,801,187	530,045	21,821,455
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	381,310	1,890,632	(2,662,797)	4,883,697

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**4,502,387**	**2,611,755**	**5,274,552**	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 4,883,697**	**$ 4,502,387**	**$ 2,611,755**	**$ 4,883,697**
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**
	$	**$**	**$**	**$**
Income tax paid	**$**	**$**	**$**	**$**
Interest paid	**$**	**$**	**$**	**$**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Notes to the Financial Statements

For the years ended December 31, 2002, 2001 and 2000, and the cumulative period

from August 29, 1996 (date of incorporation) to December 31, 2002

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 this Form 10-KSB have been adjusted to reflect the reverse stock split.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 4 to the financial statements, the Company s cash resources are limited and additional capital will need to be raised in the near future. The Company s recent activities in regard to this situation are also described in Note 4. The financial statements do not include any adjustments that might result from the success or failure of management to raise additional capital in the near future.

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, the technology for which has been licensed from Antares Pharma, Inc. The 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.

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.

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. R&D is capitalized only when FDA approval has occurred. To date, no R&D expenses have been capitalized.

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, 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.

		2002		2001		2000
Net Loss						
As reported	**$**	**(3,810,690)**	$	(2,611,361)	$	(3,437,195)
Total stock-based employee compensation determined under fair value based method for all awards		**(374,866)**		(890,461)		(523,015)
Net loss, pro forma	**$**	**(4,185,556)**	$	(3,501,822)	$	(3,960,210)
Basic and diluted net loss per share						
As reported	**$**	**(0.51)**	$	(0.40)	$	(0.60)
Pro forma	**$**	**(0.56)**	$	(0.54)	$	(0.69)
Cumulative net loss						
As reported	**$**	**(22,061,723)**				
Total stock-based employee compensation determined under fair value based method for all awards		**(2,818,055)**				
Pro forma	**$**	**(24,879,778)**				

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The weighted average fair value of the options at the date of grant for options granted during 2002, 2001 and 2000 was $2.44, $5.00 and $9.00, 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:

	2002	2001	2000
Expected option life (years)	**10**	10	10
Risk free interest rate	**4.61%**	5.39%	6.03%
Expected stock price volatility	**45.47%**	118.79%	157.06%
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. Interest income on invested cash balances is recognized on the accrual basis as earned.

New Statements of Financial Accounting Standards

In December 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 148, Accounting for Stock Based Compensation Transition and Disclosure, (SFAS 148), which amends SFAS No. 123, Accounting for Stock-Based Compensation to provide alternative methods of transition for an entity that voluntarily changes to the fair value method of accounting for stock-based compensation. This standard also amends disclosure provisions to require prominent disclosures, in both annual and interim financial statements, about the method of accounting for stock-based compensation and the effects of the method used on reporting results. SFAS 148 became effective for financial statements for fiscal years ending after December 15, 2002. The Company has chosen not to convert to the fair value method of accounting for stock-based compensation, and does not believe that adoption of SFAS 148 will have an impact on the Company s financial position or result of operations.

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.

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. FINANCING

On September 6, 2002, the Company raised $4.4 million in a best-efforts, self-underwritten offering of 2,250,000 shares of the Company s common stock. Transaction costs related to the offering have been netted against the proceeds.

The Company currently does not have sufficient resources to complete the commercialization of any of its proposed products. Therefore, the Company will need to raise additional capital in the near future to fund its operations and may be unable to raise such funds when needed and on acceptable terms.

The Company cannot be certain that any financing will be available when needed. If the Company fails to raise additional financing as needed, it may have to delay or terminate product development programs.

5. 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 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 requires the Company to undertake various obligations as described in Note 14.

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 female hormone therapy products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in the Company, make future 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 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, 2002, the amount owed to Antares for such services was $35,303.

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-licensed 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, 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 will 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.

