BIOSANTE PHARMACEUTICALS INC
Form 10KSB40
March 28, 2002

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, 2001

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, Suite 280 Lincolnshire, Illinois	**60069**
(Address of Principal Executive Offices)	(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, 2001 were $1,921,802.

As of March 1, 2002, 63,218,798 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 $22,333,603.

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 2002 Annual Meeting of Stockholders to be held May 21, 2002.

TRANSITIONAL SMALL BUSINESS DISCLOSURE FORMAT (CHECK ONE): YES o NO ý

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EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-KSB

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. 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 or us refer to BioSante Pharmaceuticals, Inc., unless the context otherwise indicates. We own or have the rights to use various trademarks, trade names or service marks, including BioSante , Bio-Vant , NanoVant , CAP-Oral , Bio-Air , Bio-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

Item 1. DESCRIPTION OF BUSINESS

General

We are a development stage biopharmaceutical company that is developing a pipeline of hormone replacement products to treat hormone deficiencies in men and women. We also are engaged in the development of our proprietary calcium phosphate, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants, proprietary novel vaccines, drug delivery systems and to purify the milk of transgenic animals.

To enhance the value of our current pharmaceutical portfolio, we are pursuing the following corporate growth strategies:

accelerate the development of our hormone replacement products;

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

license or otherwise acquire other drugs that will add value to our current product portfolio; and

implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

Our primary focus is to build a pipeline of hormone replacement 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.

Our hormone replacement products, which we license on an exclusive basis from Antares Pharma Inc., are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and a progestogen. The gels are designed to be absorbed quickly through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the

bloodstream evenly and in a non-invasive, painless manner. Human clinical trials have begun on four of our hormone replacement products, a necessary step in the process of obtaining United States Food and Drug Administration, or FDA, approval to market the products.

The following is a list of our hormone replacement gel products in development:

LibiGel a transdermal testosterone gel in Phase II clinical development for treatment of female sexual dysfunction.

Bio-T-Gel a transdermal testosterone gel in development for testosterone deficiency in men.

Bio-E-Gel a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.

Bio-E/P-Gel a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.

LibiGel-E/T a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

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. We have identified four potential initial applications for our CAP technology:

the creation of improved versions of current vaccines by the adjuvant activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response;

the development of new, unique vaccines against diseases for which there currently are few or no effective methods of prevention (*e.g.*, genital herpes);

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 by selectively isolating biologically active therapeutic proteins from the transgenic milk.

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

Bio-Vant CAP adjuvant technology new proprietary CAP technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases.

Bio-Air advanced proprietary technology using CAP as a delivery system for inhalable versions of therapies that currently must be injected.

CAP-Oral an advanced delivery system using proprietary CAP technology for oral administration of therapies that currently must be injected.

CAP biotechnology production use of CAP technology in a new patented process for extracting therapeutic proteins from transgenic milk.

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 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. In June 2001, our stockholders approved the reincorporation of our company to Delaware.

Business Strategy

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

Accelerate the development of our hormone replacement products. We are focused on building a pipeline of hormone replacement 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 hormone replacement 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, we believe these collaborations would 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 technology complementary to our business. We are particularly interested in entering into product co-development and co-marketing arrangements.

License or otherwise acquire other drugs that will add value to our current product portfolio. We intend to seek opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. In seeking these opportunities, we intend to target 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 targeting these 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 intend to seek opportunities to in-license or otherwise acquire products that (1) have FDA approval, (2) have been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience, and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have a full portfolio in development.

Description of Our Hormone Replacement Products

We are focused on building a pipeline of hormone replacement products to treat hormone deficiencies in men and women. Our hormone replacement products 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 a progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

The following is a list our hormone replacement gel products in development:

LibiGel a transdermal testosterone gel in Phase II clinical development for treatment of female sexual dysfunction.

Bio-T-Gel a transdermal testosterone gel in development for testosterone deficiency in men.

Bio-E-Gel a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.

Bio-E/P-Gel a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.

LibiGel-E/T a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

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 replacement therapy has been shown to restore levels of testosterone with minimal side effects.

Testosterone often is delivered through injections or dermal, or skin, patches. Delivery of testosterone through dermal patches was developed primarily to promote the therapeutic effects of testosterone replacement therapy without the often painful side effects associated with testosterone injections. Dermal patches, however, have been associated with skin irritation. Our testosterone formulated gel product for men, Bio-T-Gel, is designed to deliver the required amount of testosterone without the pain of injections

and the skin irritation and discomfort associated with dermal patches. We are aware of one gel testosterone product 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 replacement in women decreases the chance that women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately twenty million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone replacement 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, like testosterone patches, 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.

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product. Women whose uterus is intact often use a combined hormone replacement 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 these women.

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 replacement therapy 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 for women, LibiGel-E/T, for low libido or sex drive.

We believe our hormone replacement 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 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 replacement therapy using gels may allow for better dose adjustment than either patches or oral pills 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 down.

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

We license our hormone replacement products on an exclusive basis from Antares Pharma, Inc. under a license agreement we entered into in June 2000. Under the terms of our license agreement with Antares (which we have amended several times since June 2000), we acquired exclusive development and marketing rights, with the right to grant sub-licenses (1) to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, New Zealand, China, Indonesia and South Africa, (2) for the combination estradiol and progestogen product in the U.S. and Canada, and (3) for a transdermal hormone replacement gel containing a combination of estradiol and testosterone in the U.S., Canada, Mexico, Israel, Australia, New Zealand, Malaysia, China, Indonesia and South Africa.

In September 2000, we sublicensed the marketing rights for our female hormone replacement products to Paladin Labs Inc. in Canada. In August 2001, we sublicensed our estrogen/progestogen combination transdermal hormone replacement gel product to Solvay Pharmaceuticals, B.V. for development and sale in the U.S. and Canada.

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 replacement 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 replacement 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.

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. The key component, calcium phosphate, or CAP, is on the FDA s GRAS (Generally Regarded as Safe) list. 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.

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

Bio-Vant CAP adjuvant technology new proprietary CAP technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases.

Bio-Air advanced proprietary technology using CAP as a delivery system for inhalable versions of therapies that currently must be injected.

CAP-Oral an advanced delivery system using proprietary CAP technology for oral administration of therapies that currently must be injected.

CAP biotechnology production use of CAP technology in a new patented process for extracting therapeutic proteins from transgenic milk.

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 our predecessor company, 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 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 our costs down and potentially improve our profit margins;

the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays, inhalation or orally, 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 that we license from the University of California.

