UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark one)

☒ 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 ☒ 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. ☒

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 ☒

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PART I

This Form 10-KSB contains forward-looking statements. For this purpose, any statements contained in this Form 10-KSB that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as "may," "will," "should," "expects," "anticipates," "contemplates," "estimates," "believes," "plans," "projected," "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.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	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

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.

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 Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, August 29, 1996, Date of incorporation	—	$ —	—	$ —	—	$ —	$ —	$ —	$ —
Issuance of Class "C" shares August 29, 1996 ($0.0001 per share)	—	—	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
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,611,755	5,274,552	2,841,250	—
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

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

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.

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)
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

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

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.

4. LICENSE AND SUPPLY AGREEMENTS (continued)

On October 1, 2001, BioSante sub-licensed its Bio-VantÔ 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-VantÔ and sold on a commercial basis. If Corixa sub-licenses vaccines that include Bio-VantÔ, BioSante will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to Bio-VantÔ 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

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.

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)**		

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

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.

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;

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.

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 Peter Kjaer	Director

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.

FORM OF INCENTIVE STOCK OPTION AGREEMENT

THIS AGREEMENT is entered into and effective as of this day of , (the "Date of Grant"), by and between BioSante Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and (the "Optionee").

A. The Company has adopted the BioSante Pharmaceuticals, Inc. 1998 Stock Option Plan (the "Plan") authorizing the Board of Directors of the Company, or a committee as provided for in the Plan (the Board or such a committee to be referred to as the "Committee"), to grant incentive stock options to employees of the Company and its Subsidiaries (as defined in the Plan).

B. The Company desires to give the Optionee an inducement to acquire a proprietary interest in the Company and an added incentive to advance the interests of the Company by granting to the Optionee an option to purchase shares of common stock of the Company pursuant to the Plan.

Accordingly, the parties agree as follows:

1. Grant of Option.

The Company hereby grants to the Optionee the right, privilege, and option (the "Option") to purchase ( ) shares (the "Option Shares") of the Company's common stock, no par value (the "Common Stock"), according to the terms and subject to the conditions hereinafter set forth and as set forth in the Plan. Subject to Section 10 of this Agreement, the Option is intended to be an "incentive stock option," as that term is used in Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Option Exercise Price.

The per share price to be paid by Optionee in the event of an exercise of the Option will be $.

3. Duration of Option and Time of Exercise.

3.1 Initial Period of Exercisability. The Option will become exercisable with respect to the Option Shares in installments. The following table sets forth the initial dates of exercisability of each installment and the number of Option Shares as to which this Option will become exercisable on such dates:

Initial Date of Exercisability	Number of Option Shares Available for Exercise

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The foregoing rights to exercise this Option will be cumulative with respect to the Option Shares becoming exercisable on each such date, but in no event will this Option be exercisable after, and this Option will become void and expire as to all unexercised Option Shares at, 5:00 p.m. (Lincolnshire, Illinois time) on , (the "Time of Termination").

3.2 Termination of Employment.

(a) Termination Due to Death, Disability or Retirement.

(i) In the event the Optionee's employment with the Company and all Subsidiaries is terminated by reason of death or Disability, this Option will remain exercisable, to the extent exercisable as of the date of such termination, for a period of six months after such termination (but in no event after the Time of Termination).

(ii) In the event the Optionee's employment with the Company and all Subsidiaries is terminated by reason of Retirement, this Option will remain exercisable, to the extent exercisable as of the date of such termination, for a period of three months after such termination (but in no event after the Time of Termination).

(b) Termination for Reasons Other Than Death, Disability or Retirement. In the event that the Optionee's employment with the Company and all Subsidiaries is terminated for any reason other than death, Disability or Retirement, or the Optionee is in the employ of a Subsidiary and the Subsidiary ceases to be a Subsidiary of the Company (unless the Optionee continues in the employ of the Company or another Subsidiary), all rights of the Optionee under the Plan and this Agreement will immediately terminate without notice of any kind, and this Option will no longer be exercisable; provided, however, that if such termination is due to any reason other than termination by the Company or any Subsidiary for "cause" (as defined in the Plan), this Option will remain exercisable to the extent exercisable as of such termination for a period of three months after such termination (but in no event after the Time of Termination).

3.3 Change in Control. If a Change in Control (as defined in the Plan) of the Company occurs, this Option will become immediately exercisable in full and will remain exercisable until the Time of Termination, regardless of whether the Optionee remains in the employ of the Company or any Subsidiary.

4. Manner of Option Exercise.

4.1 Notice. This Option may be exercised by the Optionee in whole or in part from time to time, subject to the conditions contained in the Plan and in this Agreement, by delivery, in person, by facsimile or electronic transmission or through the mail, to the Company at its principal executive office in Lincolnshire, Illinois (Attention: Chief Financial Officer), of a written notice of exercise. Such notice must be in a form satisfactory to the Committee, must identify the Option, must specify the number of Option Shares with respect to which the Option is being exercised, and must be signed by the person or persons so exercising the Option. Such notice must be accompanied by payment in full of the total purchase price of the Option Shares purchased. In the event that the Option is being exercised, as provided by the Plan and Section 3.2 above, by any person or persons other than the Optionee, the notice must be accompanied by appropriate proof of right of such person or persons to exercise the Option. As soon as practicable after the effective exercise of the Option, the Optionee will be recorded on the stock transfer books of the Company as the owner of the Option Shares purchased, and the Company will deliver to the Optionee one or more duly issued stock certificates evidencing such ownership.

4.2 Payment. At the time of exercise of this Option, the Optionee must pay the total purchase price of the Option Shares to be purchased entirely in cash (including a check, bank draft or money order, payable to the order of the Company); provided, however, that the Committee, in its sole discretion, may allow such payment to be made, in whole or in part, by tender of a promissory note (on terms acceptable to the Committee in its sole discretion) or a Broker Exercise Notice or Previously Acquired Shares (as such terms are defined in the Plan), or by a combination of such methods. In the event the Optionee is permitted to pay the total purchase price of this Option in whole or in part with Previously Acquired Shares, the value of such shares will be equal to their Fair Market Value on the date of exercise of this Option.

5. Rights of Optionee; Transferability.

5.1 Employment. Nothing in this Agreement will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment of the Optionee at any time, nor confer upon the Optionee any right to continue in the employ of the Company or any Subsidiary at any particular position or rate of pay or for any particular period of time.

5.2 Rights as a Shareholder. The Optionee will have no rights as a shareholder unless and until all conditions to the effective exercise of this Option (including, without limitation, the conditions set forth in Sections 4 and 6 of this Agreement) have been satisfied and the Optionee has become the holder of record of such shares. No adjustment will be made for dividends or distributions with respect to this Option as to which there is a record date preceding the date the Optionee becomes the holder of record of such shares, except as may otherwise be provided in the Plan or determined by the Committee in its sole discretion.