6. PROPERTY AND EQUIPMENT

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

	2002	2001
Computer equipment	**$ 127,179**	$ 101,490
Office equipment	**86,136**	78,051
Laboratory equipment	**108,230**	103,012
Leasehold improvements Laboratory	**477,339**	477,339
	798,884	759,892
Accumulated depreciation and amortization	**(466,995)**	(374,896)
	$ 331,889	$ 384,996

7. INCOME TAXES

The components of the Company s net deferred tax asset at December 31, 2002, 2001 and 2000 were as follows:

	2002	2001	2000
Net operating loss carryforwards	**$ 6,264,525**	$ 4,861,792	$ 3,886,495
Amortization of intangibles	**1,178,212**	1,323,455	1,468,699
Research & development credits	**1,006,817**	580,141	191,358
Other	**90,977**	79,197	60,993
	8,540,531	6,844,585	5,607,545
Valuation allowance	**(8,540,531)**	(6,844,585)	(5,607,545)
	$	$	$

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2002, the Company had approximately $16,931,149 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 2011-2022. 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 $1,006,817 of research and development credits available to reduce future income taxes through the year 2022.

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:

	2002	2001	2000
Tax at U.S. federal statutory rate	**$ (1,333,742)**	$ (887,863)	$ (1,160,388)
State taxes, net of federal benefit	**(365,200)**	(355,149)	(195,854)
Change in valuation allowance	**1,695,946**	1,237,040	1,352,207
Other, net	**2,996**	5,972	4,035
	$	$	$

8. 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.

9. 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.

a) Authorized

Preference shares

An unlimited number of preference shares issuable in series subject to limitation, rights, and privileges as determined by the directors. No preference shares have been issued as of December 31, 2002.

Special Shares

An unlimited number of Class C special shares without par value, 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

An unlimited number of common shares of stock without par value, 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.

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.

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.

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, 2002.

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, 2002, 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, 2002.

10. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 1,000,000 shares of common stock have been reserved for issuance. Options for 997,300 shares of common stock have been granted as of December 31, 2002 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:

	2002	Weighted Average Exercise Price	2001	Weighted Average Exercise Price	2000	Weighted Average Exercise Price
Options outstanding, Beginning of period	**699,467**	$ 3.80	526,312	$ 3.30	497,312	$ 3.00
Options granted	**327,167**	$ 3.71	174,155	$ 5.20	51,000	$ 9.10
Options cancelled/expired	**(29,334)**	$ 3.44	(1,000)	$ 7.50	(22,000)	$ 10.00
Options exercised		$		$		$
Options outstanding, End of period	997,300	$ 3.74	699,467	$ 3.80	526,312	$ 3.30
Options exercisable, End of year	**631,611**	$ 3.55	542,483	$ 3.40	386,502	$ 2.80

The following table summarizes information about stock options outstanding at December 31, 2002:

Range of Exercise Prices	Outstanding Options Number Outstanding	Weighted Avg. Remaining Contractual Life	Weighted Avg. Exercise Price	Options Exercisable Number Outstanding	Weighted Avg. Exercise Price
$ 2.30	237,813	3.2 years	$ 2.30	237,813	$ 2.30
$ 2.80 - $2.90	227,000	2.5 years	$ 2.85	226,500	$ 2.85
$ 3.40 - $6.70	482,487	9.2 years	$ 4.32	117,298	$ 5.06
$ 9.10	50,000	0.9 years	$ 9.10	50,000	$ 9.10
	997,300			631,611	

11. 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 2002, 2001 and 2000 totaled $44,605, $30,743 and $26,296, respectively.

12. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space and laboratory facilities which expire in 2003. The future minimum lease payments during 2003 are $131,784.

Rent expense amounted to $148,184, $119,765 and $82,069 for the years ended December 31, 2002, 2001 and 2000, 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.

13. RELATED PARTY TRANSACTIONS

Included in current liabilities are $2,179, $5,074 and $379 which represent amounts due to directors and officers of the Company as of December 31, 2002, 2001 and 2000, 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 shares. 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 9.

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.