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) through inhalation, orally 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.

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 and marketing.

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 but up to 100 times lower concentrations. 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. 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 Bio-Vant, 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 November 1999, we announced that we formed a collaborative research alliance with Antares Pharma, Inc. to evaluate the efficacy of combining our nanoparticle drug delivery and adjuvant or immune system boosters with Antares needle-free pressure injection. This research alliance evaluated the ability of the combined systems to deliver DNA vaccines as part of a DNA vaccine program at a major U.S. university. In August 2000, we announced initial preclinical results from our collaboration with Antares. The initial tests demonstrated that Antares needle-free pressure assisted injections containing our CAP technology produced better cellular immune responses in the injected animals than the injections without our CAP technology. No further work apropos of CAP and Antares is planned.

In June 2000, we announced an option license agreement with ID Biomedical Corporation to use CAP as an adjuvant in a second-generation vaccine against group-A streptococcus (GAS). GAS is considered a worldwide public health threat causing strep-throat, skin infections, rheumatic fever, invasive fasciitis (flesh eating disease), toxic shock syndrome and other diseases. We believe ID Biomedical has decided to proceed without the use of CAP in their GAS vaccine.

We announced in August 2000, a non-exclusive option license agreement with Antex Biologics, Inc. to conduct preclinical tests of CAP in vaccines against *Chlamydia pneumoniae* and *H. pylori*. This collaboration is ongoing.

In October 2001, we announced a non-exclusive license agreement with Corixa Corporation to use our Bio-Vant vaccine adjuvant in potential vaccines to be development by Corixa. This is the first license agreement signed by BioSante for the development of CAP as a vaccine adjuvant. 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 Bio-Vant and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-Vant, we will share in milestone payments and royalties received by Corixa. The license agreement covers access to Bio-Vant for a variety of cancer, infectious and auto immune disease vaccines.

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 believe we may have successfully created a formulation for the inhaled delivery of insulin, which we call Bio-Air. We are in the process of contacting and meeting the insulin manufacturers and companies with devices for inhalation of drugs to pursue collaborations for this development. Furthermore, we have shown pre-clinical efficacy in the oral delivery of insulin in diabetic mouse models. In the oral insulin mouse models, our product, which we call CAP-Oral, has shown an 80% reduction of glucose levels for 12 hours versus 20-30% glucose reduction for five hours for free insulin. Our research and development efforts in this area are ongoing.

Transgenic Milk Purification. The fourth 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 transgenic milk. 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 very limited sales and marketing personnel to sell on a commercial basis any of our proposed products. If and when we are ready to commercially launch a product, 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 $2,142,000 in 2001 and $1,888,000 in 2000 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 $200,000 to $250,000 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.

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. We will either find our own manufacturing facilities, hire additional personnel with manufacturing experience and comply with the extensive Good Manufacturing Practices, or GMP, regulations of the FDA and other regulations applicable to such a facility or we will more likely rely upon third-party manufacturers to manufacture our proposed products in accordance with these regulations.

In September 1999, we entered into an arrangement with the University of Iowa to manufacture our CAP nanoparticles for use in our Phase I human clinical trial. Under the arrangement, the University of Iowa manufactured both a trial batch of our CAP nanoparticles and a clinical batch which was used in the clinical trial.

Currently, our gel hormone products are manufactured through an exclusive agreement with Antares Pharma, Inc.

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 hormone replacement products for the treatment of testosterone deficiency in men and women and estrogen deficiency in women, including rights to sublicense the hormone replacement technology, in order to develop and market the hormone replacement technology in certain territories. Antares has an issued patent for these technologies 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 BioSante and Antares, BioSante 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, BioSante 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 BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for a transdermal hormone replacement gel combination of testosterone and estradiol.

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 technology 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 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

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 $11,358 in fiscal 2001;

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 one United States patent 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 was 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 vaccine adjuvants, conventional DNA and RNA vaccines and drug delivery, including aerosol delivery into the lungs. In addition, there are two other patent applications pending 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 hormone replacement products. Both applications have 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 registered in the European Union and Israel, and BIO-E-GEL and BIO-T-GEL are registered in Mexico. In addition, there are 17 other applications pending in the European Union and other countries for marks including the BIOSANTE mark. 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 replacement 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 hormone replacement products and products we may develop that incorporate our CAP technology. Several competing companies, including Wyeth-Ayerst Pharmaceuticals, Novartis AG, Solvay Pharmaceuticals, Inc., Noven Pharmaceuticals, Inc. and Berlex Laboratories, Inc., dominate the international hormone replacement 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 replacement 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, ID Biomedical Corporation and Antex Biologicals Inc., 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 eight full-time employees as of December 31, 2001, including six in research and development and two 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 $2,611,361 for the year ended December 31, 2001, and as of December 31, 2001, our accumulated deficit was $18,251,033.

All of our revenue to date has been derived from interest earned on invested funds and license fees. We have not commercially introduced any products. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;

the costs of licensure or acquisition of new products;

the timing and cost of obtaining necessary regulatory approvals; and

the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our own proposed products or 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 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.

We do not anticipate that any of our proposed products will receive the requisite regulatory approvals for commercialization in the United States or abroad until approximately late 2003, or later, if at all, and we cannot assure you that any of our proposed products, if approved and marketed, will generate significant product revenue and provide an acceptable return on our investment.

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 may 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, 2001 was $4,502,387. We believe this cash will be sufficient to fund our operations through December 2002. 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 shareholders, and debt financing, if available, may involve restrictive covenants on our business. 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.

Our strategy to acquire products in the late-stage development phase or products already on the market is risky and the market for acquiring these products is competitive.

We may acquire, through outright purchase, license, joint venture or other methods, products in the late-stage development phase and assist in the final development and commercialization of those products or products already on the market. There are a number of companies that have similar strategies to ours, many of whom have substantially greater resources than us. It is difficult to determine the value of a product that has not been fully developed or commercialized, and the possibility of significant competition for these products may tend to increase the cost to us of these products beyond the point at which we will experience an acceptable return on our investment. We cannot assure you that we will be able to acquire any products on commercially acceptable terms or at all, that any product we may acquire will be approved by the FDA or if approved, will be marketable, or that even if marketed, that we will be able to obtain an acceptable return on our investment.