5.3 Restrictions on Transfer. Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by the Plan, no right or interest of the Optionee in this Option prior to exercise may be assigned or transferred, or subjected to any lien, during the lifetime of the Optionee, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise. The Optionee will, however, be entitled to designate a beneficiary to receive this Option upon such Optionee's death, and, in the event of the Optionee's death, exercise of this Option (to the extent permitted pursuant to Section 3.2(a) of this Agreement) may be made by the Optionee's legal representatives, heirs and legatees.

5.4 Breach of Confidentiality or Non-Compete Agreements. Notwithstanding anything in this Agreement or the Plan to the contrary, in the event that the Optionee materially breaches the terms of any confidentiality or non-compete agreement entered into with the Company or any Subsidiary, whether such breach occurs before or after termination of the Optionee's employment with the Company or any Subsidiary, the Committee in its sole discretion may immediately terminate all rights of the Optionee under the Plan and this Agreement without notice of any kind.

6. Securities Law and Other Restrictions.

Notwithstanding any other provision of the Plan or this Agreement, the Company will not be required to issue, and the Optionee may not sell, assign, transfer or otherwise dispose of, any Option Shares, unless (a) there is in effect with respect to the Option Shares a registration statement under the Securities Act of 1933, as amended, and any applicable state or foreign securities laws or an exemption from such registration, and (b) there has been obtained any other consent, approval or permit from any other regulatory body which the Committee, in its sole discretion, deems necessary or advisable. The Company may condition such issuance, sale or transfer upon the receipt of any representations or agreements from the parties involved, and the placement of any legends on certificates representing Option Shares, as may be deemed necessary or advisable by the Company in order to comply with such securities law or other restrictions.

7. Withholding Taxes.

The Company is entitled to (a) withhold and deduct from future wages of the Optionee (or from other amounts that may be due and owing to the Optionee from the Company), or make other arrangements for the collection of, all legally required amounts necessary to satisfy any federal, state or local withholding and employment-related tax requirements attributable to the Option, including, without limitation, the grant or exercise of this Option or a disqualifying disposition of any Option Shares, or (b) require the Optionee promptly to remit the amount of such withholding to the Company before acting on the Optionee's notice of exercise of this Option. In the event that the Company is unable to withhold such amounts, for whatever reason, the Optionee agrees to pay to the Company an amount equal to the amount the Company would otherwise be required to withhold under federal, state or local law.

8. Adjustments.

In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin-off), or any other similar change in the corporate structure or shares of the Company, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation), in order to prevent dilution or enlargement of the rights of the Optionee, will make appropriate adjustment (which determination will be conclusive) as to the number and kind of securities or other property (including cash) subject to, and the exercise price of, this Option.

9. Subject to Plan.

The Option and the Option Shares granted and issued pursuant to this Agreement have been granted and issued under, and are subject to the terms of, the Plan. The terms of the Plan are incorporated by reference in this Agreement in their entirety, and the Optionee, by execution of this Agreement, acknowledges having received a copy of the Plan. The provisions of this Agreement will be interpreted as to be consistent with the Plan, and any ambiguities in this Agreement will be interpreted by reference to the Plan. In the event that any provision of this Agreement is inconsistent with the terms of the Plan, the terms of the Plan will prevail.

10. Incentive Stock Option Limitations.

10.1 Limitation on Amount. To the extent that the aggregate Fair Market Value (determined as of the date of grant) of the shares of Common Stock with respect to which incentive stock options (within the meaning of Section 422 of the Code) are exercisable for the first time by the Optionee during any calendar year (under the Plan and any other incentive stock option plans of the Company or any subsidiary or parent corporation of the Company (within the meaning of the Code)) exceeds $100,000 (or such other amount as may be prescribed by the Code from time to time), such excess incentive stock options will be treated as non-statutory stock options in the manner set forth in the Plan.

10.2 Limitation on Exercisability; Disposition of Option Shares . Any incentive stock option that remains unexercised more than one year following termination of employment by reason of Disability or more than three months following termination for any reason other than death or Disability will thereafter be deemed to be a non-statutory stock option. In addition, in the event that a disposition (as defined in Section 424(c) of the Code) of shares of Common Stock acquired pursuant to the exercise of an incentive stock option occurs prior to the expiration of two years after its date of grant or the expiration of one year after its date of exercise (a "disqualifying disposition"), such incentive stock option will, to the extent of such disqualifying disposition, be treated in a manner similar to a non-statutory stock option.

10.3 No Representation or Warranty. Section 422 of the Code and the rules and regulations thereunder are complex, and neither the Plan nor this Agreement purports to summarize or otherwise set forth all of the conditions that need to be satisfied in order for this Option to qualify as an incentive stock option. In addition, this Option may contain terms and conditions that allow for exercise of this Option beyond the periods permitted by Section 422 of the Code, including, without limitation, the periods described in Section 10.2 of this Agreement. Accordingly, the Company makes no representation or warranty regarding whether the exercise of this Option will qualify as the exercise of an incentive stock option, and the Company recommends that the Optionee consult with the Optionee's own advisors before making any determination regarding the exercise of this Option or the sale of the Option Shares.

11. Miscellaneous.

11.1 Binding Effect. This Agreement will be binding upon the heirs, executors, administrators and successors of the parties to this Agreement.

11.2 Governing Law. This Agreement and all rights and obligations under this Agreement will be construed in accordance with the Plan and governed by the laws of the State of Delaware, without regard to conflicts of laws provisions. Any legal proceeding related to this Agreement will be brought in an appropriate Illinois court, and the parties to this Agreement consent to the exclusive jurisdiction of the court for this purpose.

11.3 Entire Agreement. This Agreement and the Plan set forth the entire agreement and understanding of the parties to this Agreement with respect to the grant and exercise of this Option and the administration of the Plan and supersede all prior agreements, arrangements, plans and understandings relating to the grant and exercise of this Option and the administration

of the Plan.

11.4 Amendment and Waiver. Other than as provided in the Plan, this Agreement may be amended, waived, modified or canceled only by a written instrument executed by the parties to this Agreement or, in the case of a waiver, by the party waiving compliance.

The parties to this Agreement have executed this Agreement effective the day and year first above written.

BIOSANTE PHARMACEUTICALS, INC.

By _____

Its _____

By execution of this Agreement, the Optionee acknowledges having received a copy of the Plan.