14. COMMITMENTS

University of California License

The Company s license agreement with the University of California requires it to undertake various obligations, including:

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

Payment of minimum annual royalties on February 28 of each year beginning in the year 2004 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
	$ 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 year ended December 31, 2002 have amounted to $12,240 and which management estimates will equal approximately $15,000 per year;

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;

Obtaining government approvals;

Conducting clinical trials; and

Introducing products incorporating the licensed technology into the market.

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

The Company has agreed to indemnify, hold harmless and defend 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 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.

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, 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, regulatory milestones, maintenance payments and royalty payments by the Company if the product gets approved and subsequently marketed.

Future minimum payments due under this agreement are as follows:

Year		Minimum Annual Royalty Due
2004	$	10,000
2005		45,000
2006		55,000
2007		90,000
2008		90,000
2009		40,000
2010		140,000
2011		265,000
2012		165,000
2013		240,000
	$	1,140,000

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.

Item 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISC

PART III

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

Directors, Executive Officers, Promoters and Control Persons

The information under the captions Election of Directors Information About Nominees and Directors and Election of Directors Other Information About Nominees and Directors in our Proxy Statement for our 2003 annual meeting of stockholders is incorporated herein by reference. The information concerning our executive officers is included in this Report under Item 4a, Executive Officers of the Company.

Section 16(a) Beneficial Ownership Reporting Compliance

The information under the caption Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement for our 2003 annual meeting of stockholders is incorporated herein by reference.

Item 10. EXECUTIVE COMPENSATION

The information under the captions Election of Directors Director Compensation and Executive Compensation and Other Benefits in our Proxy Statement for our 2003 annual meeting of stockholders is incorporated herein by reference.

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

The information under the caption Principal Shareholders and Beneficial Ownership of Management in our Proxy Statement for our 2003 annual meeting of stockholders is incorporated herein by reference.

Item 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information under the caption Certain Transactions in our Proxy Statement for our 2003 annual meeting of stockholders is incorporated herein by reference.

PART IV

Item 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

The exhibits to this Report are listed on the Exhibit Index on pages 68 73. 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. Amended and Restated 1998 Stock Option Plan (incorporated by reference to Exhibit 3.1 to BioSante s Registration Statement on Form SB-2 (File No. 333-87542)).

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. 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)).

E. 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)).

F. 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)).

G. Separation and Release Agreement, dated February 1, 2002, between BioSante Pharmaceuticals, Inc. and John E. Lee (incorporated by reference to Exhibit 10.24 to BioSante s Annual Report on Form 10-KSB as filed on March 28, 2002 (File No. 0-28637)).

(a) Exhibits

(b) Reports on Form 8-K

None.

Item 14. CONTROLS AND PROCEDURES

Within the 90 days prior to the filing date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 13a-15 under the Securities Exchange Act of 1934, as amended. Based upon that evaluation, our President and Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of our evaluation.

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 19, 2003

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 19, 2003 by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

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

/s/ Peter Kjaer	Director
Peter Kjaer	

CERTIFICATIONS

I, Stephen M. Simes, certify that:

1. I have reviewed this annual report on Form 10-KSB of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report; and

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report.

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

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

I, Phillip B. Donenberg certify that:

1. I have reviewed this annual report on Form 10-KSB of BioSante Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report; and

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report.

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

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

BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-KSB

FOR THE YEAR ENDED DECEMBER 31, 2002

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)

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	Amended and Restated 1998 Stock Option Plan	Incorporated by reference to Exhibit 10.3 contained in BioSante s Registration Statement on Form SB-2, as amended (File 333-87542)
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 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)

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)

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)

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	Separation and Release Agreement, dated February 1, 2002, between BioSante Pharmaceuticals, Inc. and John E. Lee	Incorporated by reference to Exhibit 10.24 to BioSante s Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.25	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma and BioSante Pharmaceuticals, Inc. (2)	Filed herewith electronically

23.1	Consent of Deloitte & Touche LLP	Filed herewith electronically
99.1	Certifications 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.

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