If we purchase any products, we could issue common or preferred stock that would dilute our existing stockholders percentage ownership, incur substantial debt or assume contingent liabilities by paying cash for such products. For example, we paid a $1.0 million upfront license fee for our hormone replacement products in June 2000. In September 2000, we sublicensed some of these products to a Canadian company and in connection with this transaction and subject to our achieving certain milestones we agreed to sell shares of our common stock to this licensee in the future at a premium of the then market value of our common stock. Purchases of new products also involve numerous other risks, including:

problems assimilating the purchased products;

unanticipated costs associated with the purchase;

incorrect estimates made in the accounting for acquisitions; and

risks associated with entering markets in which we have no or limited prior experience.

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.

If we fail to obtain an adequate level of reimbursement for our products by third party payors, there may be no commercially viable markets for our products.

Our ability to commercialize our products successfully will depend in part upon the price we may be able to charge for our products and on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health insurers and other third party payors. We currently have limited expertise obtaining reimbursement. We will need to seek additional reimbursement expertise unless we enter into collaborations with other companies with the necessary expertise. Even if we are able to obtain reimbursement from third party payors, we cannot be certain that reimbursement rates will be high enough to allow us to profit from sales of our products and realize an acceptable return on our investment in product development.

We license our hormone replacement products and our CAP technology from third parties and may lose the rights to license them.

We license our hormone replacement products from Antares Pharma, Inc. and 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 our hormone replacement 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 replacement products 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 ensure the protection of our intellectual property for a number of other reasons:

We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease 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, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations 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. We are not the stated beneficiary of key person life insurance on any of our key personnel. 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. We also lease approximately 2,600 square feet of office space in Atlanta, Georgia for approximately $3,500 per month. This lease expires in mid-September 2002 and will not be renewed. In September 1999, we entered into a sublease agreement for the Atlanta office space under which we receive approximately $3,400 per month from the sub-tenant through mid-September 2002. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

Item 3. LEGAL PROCEEDINGS

We are not a party to any material 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, 2001.

Item 4A. EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers, their ages and the offices held, as of March 1, 2002, are as follows:

Name	Age	Title
Stephen M. Simes	50	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	41	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	38	Vice President, Clinical Development
Steven J. Bell, Ph.D.	42	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. 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 has traded in the United States in the over-the-counter market on the OTC Bulletin Board, under the symbol BTPH, since May 5, 2000. 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. From September 10, 1999 to May 4, 2000, our common stock was traded in the United States on the National Quotation Bureau, commonly referred to as the Pink Sheets, under the symbol BTPH.

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 and the Pink Sheets. 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.

OTC Bulletin Board

2001	**High**	**Low**
First Quarter	$0.75	$0.38
Second Quarter	$1.07	$0.39
Third Quarter	$1.00	$0.46
Fourth Quarter	$1.05	$0.48

2000	**High**	**Low**
Second Quarter	$1.25	$0.47
Third Quarter	$1.03	$0.80
Fourth Quarter	$0.92	$0.52

National Quotation Bureau (Pink Sheets)

2000	**High**	**Low**
First Quarter	$1.50	$0.28

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	$0.72	$0.46
Second Quarter	$1.07	$0.35
2000		
First Quarter	$1.38	$0.22
Second Quarter	$1.07	$0.46
Third Quarter	$1.01	$0.71
Fourth Quarter	$0.95	$0.49

Number of Record Holders; Dividends

As of March 1, 2002, there were 1,624 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, 2001, 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, 2001. Options granted in the future under the plan are within the discretion of BioSante s Compensation Committee and therefore cannot be ascertained at this time.

	(a)	**(b)**	**(c)**
Plan Category	**Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights**	**Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights**	**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	6,994,657	$0.38	1,505,343
Equity compensation plans not approved by security holders	0	N/A	0
Total	6,994,657	$0.38	1,505,343

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 2002 Annual Meeting of Stockholders is to approve an increase in the number of shares of our common stock available for issuance under the plan by 1,500,000 shares of common stock. We do not have any other equity compensation plans.

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

General

We are a development stage biopharmaceutical company engaged in the development and commercialization of hormone replacement products to treat hormone deficiencies in men and women. We also are engaged in the development and commercialization of vaccine adjuvants or immune system boosters, proprietary novel vaccines, drug delivery systems and the purification of the milk of transgenic animals, all applications using calcium phosphate nanoparticles, or CAP.

Our hormone replacement products, which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone deficiencies that affect both men and women.

The following is a list of our hormone replacement gel products in development:

LibiGel a transdermal testosterone gel in Phase II clinical development for treatment of female sexual dysfunction.

Bio-T-Gel a transdermal testosterone gel in development for testosterone deficiency in men.

Bio-E-Gel a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms

Bio-E/P-Gel a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.

LibiGel-E/T a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

These gel products 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 development and 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, New Zealand, China and South Africa. We acquired exclusive development and 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 replacement products, we paid Antares an upfront license fee of $1.0 million. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, after all necessary regulatory approvals are received, pay royalties to Antares on sales of the products.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante 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, BioSante 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 BioSante a credit for approximately

$600,000 of manufacturing and formulation services and a license for a transdermal hormone replacement gel combination of estradiol and testosterone.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone replacement 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 BioSante 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 $1.05 per share. On August 13, 2001, BioSante exercised its right and declared the debenture converted in full. Accordingly, 476,190 shares of BioSante common stock were issued to Paladin on August 23, 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 BioSante issuing an additional 189,394 shares of its common stock to Paladin.

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 replacement 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 replacement 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 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

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

Our strategy with respect to our CAP technology over the next 12 months is to continue development and actively 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.

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

Our goal is to develop and commercialize our portfolio of hormone replacement 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:

Accelerate the development of our hormone replacement products

Continue to develop 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.

License or otherwise acquire other drugs that will add value to our current product portfolio.

We currently expect to add employees as we continue to develop and commercialize our hormone replacement products and products incorporating our CAP technology or in-license or otherwise acquire products in late-stage human clinical development.

All of our revenue to date has been derived from interest earned on invested funds and license payments earned on sub-licensing transactions. We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $2,611,361 for the year ended December 31, 2001, resulting in an accumulated deficit of $18,251,033. We expect to incur substantial and continuing losses for the foreseeable future as our product development programs expand and various preclinical and clinical trials commence. 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 approvals; and

the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our proposed products in pre-clinical development, in late-stage human clinical development, 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.

Results of Operations

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

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% is 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.

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 is the result of increased expenses during the year ended December 31, 2001 associated with the clinical development of our hormone replacement 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. As a result of our hormone replacement product in-license agreement with Antares, we expect to continue to incur significant expenses, primarily relating to our research and development activities. Management estimates that it is currently expending approximately $200,000 to $250,000 per month on research and development activities and approximately $350,000 to $400,000 per month in total expenses, including research and development activities. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds dedicated to research and development activities. The amount of BioSante s 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.