OPTIONEE

_____
(Signature)

_____
(Name and Address)

_____

_____

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

Exhibit 10.18

Amendment No. 1

to the

License Agreement
dated 13th of June 2000 (the "Agreement")

by and between

Antares Pharma IPL AG, Zug, Switzerland as Licensor
(formerly known as Permatec Technologie AG)

and

BioSante Pharmaceuticals, Inc., Lincolnshire, IL, U.S.A. as Licensee

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Recitals:

WHEREAS, Permatec Technologie AG has changed its corporate name into Antares Pharma IPL AG ("ANTARES"); and

WHEREAS, "ANTARES" has secured a third party being interested in a license package which package would — *inter alia* — include the rights to certain Products (all capitalized terms used herein but not defined shall have such meaning as ascribed to such terms in the Agreement) in specified countries of the Territory as licensed to BioSante Pharmaceuticals, Inc. ("BIOSANTE") under the Agreement; and

WHEREAS, BIOSANTE is prepared to return such rights to certain Products in specified countries included in the license under the Agreement for the consideration described and under the terms and conditions set forth herein below.

NOW THEREFORE, the Parties hereby agree pursuant to this Amendment No. 1 to the License Agreement dated 13th of June 2000 (the "Agreement") ("Amendment No. 1") to amend the Agreement as follows:

1. Change of Corporate Name

Following the change of corporate name from Permatec Technologie AG into Antares Pharma IPL AG effective as of 15th February 2001, the Agreement is hereby amended as follows for clarification and to make the Agreement consistent with this Amendment No. 1.

(a) all references in the Agreement to Permatec Technologie AG shall be substituted by Antares Pharma IPL AG; and

(b) all references in the Agreement to PERMATEC shall be substituted by ANTARES.

2. Return of Rights

2.1 BIOSANTE hereby returns its rights granted under the Agreement as part of the license (including without limitation rights to Develop, apply and receive Approval as applicant, Market, use and sell) to ANTARES with respect to:

(a) all rights to the Product Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin) for all countries of the Territory; and

(b) the rights to the Product Gel E2 (where estradiol is the sole active ingredient and where the gel is applied to the skin), for the countries Australia and Malaysia; and

(c) the rights to the Product Gel Testosterone (where testosterone is the sole active ingredient and where the gel is applied to the skin), for the countries Australia and Malaysia.

All such rights returned to ANTARES as described in this Section 2.1 shall be collectively referred to hereinafter as the "Returned Rights").

2.2 In order to give effect to the waiver and return of the Returned Rights, the parties agree to amend the Agreement as follows:

(a) the Product Patch E2 (where estradiol is the sole active ingredient and where the patch is applied to the skin) is deleted from the list of Products attached to the Agreement as Exhibit B, and all references to Patch E2 in the Agreement are deleted and eliminated without substitution; and

(b) the definition of the term "Territory" in Section 1.14 of the Agreement is deleted in its entirety and substituted by the following definition:

1.14 "Territory" shall mean the United States of America and those of its territories and possessions over which the FDS has regulatory authority (the "USA"); Canada; Australia; New Zealand; South Africa; Israel; Mexico; The People's Republic of China (including Hong Kong) ("China"); Malaysia; and Indonesia, except for the Products Gel E2 and Gel Testosterone, for which Products the term "Territory" shall mean the United States of America and those of its territories and possessions over which the FDS has regulatory authority (the "USA"); Canada; New Zealand; South Africa; Israel; Mexico; The People's Republic of China

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(including Hong Kong) ("China"); and Indonesia. The countries are classified according to **Exhibit C** in three tiers.

3. Data Sharing

3.1 In order to secure the mutual exchange and sharing of data relating to the Products in the Territory (as amended hereby) by BIOSANTE and its sub-licensees, and outside the Territory (as amended hereby) by ANTARES and/or its third party licensees, the parties hereby agree that Section 5.2 of the Agreement shall in particular also include the use

of any data and results generated in the Territory by BIOSANTE or any of its sub-licensees (if any) for use by ANTARES or any licensee with respect to the Returned Rights outside the Territory, and any data and results generated by ANTARES or any licensee with respect to the Returned Rights for use by BIOSANTE or its sub-licensees in the Territory.

3.2 ANTARES undertakes to include a respective obligation giving effect to such data sharing also with respect to the Returned Rights in any eventual license agreement with a third party on the Returned Rights (or any part thereof).

4. Changes in Payment Obligations

4.1 As consideration for the Returned Rights by BIOSANTE, the parties agree to eliminate certain payment obligation of BIOSANTE under the Agreement as specified herein below:

(a) the payment obligation of BIOSANTE under Section 3.3.1 of the Agreement in the amount of XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX shall be eliminated from the Agreement; and **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

(b) the payment obligation of BIOSANTE under Section 3.3.2 of the Agreement in the amount of XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX shall be eliminated from the Agreement; and **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

(c) the milestone payment obligation of BIOSANTE under Section10.3.3.1 of the Agreement in the amount of XXXXXXXXXXXXXXXXXX XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX, shall be

eliminated from the Agreement. [Portions of this section have been omitted pursuant to a request for **confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

4.2 As further consideration for the Returned Rights by BIOSANTE, ANTARES agrees that its obligation under Section 4.1.3 of the Agreement is not diminished by this Amendment No. 1, such that ANTARES remains obligated to expend funds for the formulation and production of the Products remaining under the Agreement, up to a potential maximum of XXXXXXXXXXXXXXX (XXXXXXXX), and such that the funds it was to have expended on the Product Patch E2, up to XXXXXXXXXXXXXX (XXXXXXXX), will be allocated as additional formulation and production expenditures for Product Gel E2 and Product Gel Testosterone. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

4.3 The parties hereby confirm that the consideration described above is sufficient and adequate for the Returned Rights.

5. No Further Changes

5.1 The parties hereby agreed and acknowledge that the Agreement shall, except for and in due incorporation of the changes agreed upon in this Amendment No. 1, remain in full force and effect and, subject to Section 5.2 below, not be otherwise changed, altered or amended.

5.2 The parties further agree that in the event that any further amendment, change or alteration of the language or wording of any Section of the Agreement would be required to give full effect to any of the changes agreed upon in this Amendment, then such further amendment, change or alteration of the language or wording shall be made upon reasonable request of either party.

5.3 This Amendment is agreed to be subject to the provisions of the Agreement of 11.1. (Governing Law) and 11.2 (Dispute Resolution) by reference.

IN WITNESS WHEREOF, the parties hereto have caused this instrument to be executed by their duly authorized officers with effect as of the 20th day of May, 2001.

Antares Pharma IPL AG

/s/ Dario Carrara	
By: Dario Carrara	By:
Its: Executive Director	Its:

BIOSANTE PHARMACEUTICALS, INC.