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 replacement 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 replacement 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 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

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 expect interest income to decline in future periods as we use our cash balances for operations.

BioSante 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 is 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 BioSante 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 replacement product portfolio and payment to Antares for certain manufacturing and formulation services. We anticipate that our operating losses will continue for the foreseeable future.

Year Ended December 31, 2000 Compared to Year Ended December 31, 1999

General and administrative expenses increased from $853,389 during the year ended December 31, 1999 to $1,678,581 during the year ended December 31, 2000. This increase of approximately 97% is 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.

Research and development expenses increased from $660,588 during the year ended December 31, 1999 to $1,887,832 during the year ended December 31, 2000. This overall increase is the result of a $1.0 million upfront license fee paid to Antares during the year ended December 31, 2000 and increased expenses related to the clinical development of our hormone replacement product portfolio.

Interest income increased from $198,683 during the year ended December 31, 1999 to $227,718 during the year ended December 31, 2000 as a result of higher average cash balances in 2000.

BioSante incurred a net loss of $3,437,195 for the year ended December 31, 2000, compared to a net loss of $1,406,259 for the year ended December 31, 1999. The overall increase in the net loss is the result of a $1.0 million upfront license fee paid to Antares during the year ended December 31, 2000, in addition to increases in (1) personnel-related expenses, (2) legal expenses related to increased patent, collaboration and licensing activities, and (3) expenses associated with the clinical development of our hormone replacement product portfolio.

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 $12.9 million from private equity financings, class A and class C stock conversions, warrant exercises and in the third quarter 2000, the issuance of a $500,000 convertible debenture, which was converted into 476,190 shares of common stock in the third quarter of 2001. In addition, as a result of licensing upfront payments and milestones, we have received an additional $2.1 million.

Our cash and cash equivalents were $4,502,387 and $2,611,755 at December 31, 2001 and 2000, respectively. The increase in our cash balance is due to our $3.7 million private placement that closed in April 2001, and the $2.5 million upfront payment received from Solvay in 2001 from the sub-license of one of our hormone replacement transdermal gel products, offset by continued expenditures related to the clinical development of our hormone replacement products.

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 replacement product portfolio 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 replacement products.

We used cash in operating activities of $3,149,604 for the year ended December 31, 2000 versus cash used in operating activities of $1,787,822 for the year ended December 31, 1999. This change was driven by the increase in research and development expenses, including the hormone product portfolio in-license upfront payment of $1.0 million to Antares Pharma, Inc. during 2000. Net cash used in investing activities was $43,238 for the year ended December 31, 2000 versus $4,219 for the year ended December 31, 1999. The significant uses of cash in investing activities for the year ended December 31, 2000 were capital expenditures for the purchase of office furniture and computer equipment. The significant uses of cash in investing activities for the year ended December 31, 1999 included capital expenditures for office furniture and a computer. Net cash provided by financing activities was $530,045 for the year ended December 31, 2000 compared to $4,225,343 for the year ended December 31, 1999. 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 replacement products. Net cash provided in 1999 was primarily the result of our private placement in May 1999.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will likely 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. We expect to continue to spend capital on:

research and development programs;

pre-clinical studies and clinical trials;

regulatory processes;

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

the licensure or acquisition of new products

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

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

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

time and cost necessary to obtain regulatory approvals;

time and cost necessary to seek third party manufacturers to manufacture our products for us;

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.

Commitments

We have several financial commitments, including those relating to our license agreement with the University of California.

Under our license agreement with the University of California, we are required to:

pay 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;

maintain 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; and

pay the costs of patent prosecution and maintenance of the patents included in the agreement.

In addition, our license agreement with Antares, the licensor of our hormone 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, we also have minimum annual lease payments.

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	$ 274,688	$ 142,811	$ 131,877		

Commitments Under License Agreement with UCLA	6,800,000			50,000	$ 250,000	$ 6,500,000
Total Contractual Cash Obligations	$ 7,074,688	$ 142,811	$	181,877	$ 250,000	$ 6,500,000

The capital equipment expenditures of $86,735 during 2001 were principally for the acquisition of office furniture and computer equipment. We expect to spend approximately $25,000 to $50,000 in capital expenditures during the next 12 months.

Outlook

Based on our current cash resources, we believe we should be able to maintain our current pace and level of expenditures through December 2002, 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 2002. We are in the process of exploring alternatives for raising additional financing. We currently have no commitments for additional funding and so our ability to meet our long-term liquidity needs 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

On July 20, 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations (SFAS 141) and SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). These statements establish new accounting and reporting standards for business combinations and associated goodwill and intangible assets. They require, among other things, elimination of the pooling of interests method of accounting, no amortization of acquired goodwill, and a periodic assessment for impairment of all goodwill and intangible assets acquired in a business combination. SFAS 141 is effective for all business combinations accounted for by the purchase method that are completed after June 30, 2001. SFAS 142 will be effective for our fiscal year beginning January 1, 2002.

On August 16, 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations . The pronouncement addresses the recognition and remeasurement of obligations associated with the retirement of tangible long-lived assets. On October 3, 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets . SFAS 144, which supercedes SFAS No. 121 Accounting for Long-lived Assets and for Long-Lived Assets to be Disposed Of and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions, applies to long-lived assets (including discontinued operations) and it develops one accounting model for long-lived assets that are to be disposed of by sale. SFAS 143 will be effective for our fiscal year beginning January 1, 2003. SFAS 144 will be effective for our fiscal year beginning January 1, 2002.

The Company does not believe that the issuance of these pronouncements will have an impact on its financial statements.

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 exposure.

Item 7. FINANCIAL STATEMENTS

Description

Independent Auditors Report

Balance Sheets as of December 31, 2001 and 2000

Statements of Operations for the years ended December 31, 2001, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

Statements of Stockholders Equity for the years ended December 31, 2001, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

Statements of Cash Flows for the years ended December 31, 2001, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

Notes to the Financial Statements for the years ended December 31, 2001, 2000 and 1999 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

We are exposed to interest rate risk on the investments of our excess cash. The primary objective of our investme

Independent Auditors Report

Board of Directors

BioSante Pharmaceuticals, Inc.

Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (a development stage company) as of December 31, 2001 and 2000 and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2001, and for the period from August 29, 1996 (date of incorporation) through December 31, 2001. 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. The Company s financial statements for the period from August 29, 1996 (date of incorporation) through December 31, 1998 were audited by other auditors whose report, dated February 19, 1999, expressed an unqualified opinion on those statements. The financial statements for the period August 29, 1996 (date of incorporation) through December 31, 1998 reflect total revenues and net loss of $320,135 and $10,796,218, respectively, of the related totals. The other auditors report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such prior period, is based solely on the report of such other auditors.