/s/ Stephen M. Simes
By: Stephen M. Simes
Its: President and CEO

EXHIBIT C

COUNTRY CLASSIFICATION

First Tier:	USA
Second Tier:	Canada; China

Third Tier:	All other countries of the Territory

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

AMENDMENT NO. 2

to the

License Agreement dated 13th of June, 2000

as amended by Amendment No. 1 to that License Agreement dated May 20, 2001 by and between

ANTARES Pharma IPL AG, Zug, Baarerstrasse 95, 6301 Zug, Switzerland as Licensor (formerly known as Permatec Technologie AG)

and

BioSante Pharmaceuticals, Inc., 175 Olde Half Day Road, Lincolnshire, IL., 60069 U.S.A. as Licensee

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Recitals:

WHEREAS, Antares Pharma IPL AG ("ANTARES") and BioSante Pharmaceuticals, Inc. ("BIOSANTE") have entered into that certain License Agreement dated 13th of June, 2000 (the "Agreement"), regarding the grant of a license with the right to sublicense products as defined in the Agreement, and have entered into a May 20, 2001 amendment to that Agreement entitled in part "Amendment No. 1 to the License Agreement dated 13th of June 2000" ("Amendment No. 1")

WHEREAS, ANTARES has granted BIOSANTE an option regarding the licensing of XXXX Combi-Gel in the Agreement; **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

WHEREAS, ANTARES has offered within the "offering period" and BIOSANTE has an interest in licensing XXXX Combi-Gel. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

WHEREAS, the parties acknowledge that the prerequisites provided for in 10.3.1 of the Agreement have been met;

NOW, THEREFORE, the Parties hereby agree according to this Amendment No. 2 to the License Agreement dated 13th of June 2000 (the "Agreement") ("Amendment No. 2") to amend the Agreement as follows:

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1. BIOSANTE hereby agrees to accept an exclusive license of the XXXX Combi-Gel pursuant to the terms and conditions set forth in the Agreement as amended by Amendment No. 1. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

2. The Parties hereby reaffirm their agreement to the terms and conditions under 10.3.2 and 10.3.3 of the Agreement, and reaffirm that the payment obligations in 10.3.3.1 of the Agreement have been fully eliminated pursuant to 4.1(c) of Amendment No. 1.

3. Except for the amendments and changes to the Agreement as set forth in Amendment No. 1 and in this Amendment No. 2, which shall upon execution hereof become an integral part of the Agreement, any and all terms and conditions contained in the Agreement as agreed upon by the Parties shall remain in full force and effect and shall not be changed, amended or altered by this Amendment.

4. Any and all capitalized terms used herein but not defined shall have the meaning ascribed to such terms in the Agreement.

5. The parties further agree that in the event that any further amendment, change or alteration of the language or wording etc. of any Section of the Agreement would be required to give full effect to any of the changes agreed upon in this Amendment, then such further amendment, change or alteration of the language or wording shall be made upon reasonable request of either party.

IN WITNESSETH WHEREOF, the Parties have duly executed this Amendment effective as of the 5th day of July, 2001.

Antares Pharma IPL AG

Allschwie June 27, 2001 — /s/ Dario Carrara
Place and Date — By: Dario Carrara
Its: Executive Director

BioSante Pharmaceuticals, Inc.

Lincolnshire, IL July 5, 2001 — /s/ Stephen M. Simes
Place and Date — By: Stephen M. Simes
Its: President and CEO

[Portions of this Exhibit have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Exhibit with all sections intact has been filed separately with the Securities and Exchange Commission.]

AMENDMENT NO. 3

to the

License Agreement dated 13th of June, 2000 (the "Agreement")

by and between

ANTARES Pharma IPL AG, Zug, Baarerstrasse 95, 6301 Zug, Switzerland as Licensor (formerly known as Permatec Technologie AG) as **Licensor**

and

BioSante Pharmaceuticals, Inc., Lincolnshire, IL, U.S.A. as **Licensee**

Recitals:

WHEREAS, ANTARES Pharma IPL AG ("ANTARES") and BioSante Pharmaceuticals, Inc. ("BIOSANTE") have entered into that certain License Agreement dated of June 13, 2000 (the "Agreement"), regarding the grant of a license with the right to sublicense products as defined in the Agreement;

WHEREAS, ANTARES Pharma IPL AG ("ANTARES") and BioSante Pharmaceuticals, Inc. ("BIOSANTE") have entered into a Supply Agreement dated of June 13, 2000 (the "Supply Agreement") regarding the manufacturing and the supply of products (according to Exhibit D of the Supply Agreement);

WHEREAS, ANTARES and BIOSANTE have concluded some alterations to the Agreement in Amendment No. 1 of May 20, 2001 ("Amendment No. 1");

WHEREAS, ANTARES has granted BIOSANTE the licensing of XXXX Combi-Gel which is set out in Amendment No. 2 of July 5, 2001 ("Amendment No. 2") **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

WHEREAS, the parties have negotiated this third set of terms and conditions in alteration of the Agreement;

NOW, THEREFORE, the Parties agree according to this Amendment No. 3 ("Amendment No. 3") to amend the Agreement as follows:

1. Royalties

(a) Royalty payment

BIOSANTE will receive from ANTARES in modification of section 3.2 of the "Agreement" a commission on royalty for the sale of the combination product "Estradiol plus XXXXXXXXXXXXXX ("E2-XXXX Combi Gel"). The commission on royalties for the said product will be XXX for sales amounting up to XXXXXXXX (XXXXXXXXXX) and XXX for sales over XXXXXXXXX (XXXXXXXXXX). This modification comes into effect as per the date of signature (effective date) of this Amendment No. 3. However, this modification of the royalties does not apply for the products "Estradiol single gel", "Testosterone single gel" and the combination product "Estradiol plus Testosterone" but only and exclusive for E2-XXXX Combi Gel. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

(b) Reduction in Royalty Payments

Consistent with the principles in the BIOSANTE-SOLVAY agreement, in the instance in which an A/B rated generic equivalent or substitute of E2-XXXX Combi Gel ("Product") is reasonably notified by BIOANTE, SOLVAY or ANTARES to infringe a patent available for such product in the United States or Canada, and SOLVAY may give evidence that the marketing of such competitive product has led to a reduction in sales of the product in either such country of more than XXXXXXXX (XXXX) in an average three (3) month period, then the Royalty payable by BIOSANTE to ANTARES for E2-XXXX Combi-Gel after such reasonable notice in that country of the Territory will be XXXXXXXXXXX (XXXX) up to total sales of XXXXXXXXXX (XXXXXXX) and XXXXXXXX (XXX) for sales over XXXXXXXXXXXX (XXXXXXXX), for as long as (1) such competing product is on sale, and (2) BIOSANTE's Royalty obligation exists under this Agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

(c) Books and records

Pertaining to E2-XXXX Combi Gel BIOSANTE shall keep full, true and accurate books of accounting containing all particulars and reasonable supporting documentation which may be necessary for the purpose of the accurate determination of the Net Sales achieved by SOLVAY. The inspection of the books and records will be carried out according to the terms and conditions of the Agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