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 and the report of other auditors, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2001 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, and for the period from August 29, 1996 (date of incorporation) through December 31, 2001 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 15, 2002
Chicago, Illinois

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Balance Sheets

December 31, 2001 and 2000

	2001	2000
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 4,502,387	$ 2,611,755
Prepaid expenses and other sundry assets	91,859	64,341
	4,594,246	2,676,096
PROPERTY AND EQUIPMENT, NET (Note 5)	384,996	390,821
	$ 4,979,242	$ 3,066,917
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 12)	$ 90,653	$ 44,746
Accrued compensation	379,346	258,598
Other accrued expenses	24,444	137,919
Due to Antares (Note 4)	433,319	
Convertible debenture (Notes 7 and 13)		500,000
	927,762	941,263
COMMITMENTS (Notes 11 and 13)		
STOCKHOLDERS EQUITY (Note 8)		
Capital stock		
Issued and Outstanding		
2001 4,666,024; 2000 4,687,684 Class C special stock	467	469
2001 63,218,798; 2000 52,952,943 Common stock	22,302,046	17,782,857
	22,302,513	17,783,326
Deferred unearned compensation		(18,000)
Deficit accumulated during the development stage	(18,251,033)	(15,639,672)
	4,051,480	2,125,654
	$ 4,979,242	$ 3,066,917

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Operations

Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	Year ended December 31, 2001	Year ended December 31, 2000	Year ended December 31, 1999	Cumulative period from August 29, 1996 (date of incorporation to) December 31, 2001
REVENUE				
Licensing income, net (Note 4)	$ 1,747,386	$	$	$ 1,747,386
Interest income	174,416	227,718	198,683	920,952
	1,921,802	227,718	198,683	2,668,338
EXPENSES				
Research and development	2,141,944	1,887,832	660,588	6,426,316
General and administration	2,298,659	1,678,581	853,389	8,108,897
Depreciation and amortization	92,560	98,500	90,965	474,394
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
	4,533,163	3,664,913	1,604,942	20,919,371
NET LOSS	$ (2,611,361)	$ (3,437,195)	$ (1,406,259)	$ (18,251,033)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.04)	$ (0.06)	$ (0.03)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	64,853,492	57,536,761	49,424,140	

See accompanying notes to the financial statements.

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BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Stockholders Equity

Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	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)			4,150,000	415					415
Issuance of Class A shares September 23, 1996									
($0.0001 per share)	20,000,000	2,000							2,000
Issuance of common shares									
September 23, 1996					4,100,000	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)					7,434,322	4,545,563			4,545,563
Exercise of Series X warrants (Note 7)					215,714	275,387			275,387
Exercise of Series Z warrants (Note 7)					1,428	2,553			2,553
Net loss								(6,246,710)	(6,246,710)
Balance, December 31, 1996	20,000,000	2,000	4,150,000	415	11,751,464	8,513,503		(6,246,710)	2,269,208
Conversion of shares									
January 13, 1997			(282,850)	(28)	282,850	70,741			70,713
January 13, 1997			(94,285)	(9)	94,285	23,580			23,571
December 2, 1997			(106,386)	(11)	106,386	26,607			26,596
December 2, 1997			(100,000)	(10)	100,000	25,010			25,000
Exercise of Series V warrants (Note 7)					24,000	36,767			36,767
Exercise of Series X warrants (Note 7)					28,571	36,200			36,200
Exercise of Series W warrants (Note 7)					20,000	25,555			25,555
Adjustment for partial shares issued									
upon amalgamation					130				
Financing fees reversed						410,000			410,000
Net loss								(1,890,093)	(1,890,093)
Balance, December 31, 1997	20,000,000	2,000	3,566,479	357	12,407,686	9,167,963		(8,136,803)	1,033,517
Conversion of shares									
March 4, 1998			(20,000)	(2)	20,000	5,002			5,000
March 16, 1998			(10,000)	(1)	10,000	2,501			2,500
May 8, 1998	(15,000,000)	(1,500)			15,000,000	3,751,500			3,750,000

June 1, 1998	(1,000,000)	(100)			1,000,000	250,100			250,000
June 1, 1998	(1,000,000)	(100)			1,000,000	250,100			250,000
Return of shares to treasury									
May 8, 1998	(1,468,614)	(147)							(147)
May 8, 1998			(250,000)	(25)					(25)
Net loss								(2,659,415)	(2,659,415)
Balance, December 31, 1998	1,531,386	153	3,286,479	329	29,437,686	13,427,166		(10,796,218)	2,631,430
Conversion of shares									
February 2, 1999			(10,000)	(1)	10,000	2,501			2,500
Private placement of common shares, net									
May 6, 1999					23,125,000	4,197,843			4,197,843
Share redesignation									
July 13, 1999	(1,531,386)	(153)	1,531,386	153					
Issuance of common shares									
August 15, 1999					70,000	25,000			25,000
Net loss								(1,406,259)	(1,406,259)
Balance, December 31, 1999			4,807,865	481	52,642,686	17,652,510		(12,202,477)	5,450,514
Conversion of shares									
March 17, 2000			(10,000)	(1)	10,000	2,501			2,500
March 24, 2000			(31,840)	(3)	31,840	7,963			7,960
June 12, 2000			(50,000)	(5)	50,000	12,505			12,500
July 13, 2000			(28,341)	(3)	28,341	7,088			7,085
Issuance of common shares									
July 18, 2000					190,076	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			4,687,684	469	52,952,943	17,782,857	(18,000)	(15,639,672)	2,125,654
Conversion of shares									
September 15, 2001			(11,660)	(1)	11,660	2,916			2,915
December 15, 2001			(10,000)	(1)	10,000	2,501			2,500
Private placement of common shares, net									
April 4, 2001					9,250,000	3,659,408			3,659,408
Issuance of common shares									
August 15, 2001					155,000	93,000			93,000
August 15, 2001					476,190	500,000			500,000
September 15, 2001					173,611	125,000			125,000
September 15, 2001					189,394	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		$	4,666,024	$ 467	63,218,798	$22,302,046	$	(18,251,033)	$4,051,480

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	Year ended December 31, 2001	Year ended December 31, 2000	Year ended December 31, 1999	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	$ (2,611,361)	$ (3,437,195)	$ (1,406,259)	$ (18,251,033)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	92,560	98,500	90,965	474,394
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	58,000	151,000
Purchased in-process research and development				5,377,000
Loss on disposal of equipment				157,545
Changes in other assets and liabilities affecting cash flows from operations				
Prepaid expenses and other sundry assets	(27,518)	(5,347)	16,272	(88,891)
Accounts payable and accrued expenses	146,180	102,148	(444,483)	(245,744)
Due to licensor (Antares/Regents)	433,319	(25,000)	(102,317)	433,319
Due from SBI				(128,328)
Net cash used in operating activities	(1,823,820)	(3,149,604)	(1,787,822)	(11,953,448)
CASH FLOWS USED IN INVESTING ACTIVITIES				
Purchase of capital assets	(86,735)	(43,238)	(4,219)	(982,825)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture		500,000		500,000
Proceeds from sale or conversion of shares	3,801,187	30,045	4,225,343	16,938,660
Net cash provided by financing activities	3,801,187	530,045	4,225,343	17,438,660
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,890,632	(2,662,797)	2,433,302	4,502,387
	2,611,755	5,274,552	2,841,250	

CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD				
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 4,502,387**	**$ 2,611,755**	**$ 5,274,552**	**$ 4,502,387**
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, 2001, 2000, 1999, and the cumulative period
from August 29, 1996 (date of incorporation) to December 31, 2001

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 7,434,322 subordinate voting shares of BAT (1 such share for every 3 1/2 shares held in SBI). On November 10, 1999, BAT changed its name to BioSante Pharmaceuticals, Inc. (the Company).

The Company was established to develop prescription pharmaceutical products, vaccines and vaccine adjuvants 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 replacement 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

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 costs are charged to expense as incurred.

Basic and Diluted Net Loss Per Share

The basic and diluted net loss per share is computed based on the weighted average number of the aggregate of common stock and Class C shares outstanding, all being considered as equivalent of one another. Basic 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, 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 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. 123, Accounting for Stock-Based Compensation, requires certain additional disclosures of the pro

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BIOSANTE PHARMACEUTICALS, INC.
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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 Company has disclosed the required pro forma net loss and loss per share data in Note 9 as if the Company had recorded compensation expense using the fair value method per SFAS No. 123. 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. 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

The Company adopted SFAS No. 133, Accounting for Derivatives Instruments and Hedging Activities, effective January 1, 2001. This Statement establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. No cumulative transition adjustment was required.

On July 20, 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations (SFAS 141), and SFAS No. 142, Goodwill and Other Intangible Assets (SFAS 142). These statements establish new accounting and reporting standards for business combinations and associated goodwill and intangible assets. They require, among other things, elimination of the pooling of interests method of accounting, no amortization of acquired goodwill, and a periodic assessment for impairment of all goodwill and intangible assets acquired in a business combination. SFAS 141 is effective for all business combinations accounted for by the purchase method that are completed after June 30, 2001. SFAS 142 will be effective for the Company s fiscal year beginning January 1, 2002.

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

On August 16, 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. The pronouncement addresses the recognition and remeasurement of obligations associated with the retirement of tangible long-lived assets. On October 3, 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS 144, which supercedes SFAS No. 121 Accounting for Long-lived Assets and for Long-Lived Assets to be Disposed Of and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions, applies to long-lived assets (including discontinued operations) and it develops one accounting model for long-lived assets that are to be disposed of by sale. SFAS 143 will be effective for the Company s fiscal year beginning January 1, 2003. SFAS 144 will be effective for the Company s fiscal year beginning January 1, 2002.

The Company does not believe that the issuance of these four new pronouncements will have an impact on its financial statements.

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 7,434,322 shares of common stock of the Company (1 such share for every 3½ 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**

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
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3. ACQUISITION (continued)

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 for the 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. LICENSE AND SUPPLY AGREEMENTS

On June 13, 2000, BioSante entered into a licensing agreement and a supply agreement with Antares Pharma, Inc. (Antares), covering four hormone products for the treatment of hormone deficiencies in men and women. The agreement requires BioSante to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, BioSante is also obligated to make milestone payments upon the occurrence of certain future events. Under terms of the supply agreement, Antares has agreed to manufacture or have manufactured and sell exclusively

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
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4. LICENSE AND SUPPLY AGREEMENTS (continued)

to BioSante, and BioSante has agreed to purchase exclusively from Antares, BioSante s total requirements for the products covered under the license agreement between the two parties.

As allowed by the licensing agreement with Antares, on September 1, 2000, BioSante entered into a sub-license agreement with Paladin Labs Inc. (Paladin) to market the female hormone replacement products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in BioSante, 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 BioSante s common stock at a 10% premium to the market price of BioSante s common stock at the date of the equity investment.

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 BioSante issuing an additional 189,394 shares of its common stock to Paladin at a 10 percent premium to BioSante 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 between BioSante and Antares, BioSante 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, BioSante 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 BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for an undisclosed transdermal hormone replacement gel product. 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, 2001, the amount owed to Antares for such services was $433,319.

On August 7, 2001, BioSante 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 replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay has sub-licensed BioSante s estrogen/progestogen combination transdermal hormone replacement gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. Solvay will be responsible for all costs of development and marketing of the product. BioSante has retained co-promotion rights to the product and will be compensated for sales generated by BioSante 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 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

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4. LICENSE AND SUPPLY AGREEMENTS (continued)

On October 1, 2001, BioSante sub-licensed its Bio-Vant™ 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 BioSante milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using Bio-Vant™ and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-Vant™, BioSante will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to Bio-Vant™ for a variety of cancer, infectious and autoimmune disease vaccines.

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 as described in Note 13.

5. PROPERTIES AND EQUIPMENT

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

		2001		**2000**
Computer equipment	**$**	**101,490**	$	61,643
Office equipment		**78,051**		34,208
Laboratory equipment		**103,012**		103,012
Leasehold improvements Laboratory		**477,339**		474,294
		759,892		673,157
Accumulated depreciation and amortization		**(374,896)**		(282,336)
	$	384,996	$	390,821

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
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6. INCOME TAXES

The components of the Company s net deferred tax asset at December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Net operating loss carryforwards	**$ 4,861,792**	$ 3,886,495	$ 2,367,292
Amortization of intangibles	**1,323,455**	1,468,699	1,613,942
Research & development credits	**580,141**	191,358	235,310
Other	**79,197**	60,993	38,794
	6,844,585	5,607,545	4,255,338
Valuation allowance	**(6,844,585)**	(5,607,545)	(4,255,338)
	$	$	$

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2001, the Company had approximately $13,140,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2011-2021. 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 $580,000 of research and development credits available to reduce future income taxes through the year 2014.