(d) Audits

ANTARES has the right to notify BIOSANTE that it would like to audit the books and records of SOLVAY to inspect the accuracy of SOLVAY Net Sales reported to BIOSANTE, in which instance BIOSANTE will in turn notify SOLVAY that it would like to exercise its right to audit pursuant to the agreement between BIOSANTE and SOLVAY. SOLVAY shall permit a firm of certified public accountants, acceptable to ANTARES, BIOSANTE and SOLVAY, upon request by ANTARES, to examine all books and records relating to the sales of E2-XXXX Combi Gel, at all reasonable times and upon reasonable notice, to verify BIOSANTE's reports and accountings determining the correctness of the sublicense royalties. The expenses for such audit will be borne by ANTARES as per the BIOSANTE-SOLVAY agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

2. Reallocation of XXXXXXX

As consideration for the successful sub-license of the E2-XXXX Combi Gel (see 3), hereinafter, ANTARES reallocates as follows the XXXXXXX (XXXXXXXXXXX) obligation (as per section 4.1.2 of the Agreement) corresponding to E2-XXXX Combi Gel formulation and production costs: XXXXXXX (XXXXXXXXXXX) for "Estradiol single gel" and additional XXXXXXX (XXXXXXXXXXX) for "Testosterone single gel". The reallocation will take effect as per the date of signature (effective date) of this Amendment No. 3. This reallocation is in addition to the reallocation stipulated in section 4.2 of Amendment No. 1. The net effect of these reallocations is that ANTARES is obliged to expend funds for the formulation and production of Product Gel E2 ("Estradiol single gel") and of Product Gel Testosterone ("Testosterone single gel") up to a potential maximum of XXXXXXX (XXXXXXXXXXX) **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

3. Manufacturing rights (Sublicense)

ANTARES grants to BIOSANTE the right to grant manufacturing of E2-XXXX Combi Gel exclusively to Solvay Pharmaceuticals, B.V. ("SOLVAY"). In the event of termination of the Agreement between ANTARES and BIOSANTE, BIOSANTE's rights under the BIOSANTE-SOLVAY Agreement will be assigned to ANTARES, except that BIOSANTE will continue to receive its share of milestone and royalty payments paid by SOLVAY pursuant to the terms of the BIOSANTE-SOLVAY Agreement. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

4. Assistance of ANTARES

The parties agree to draft and sign a separate **Manufacturing Assistance Agreement** within a period of 60 days after the signing of this Amendment No. 3 As pertains E2-XXXX Combi Gel, the Manufacturing Assistance Agreement shall: (1) Replace the Supply Agreement for E2-XXXX Combi-Gel; (2) Eliminate any and all ANTARES obligations contained in the Supply Agreement for E2-XXXX Combi-Gel; and (3) Govern all manufacturing aspects related to E2-XXXX Combi Gel. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

The Manufacturing Assistance Agreement shall inter alia contain the following points:

ANTARES agrees during the term of the Manufacturing Assistance Agreement to provide technical and scientific assistance to BIOSANTE or its sublicensee against reimbursement applying a rate of XXXX (XXXXXXXXXXXX) XXXXXXX spent by ANTARES personnel. BIOSANTE further undertakes and agrees to reimburse any and all reasonable out-of-pocket expenses incurred by ANTARES and agreed to in advance in writing by BIOSANTE in connection with any such assistance to BIOSANTE. Such assistance shall be provided by ANTARES within a reasonable time in response to requests in connection with BIOSANTE's or the sublicensee's efforts to manufacture the product. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

5. Discount of XXXXXXX

ANTARES grants a XXXXXXX to BIOSANTE of XXXXXXX (XXXXXXXXXX) for its development work already performed on "Estradiol single gel" and "Testosterone single gel". This discount may be implemented by reduction of the invoice of ANTARES to BIOSANTE dated June 30, 2001. Nothing herein shall prevent the parties from negotiating or entering into further agreements on adjustments to the June 30, 2001 invoice. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

6. No Further Funding for E2-XXXX Combi-Gel

After the execution of this Amendment 3 including the execution of the Manufacturing Assistance Agreement, ANTARES has no further obligation to financially fund, develop, market, assist or otherwise support E2-XXXX Combi Gel as outlined in the Agreement and the Supply Agreement except for those obligations contained in this Amendment 3. **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

7. No Further Changes

The parties hereby agree and acknowledge that the Agreement shall, except for and in due incorporation of the changes agreed upon in Amendment No. 1, Amendment No. 2 and this Amendment No. 3, remain in full force and effect and, subject to the following, not be otherwise altered or amended.

The amendments and changes to the Agreement as set forth in this Amendment No. 3 shall upon execution become an integral part of the Agreement.

The parties further agree that in the event that any further amendment, change or alteration of the language or wording of any Section of the Agreement would be required to give full effect to any of the changes agreed upon in this Amendment, then such further amendment, change or alteration of the language or wording shall be made upon reasonable request of either party.

8. Governing Law

This Amendment No. 3 is construed under and governed by Illinois Law.

IN WITNESSETH WHEREOF, the Parties have duly executed this Amendment effective as of the day of , 2001.

ANTARES Pharma IPL AG

Allschwie August 28, 2001 — /s/ Dario Carrara
Place and Date — By: Dr. Dario Carrara
Its: Managing Director, Swiss Operations

BioSante Pharmaceuticals, Inc.

Lincolnshire, IL August 30, 2001 — /s/ Stephen M. Simes
Place and Date — By: Stephen M. Simes
Its: President and CEO

CONSULTING AGREEMENT

This Agreement is made and entered into this 1st day of January 2001, by and between BioSante Pharmaceuticals, Inc., a Delaware corporation, 111 Barclay Blvd., Lincolnshire, Illinois 60069 ("BioSante") and Scientific Research Development Corporation, an Illinois corporation, 14308 W. Braemore Close, Libertyville, Illinois 60048 ("SRDC").

WITNESSETH:

Whereas, SRDC desires to be retained as a consultant to BioSante and BioSante desires to retain SRDC on all of the terms and conditions hereof.

Now, therefore, in consideration of the promises, covenants and agreements hereinafter contained, the sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Duties of SRDC

SRDC agrees to consult for and on behalf of BioSante when expressly called upon by the management of BioSante, and services will include, but not be limited to, statistical consultation, database and statistical programming, database management, medical writing, and project management.

2. Compensation

a) For bid/proposal-specific services provided by SRDC under this Agreement, BioSante agrees to compensate SRDC according to terms of compensation written into a signed amendment to this Agreement.

b) For services provided "as-needed" by SRDC under this Agreement (i.e., services not specific to a project bid/proposal), BioSante agrees to compensate SRDC at the following rates: $125/hour for statistical consultation, $125/hour for programming, $105/hour for database management, $105/hour for medical writing, and $105/hour for project management.

c) SRDC shall prepare and submit every month, detailed time reports setting forth the type of "as-needed" services performed, the time spent in performing such service, and the dates the service was performed. Payment by BioSante for SRDC's services hereunder will be made within thirty (30) days of receipt of such reports.