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate of 34% to pre-tax income as follows:

	2001	2000	1999
Tax at U.S. federal statutory rate	**$ (887,863)**	$ (1,160,388)	$ (469,799)
State taxes, net of federal benefit	**(355,149)**	(195,854)	(91,015)
Change in valuation allowance	**1,237,041**	1,352,207	556,972
Other, net	**5,971**	4,035	3,842
	$	$	$

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7. CONVERTIBLE DEBENTURE

In September 2000, in connection with entering into a sub-license agreement, the Company issued a convertible debenture to Paladin Labs Inc. (Paladin) in the face amount of $500,000. The debenture did not bear interest and was due September 1, 2001, unless converted into shares of the Company s common stock. On August 13, 2001, the Company exercised its right and declared the debenture converted in full at a price of $1.05 per share. Accordingly, 476,190 shares of the Company s common stock were issued to Paladin. This was a non-cash financing transaction.

8. STOCKHOLDERS EQUITY

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

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, 2001.

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. $0.25. 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 20,000,000 shares of the Company s Class A stock for $0.0001 per share, 4,150,000 shares of Class C stock for $0.0001 per share and 4,100,000 shares of the Company s common stock for $1.00 per share.

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8. STOCKHOLDERS EQUITY (continued)

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 7,434,322 shares of common stock of the Company (1 common share of the Company for every 3½ 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 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. Pursuant to the agreement, Dr. Ben-Abraham converted shares of the Company s Class A stock held by him into 15,000,000 shares of common stock at $0.25 per share for proceeds to the Company of $3,750,000. In addition, Dr. Ben-Abraham agreed to return to the Company 1,468,614 shares of Class A stock and 250,000 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 2,000,000 shares of common stock pursuant to the conversion of Class A stock at a conversion price of $0.25 per share.

On May 6, 1999, the Company sold an aggregate of 23,125,000 common shares and warrants to purchase 11,562,500 shares of common stock at an exercise price of $0.30 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 70,000 shares of common stock.

In July 2000, 190,076 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 9,250,000 common shares and warrants to purchase 4,625,000 shares of common stock at an exercise price of $0.50 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.

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8. STOCKHOLDERS EQUITY (continued)

During the third quarter 2001, Paladin made a series of equity investments in BioSante as result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 189,394 shares of its common stock to Paladin at a 10 percent premium to BioSante 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, BioSante 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 replacement 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 173,611 shares of BioSante common stock with a market value of $125,000 at the date of the transaction.

In August 2001, 155,000 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 $1.05 per share. See Note 7. Accordingly, 476,190 shares of the Company s common stock were issued to Paladin.

b) Warrants

The Company, upon the acquisition of SBI, assumed 2,577,129 exercisable warrants to purchase common stock, all of which expired prior to or as of December 31, 1998. Of this amount, 72,571 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 11,562,500 shares of common stock were issued at an exercise price of $0.30 per share with a term of five years. These warrants remain outstanding and are all exercisable as of December 31, 2001.

In June 2000, a five-year warrant to purchase 250,000 shares of common stock at an exercise price of $0.88 was issued to a communications firm for various consulting services. The warrant vests quarterly over the first year. As of December 31, 2001, all 250,000 of these shares were exercisable. The Company recognized expense of approximately $18,000 for this warrant grant in 2000 and 2001.

Pursuant to the Company s private placement financing in April 2001, warrants to purchase an aggregate of 4,625,000 shares of common stock were issued at an exercise price of $0.50 per share with a term of five years. These warrants remain outstanding and are all exercisable as of December 31, 2001.

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9. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 8,500,000 shares of common stock have been reserved for issuance. Options for 6,994,657 shares of common stock have been granted as of December 31, 2001 at prices equal to either the ten-day weighted average closing price, or the closing 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 five or ten years from the date of the grants.

The Company applies APB Opinion No. 25 and related interpretations in accounting for its plan. Accordingly, no compensation cost has been recognized for the plan. Had the compensation cost for the Company s plan been determined based on the fair value of the awards under the plan consistent with the method of SFAS No. 123 the Company s net loss, cumulative net loss, and basic net loss per common share would have been increased to the pro forma amounts indicated below:

	2001	2000	1999
Net loss			
As reported	**$ (2,611,361)**	$ (3,437,195)	$ (1,406,259)
Pro forma	**$ (3,501,822)**	$ (3,960,210)	$ (1,713,693)
Basic and diluted net loss per share			
As reported	**$ (0.04)**	$ (0.06)	$ (0.03)
Pro forma	**$ (0.05)**	$ (0.07)	$ (0.03)
Cumulative net loss			
As reported	**$ (18,251,033)**		
Pro forma	**$ (20,318,982)**		

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9. STOCK OPTIONS (continued)

The weighted average fair value of the options at the date of the grant for options granted during 2001, 2000 and 1999 was $0.50, $0.90 and $0.33 was estimated using the Cox Rubinstein binomial model and the Black-Scholes option-pricing model with following weighted average assumptions:

	2001	2000	1999
Expected option life (years)	**10**	10	5
Risk free interest rate	**5.39**%	6.03%	4.59%
Expected stock price volatility	**118.79**%	157.06%	238.08%
Dividend yield			

The following table summarizes the Company s stock option activity:

	2001	Weighted Average Exercise Price	2000	Weighted Average Exercise Price	1999	Weighted Average Exercise Price
Options outstanding, Beginning of period	**5,263,125**	$ 0.33	4,973,125	$ 0.30	2,465,000	$ 0.37
Options granted	**1,741,532**	$ 0.52	510,000	$ 0.91	3,068,125	$ 0.24
Options cancelled/expired	**(10,000)**	$ 0.75	(220,000)	$ 1.00	(560,000)	$ 0.31
Options exercised		$		$		$
Options outstanding, End of period	6,994,657	$ 0.38	5,263,125	$ 0.33	4,973,125	$ 0.30
Options exercisable, End of year	**5,424,835**	$ 0.34	3,865,025	$ 0.28	2,117,113	$ 0.35

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9. STOCK OPTIONS (continued)

The following table summarizes information about stock options outstanding at December 31, 2001:

	Outstanding Options				Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life	Weighted Avg. Exercise Price	Number Outstanding	Weighted Avg. Exercise Price
$ 0.23	2,378,125	2.2 years	$ 0.23	2,255,713	$ 0.23
$ 0.28 $0.29	2,325,000	2.1 years	$ 0.28	2,315,000	$ 0.28
$ 0.40 $0.67	1,741,532	9.2 years	$ 0.52	304,122	$ 0.53
$ 0.91 $1.04	550,000	8.5 years	$ 0.92	550,000	$ 0.92
	6,994,657			5,424,835	

10. RETIREMENT PLAN

In July 1998, the Company began offering 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 2001, 2000 and 1999 totaled $30,743, $26,296 and $23,899, respectively.

11. LEASE ARRANGEMENTS

The Company has entered into lease commitments for rental of its office space and laboratory facilities. The future minimum lease payments are:

2002	**$142,811**
2003	**131,877**
Thereafter	
	$274,688

Rent expense amounted to $119,765, $82,069 and $89,110 for the years ended December 31, 2001, 2000 and 1999, respectively. Effective September 16, 1999, the Company entered into a sublease agreement for its Atlanta office space under which the Company receives approximately $3,400 per month from the sub-tenant through September 14, 2002.

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12. RELATED PARTY TRANSACTIONS

Included in current liabilities are $5,074, $379, and $5,588 which represent amounts due to directors and officers of the Company as of December 31, 2001, 2000 and 1999, respectively.

Prior to the Amalgamation on December 6, 1996, the Company issued 20,000,000 shares of class A stock and 4,150,000 shares of class C stock for $0.0001 per shares. 17,000,000 of the class A shares were sold to a director of the Company. 1,050,000 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; 500,000 of the class C shares were sold to a separate company controlled by a then officer of the Company; and 2,000,000 of the class C shares were sold to other directors of the Company.

The 20,000,000 class A shares and 4,150,000 class C shares were founder s shares and the terms under the authorization of these shares, provided for their conversion to common stock at $0.25 per share.

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

In connection with the May 1999 private placement of 23,125,000 shares of common stock and warrants to purchase 11,562,500 shares of common stock, the Company s Chief Executive Officer purchased 250,000 shares of the common stock sold and warrants to purchase 125,000 shares of common stock. Three other individuals, who purchased either individually or through affiliated entities, an aggregate 10,250,000 shares of common stock and warrants to purchase 5,125,000 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 9,250,000 shares of common stock and warrants to purchase 4,625,000 shares of common stock, the Company s Chief Executive Officer, Chief Financial Officer and other senior officers purchased an aggregate of 528,750 shares of the common stock sold and warrants to purchase 264,375 shares of common stock. Three directors, either individually or through affiliated entities, purchased an aggregate 3,125,000 shares of common stock and warrants to purchase 1,562,500 shares of common stock.

13. 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;

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13. COMMITMENTS (continued)

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, 2001 have amounted to $11,358 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.

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13. COMMITMENTS (continued)

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.

Antares Pharma, Inc. License

The Company s license agreement with Antares Pharma, Inc. (formerly known as Permatec Technologie, AG) 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.

The Company s sub-license agreement in Canada (of the Antares license) with Paladin Labs Inc. required Paladin to make an initial investment in the Company of $500,000 in the form of a convertible debenture. On August 13, 2001, the Company exercised its right and declared the convertible debenture converted in full at a price of $1.05 per share. Accordingly, 476,190 shares of the Company s common stock were issued to Paladin.

Paladin will also make milestone payments to the Company in the form of a series of equity investments at a 10 percent premium to the Company s market price at the time the equity investment is made. In addition, Paladin will pay the Company a royalty on sales of the sub-licensed products.

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

None.

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 2002 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 2002 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 2002 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 2002 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 2002 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 63 67. 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, Suite 280, 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 10.3 to BioSante s Annual Report on Form 10-KSB as filed on March 30, 2001 (File No. 0-28637))

B. Stock Option Agreement, dated December 7, 1997, between BioSante Pharmaceuticals, Inc. and Edward C. Rosenow, III, M.D. (incorporated by reference to Exhibit 10.5 to BioSante s Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 0-28637)).

C. Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante s executive officers (filed herewith electronically).

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 August 1, 2000, between BioSante Pharmaceuticals, Inc. and John E. Lee (incorporated by reference to Exhibit 10.18 to BioSante s Annual Report on Form 10-KSB as filed on March 30, 2001 (File No. 0-28637)).

F. 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)).

G. Employment Agreement, dated October 1, 2000, between BioSante Pharmaceuticals, Inc. and Steven J. Bell, Ph.D. (filed herewith electronically).

H. Separation and Release Agreement, dated February 1, 2002, between BioSante Pharmaceuticals, Inc. and John E. Lee (filed herewith electronically).

(b) Reports on Form 8-K

On November 20, 2001, BioSante filed a Current Report on Form 8-K containing a current description of BioSante s securities.

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 20, 2002

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 20, 2002 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/ Avi Ben-Abraham, M.D. Avi Ben-Abraham, M.D.	Director
/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

BIOSANTE PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-KSB

FOR THE YEAR ENDED DECEMBER 31, 2001

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 No. 333-64218)
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	Filed herewith electronically
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)

10.13	Supply Agreement, dated June 13, 2000, between Permatec Technologie, AG and BioSante Pharmaceuticals, Inc. (1)	Incorporated by reference to Exhibit 10.2 contained in BioSante s Current Report on Form 8-K on July 11, 2000 (File No. 0-28637)
10.14	Employment Agreement, dated August 1, 2000, between BioSante Pharmaceuticals, Inc. and John E. Lee	Incorporated by reference to Exhibit 10.18 to BioSante s Annual Report on Form 10-KSB filed on March 30, 2001(File No. 0-28637)
10.15	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)
10.16	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	Sublease Agreement, dated August 29, 2001, between ICON InfoSystems, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.20 to BioSante s Registration Statement on Form SB-2, as amended, (File No. 333-64218)
10.18	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (2)	Filed herewith electronically
10.19	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (2)	Filed herewith electronically

10.20	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc. (2)	Filed herewith electronically
10.21	Consulting Agreement, dated January 1, 2001, between BioSante Pharmaceuticals, Inc. and Scientific Research Development Corp.	Filed herewith electronically
10.22	Employment Agreement, dated October 1, 2000, between BioSante Pharmaceuticals, Inc. and Steven J. Bell, Ph.D.	Filed herewith electronically
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 (2)	Filed herewith electronically
10.24	Separation and Release Agreement, dated February 1, 2002, between BioSante Pharmaceuticals, Inc. and John E. Lee	Filed herewith electronically
23.1	Consent of Deloitte & Touche LLP	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 Secretary of the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.