3. Term and Termination

a) This Agreement shall be effective on the date first above written and shall remain in effect through December 31, 2002.

b) Notwithstanding any other provision of this Agreement, BioSante or SRDC may terminate this Agreement at any time in the event of a material breach by the other party, immediately upon written notice to the other party. Either party may

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terminate this Agreement without cause upon giving thirty (30) days prior written notice to the other party.

4. Governing Law

This Agreement shall, in all respects, be construed under and interpreted in accordance with the laws of the State of Illinois, without giving effect to its conflicts of laws provisions.

5. Entirety

The terms and conditions of this Agreement constitute the entire agreement and understanding of the parties regarding the subject matter hereof, except as noted above, and supersede all previous communications whether oral or written between the parties, including any previous agreement or understanding varying or extending the same.

6. Enforceability

Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under applicable law, but in the event of a conflict between any provision of this Agreement and any applicable law, regulation, ordinance or decree, the provisions of this Agreement so affected shall be curtailed and limited to the extent necessary to bring it within the legal requirements but otherwise it shall not render null and void other provisions of this Agreement, unless either of the parties, in the absence of the provision in question, would not have entered into this Agreement.

7. Miscellaneous

SRDC shall be and act as an independent contractor and not as an agent, employee or partner of, or joint venture with, BioSante for any purpose. The rights and benefits of SRDC are personal to it and no such rights or benefits shall be subject to assignment or transfer by SRDC.

The parties acknowledge that the material provisions of this written agreement memorialize unwritten terms under which the parties have operated since January 1, 2001.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

BIOSANTE PHARMACEUTICALS, INC.		SRDC	
By:	/s/ Stephen M. Simes	By:	/s/ Ronald B. McCright
	Stephen M. Simes President and CEO		Ronald B. McCright President
Date:	3/14/02	Date:	3/14/02

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this **"Agreement**") is made as of this 1st day of October, 2000 (the "**Effective Date"**), by and between BioSante Pharmaceuticals, inc. (the "**Company**") and Steve J.D. Bell ("**Employee**").

RECITALS

WHEREAS, Employee is currently an employee of the Company, and Employee and the Company desire to memorialize the terms of Employee's employment with the Company in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Employee hereby agree as follows:

ARTICLE I

EMPLOYMENT SERVICES

1.1. Employment. The Company hereby employs Employee as vice president of research and pre-clinical development and Employee hereby accepts such employment, upon the terms and conditions of this Agreement.

1.2. Term of Employment. The term of Employee's employment under this Agreement shall be for an initial period commencing on the Effective Date and ending on October 1, 2001 (the "**Initial Term**"). Following the expiration of the Initial Term, this Agreement shall automatically renew for one-year periods (each such one-year period is referred to as a "**Renewal Term**") and continue until the earlier of (i) the Company providing Employee thirty (30) days written notice prior to the expiration of either the Initial Term or any Renewal Term of its desire to terminate this Agreement or (ii) Employee providing the Company sixty (60) days prior written notice prior to the end of either the Initial Term or any Renewal Term of his desire to terminate this Agreement. The Initial Term and any Renewal Term(s) are collectively referred to as the "**Employment Term**." Notwithstanding the provisions of this Section 1.2, this Agreement may be terminated prior to the expiration of the Initial Term or any Renewal Term in accordance with the provisions of Section 3.1 hereof.

1.3. Activities and Duties During Employment.

(a) Employee represents and warrants to the Company that he has no other commitments or obligations of any kind to anyone else which would hinder or interfere with his acceptance of his obligations hereunder, or the exercise of his best efforts as an employee of the Company.

(b) During the Employment Term, Employee shall diligently perform such duties and responsibilities consistent with the position set forth in Section 1.1 and the Company's chief executive officer (the "**CEO**"), shall from time to time assign him.

Employee shall be vice president of research and pre-clinical development of the Company with responsibility as is typical for executives with a similar title in similar entities, subject to the overall control and authority of the Company's CEO and the Company's board of directors (the **"Board"**).

(c) During the Employment Term, Employee agrees to devote, on a full time basis, all of his business hours, attention and skills to the business and affairs of the Company.

ARTICLE II

COMPENSATION

2.1. Base Salary. The Company shall pay Employee an annual base salary in the amount of One Hundred Thousand and 00/100 Dollars ($100,000.00), payable in accordance with the Company's standard payroll practices. During the Employment Term, the CEO shall give Employee an annual performance review and the CEO and the Compensation Committee of the Board shall review the base salary of Employee annually, and make such adjustments to such base salary as it deems reasonable and appropriate.

2.2. Bonus Compensation. The Company may, at its option, pay Employee a bonus in cash or otherwise in an amount determined by the CEO, in consultation with the Compensation Committee of the Board.

2.3. Withholdings and Deductions. All compensation payable to Employee pursuant to this Agreement shall be subject to such withholdings and deductions by the Company as are required by law.

2.4. Reimbursement of Expenses. The Company shall reimburse Employee for all reasonable and necessary expenses incurred by Employee while performing his duties under this Agreement, subject to provision by Employee of documentation satisfactory to the Company.

2.5. Benefit Plans, Vacation. During the Employment Term, Employee shall be entitled to receive all fringe benefits and perquisites and to participate in all benefit programs normally available to other employees holding positions similar to that of Employee hereunder (subject to all applicable eligibility rules thereof), as may be in effect from time to time, including such insurance or other benefit programs as may be implemented by the Company. During the Employment Term, Employee shall be entitled to receive three weeks of paid vacation annually. Employee's ability to carry over vacation from year to year is subject to company policy as described in the Company's Employee Handbook.

2.6. Key-Man Insurance Policy. During the Employment Term, the Company may, in its sole discretion, maintain "key-man" life insurance coverage (the "**Policy**") with respect to Employee. Employee shall submit to any reasonable physical exam required. The Company shall be the sole beneficiary of the Policy and nothing contained herein or through any course of dealing shall create any interest of Employee in the Policy. At such time as the Company elects to terminate its ownership of the Policy, it will notify Employee of said determination and allow him a reasonable period of time to elect to continue the coverage for his benefit by means of

Employee paying the Company an amount equal to the unamortized prepaid premium and the cash value of the Policy. Thereafter, Employee will be responsible to make all further payments due under the Policy.

2.7. Automobile Allowance. The Company shall provide Employee with a monthly stipend of Five Hundred and 00/100 Dollars ($500.00) for automobile use.

ARTICLE III

TERMINATION

3.1. Termination of Agreement. Notwithstanding Section 1.2 hereof, the Employment Term shall terminate immediately upon the occurrence of any of the following events: (a) death of Employee; (b) Legal Disability of Employee, as defined in Section 3.4; (c) election by the Company to terminate Employee for Cause, as defined in Section 3.2; or (d) by either the Company or Employee for any reason (whether for Cause or not) upon the giving of sixty (60) days prior written notice to the other party.

3,2. Cause. The term "**Cause**" as used herein shall mean any of the following acts or omissions:

(a) Employee's theft, embezzlement or other act of dishonesty;

(b) A material default by Employee in the performance or observance of any promise or undertaking of Employee under this Agreement, including, without limitation, willful failure to follow instructions of the CEO or the Board, which default shall continue for a period often (10) days after written notice thereof from the Company to Employee;

(c) The commission of an act or acts by Employee in the performance of his duties hereunder amounting to gross negligence or willful or wanton misconduct, as determined by the Company in the exercise of its reasonable judgment; or

(d) Employee's conviction of, guilty or nolo contendre plea to or confession of a Class A-type felony or a felony involving moral turpitude.

3.3. Effect of Termination for Cause. In the event Employee is terminated for Cause, this Agreement shall immediately terminate and the Company shall owe Employee no further amounts under this Agreement.

3.4. Legal Disability. For the purposes of this Agreement, the term "**Legal Disability**" shall mean the inability of Employee, due to illness, accident or other physical or mental incapacity, to perform substantially all of his regular duties as an employee of the Company for a period (whether continuous or periodic) of six (6) months during the Employment Term, or a physical or mental incapacity in which there is no hope of recovery within eight (8) months. In the event that there is any dispute as to Employee's Legal Disability, a determination shall be made at the written request of either the Company or Employee sent to the other (and within thirty (30) days after such request) by a majority of three physicians, one of

whom shall be selected by Employee, one by the Company and the third by the two physicians so selected.

3.5 Effect of Termination Upon Death or Legal Disability. In the event Employee is terminated for death or Legal Disability, this Agreement shall immediately terminate and the Company shall owe Employee, or Employee's estate, no further amounts under this Agreement.

3.6. Effect of Termination Other than for Cause, upon Death or for Legal Disability. In the event Employee is terminated other than for Cause or if this Agreement is not renewed, the Company shall (i) pay Employee a severance benefit equal to Employee's base salary for the shorter of (A) six months or (B) the date upon which Employee obtains full-time employment (such period is the "**Severance Period**"); (ii) continue to allow Employee to participate during the Severance Period, at the Company's expense, in the Company's group health, dental and disability insurance programs; and (iii) reimburse Employee for any and all unused vacation days accrued to the date of such termination. The compensation provided for in this Section 3.6 will constitute Employee's sole and exclusive remedy for such termination. Employee will not be entitled to any other termination or severance payment which might otherwise be payable under any other agreement between Employee and the Company or under any policy of the Company.

3.7. Property of the Company. Upon termination of his employment with the Company, Employee shall surrender to the Company any and all material, including, but not limited to, manuals, reports, documents, lists of the Company's vendors and customers, computer programs, methods of designing such programs, software, plans, drawings, proposals, designs, product information, confidential purchasing and market research information, Confidential Information (as defined in Section 4.2 below) and the like (including all copies thereof) that he has in his possession, custody or control relating to the business of the Company, its affiliates or its customers. Employee acknowledges that all such materials are and shall remain the property of the Company solely and that Employee has no right, title or other interest in or to such materials.

ARTICLE IV

RESTRICTIVE COVENANTS

4.1. Non-Disclosure of Confidential Information. Employee will not at any time (other than as may be required or appropriate directly in connection with the performance by him of his duties hereunder), directly or indirectly, use, communicate, disclose or disseminate any Confidential Information (defined below) in any manner whatsoever (except as may be required under legal process by subpoena or other court order). In the event disclosure of any Confidential Information is required of Employee pursuant to the requirements of a government agency, regulation, judicial order or by operation of law, Employee will notify the Company of the requirement to make such disclosure as far in advance of the disclosure as is possible and will assert the confidentiality of such Confidential Information.

4.2. "Confidential Information" Defined. For purposes of this Agreement, "Confidential Information" shall mean any and all information (oral or written) relating to the Company or any person controlling, controlled by, or under common control with the Company

or any of its activities, including, but not limited to, information relating to: technology, research, test procedures and results, trade secrets, machinery and equipment; manufacturing processes; financial information; products; identity and description of materials and services used; purchasing; costs; pricing; customers and prospects; advertising, promotion and marketing; and selling, servicing and information pertaining to any governmental investigation, except such information which is generally in the public domain (such information not being deemed to be in the public domain merely because it is embraced by more general information which is in the public domain), other than as a result of a breach of the provisions of Section 4.1 hereof.

4.3. Non-Competition. Employee recognizes and acknowledges that the business of the Company is highly competitive and that the services to be performed by Employee for the Company are special and unique. Employee agrees that, at any time during the Employment Term (other than with the consent of the Company) and for a period of (i) one year thereafter if either Employee or the Company elects to terminate the employment of Employee other than pursuant to Section 3.1(c) or if this Agreement expires at the end of Employment Term or (ii) three years thereafter if the employment of Employee is terminated by the Company pursuant to Section 3.1(c), Employee shall not engage or participate in, directly or indirectly (whether as an officer, director, employee, partner, consultant, equityholder, lender or otherwise), any business that makes a product that competes with the Company's current or future products, namely, calcium phosphate adjuvants, calcium phosphate delivery systems or hormone replacement gel products.

4.4. Non-Solicitation of Employees. Employee agrees that, during his employment and for a period of three years thereafter, Employee shall not, directly or indirectly, whether for Employee's account or for any other person or entity, (i) solicit for employment or hire, or attempt to solicit for employment or hire, any person who is employed by the Company or any customer of the Company, or, but for the violation of this Agreement, would have been employed by the Company or any customer of the Company, or, who was employed by the Company during the twelve (12) month period immediately preceding termination of the Employee's employment with the Company or any customer of the Company or (ii) otherwise interfere with the relationship between any such person, the Company and any third party that has a business relationship or a potential business relationship with the Company including, but not limited to, any customer, collaborator, licensor or licensee.

4.5. Remedies. The Company and Employee hereby agree that it is impossible to measure solely in money the damages, which will accrue to the Company by reason of Employee's failure to observe any of his obligations wider this Article IV. Therefore, if the Company shall institute any action or proceeding to enforce such obligations or provisions, Employee hereby waives the claim or defense that there is an adequate remedy at law and agrees in any such action or proceeding not to interpose the claim or defense that such remedy exists at law. Without limiting any other remedies that may be available to the Company, Employee hereby specifically affirms the appropriateness of injunctive or other equitable relief in any such action.

4.6. Reasonab1e Limitations. The parties hereto stipulate and agree that each of the terms of Article IV of this Agreement including, but not limited to, the scope of the activities prohibited and the time limitation, is reasonable. The parties further stipulate and agree that

in the event a court determines contrary to the agreement of the parties herein that any of the terms of Article IV of this Agreement are unreasonable or contrary to public policy, or invalid or unenforceable for any reason in fact, law or equity, then the court shall limit the application of any such provision or term or modify any provision or term to that which it finds reasonable, valid or enforceable and shall enforce this Agreement as so limited or modified.

ARTICLE V

INVENTIONS

5.1. Inventions Owned by the Company. Employee agrees that all Inventions (as defined in Section 5.2 hereof) Employee has or hereafter makes, conceives, reduces to practice or authors (either alone or with others) during or within one year after the termination of the Employment Term will be the Company's sole and exclusive property. Employee will, with respect to any such Invention: (i) keep current, accurate, and complete records, which will belong to the Company and be kept and stored on the Company's premises while Employee is employed by the Company; (ii) promptly and fully disclose the existence and describe the nature of the Invention to the Company in writing (and without request); (iii) assign (and Employee does hereby assign) to the Company all of Employee's rights to all inventions, any applications Employee makes for patents or copyrights in any country; and (iv) acknowledge and deliver promptly to the Company any written instruments, and perform any other acts necessary in the Company's opinion to preserve property rights in Inventions against forfeiture, abandonment, or loss and to obtain and maintain patents and/or copyrights on Inventions to vest the entire right and title to Inventions in the Company.

5.2. Inventions. The term "**Inventions**" as used in herein, means any discoveries, improvements, creations, ideas and inventions, including without limitation software and artistic and literary works (whether or not they can be patented or copyrighted) that: (i) relate directly to the Company's business or the Company's research or development during the Employment Term, (ii) result from any work Employee performs for the Company; (iii) use the Company's equipment, supplies, facilities or trade secret information; or (iv) Employee develops during any tune that Employee is obligated to perform his employment duties.

ARTICLE VI

MISCELLANEOUS

6.1. Notices. All notices or other communications required or permitted hereunder shall be in writing and shall be addressed as follows:

If to Employee:

Dr. Steve J.D. Bell
1046 Swaying Pines Trace
Marietta, Georgia 30066

If to the Company:

BioSante Pharmaceuticals, Inc.
175 Olde Half Day Road
Lincolnshire, Illinois 60069
Attention: Stephen M. Simes

with a copy to:

Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602
Attention: Gary I. Levenstein, Esq.

or to such other address or addresses as may hereafter be specified by notice given by any of the above to the others. Notices mailed in accordance with this Section 6.1 shall be deemed given (i) the fifth day after they are mailed and (ii) the next day after they are sent by reputable overnight courier service.

6.2. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their successors and permitted assigns. In the case of the Company, the successors and permitted assigns hereunder shall include without limitation any affiliate of the Company as well as the successors in interest to such affiliate (whether by merger, liquidation (including successive mergers or liquidations) or otherwise). This Agreement or any right or interest hereunder is one of personal service and may not be assigned by Employee. Nothing in this Agreement, expressed or implied, is intended or shall be construed to confer upon any person other than the parties and successors and assigns permitted by this Section 6.2 any right, remedy or claim under or by reason of this Agreement.

6.3. Entire Agreement; Amendments. This Agreement and the Recitals contain the entire understanding of the parties hereto with regard to the subject matter contained herein, and supersede all prior agreements, understandings or letters of intent between the parties hereto. This Agreement shall not be amended, modified or supplemented except by a written instrument signed by each of the parties hereto.

6.4. Interpretation. Article titles and section headings contained herein are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

6.5. Expenses. Each party hereto will pay all costs and expenses incident to its negotiation and preparation of this Agreement. Any costs and expenses (including reasonable attorneys' fees and costs) incurred by Employer in successfully enforcing this Agreement including, but not limited to, Sections 4.3 and 4.4, shall be borne by Employee.

6.6. Waivers. Any term or provision of this Agreement may be waived, or the time for its performance may be extended, by the party or parties entitled to the benefit thereof. Any such waiver shall be validly and sufficiently authorized for the purposes of this Agreement if, as to any party, it is authorized in writing by an authorized representative of such party. The failure of

any party hereto to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision, nor in any way to affect the validity of this Agreement or any part hereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach.

6.7. Partial Invalidity. Wherever possible, each provision hereof shall be interpreted in such manner as to be effective and valid under applicable law, but in case any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such provision shall be ineffective to the extent, but only to the extent, of such invalidity, illegality or unenforceability without invalidating the remainder of such invalid, illegal or unenforceable provision or provisions or any other provisions hereof, unless such a construction would be unreasonable.

6.8. Execution in Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be considered an original instrument, but all of which shall be considered one and the same agreement.

6.9. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws (as opposed to the conflicts of law provisions) of the State of Illinois.

6.10. Waiver of Jury Trial; Submission to Jurisdiction. THE PARTIES HERETO (i) WAIVE ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION TO ENFORCE OR DEFEND ANY MATTER ARISING FROM OR RELATED TO THIS AGREEMENT; (ii) IRREVOCABLY SUBMIT TO THE EXCLUSIVE JURISDICTION OF ANY STATE OR FEDERAL COURT LOCATED IN COOK COUNTY, ILLINOIS, OVER ANY ACTION OR PROCEEDING TO ENFORCE OR DEFEND ANY MATTER ARISING FROM OR RELATED

TO THIS AGREEMENT; AND (iii) IRREVOCABLY WAIVE, TO THE FULLEST EXTENT THEY MAY EFFECTIVELY DO SO, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF ANY SUCH ACTION OR PROCEEDING.

[signature page attached]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the day and year first above written.

COMPANY:
BIOSANTE PHARMACEUTICALS, INC.

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

EMPLOYEE:

/s/ Dr. Steve J.D. Bell 11-01-2000
Dr. Steve J.D. Bell

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

Second Amendment to
Exclusive License Agreement

for

Selected Applications of Coated Nanocrystalline Particles
between

The Regents of the University of California

and

BioSante Pharmaceuticals, Inc.

UC Case No 1989-204

SECOND AMENDMENT TO THE EXCLUSIVE LICENSE AGREEMENT
FOR SELECTED APPLICATIONS OF COATED NANOCRYSTALLINE PARTICLES

This second amendment ("Second Amendment") is effective this 7th day of May, 2001, by and between The Regents of the University of California ("The Regents"), a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200, and BioSante Pharmaceuticals, Inc. ("Licensee"), a Wyoming corporation, having a principal place of business at 175 Olde Half Day Road, Suite 247, Lincolnshire, Illinois 60069.

RECITALS

Whereas, Licensee (formerly known as Ben-Abraham Technologies, Inc.) and The Regents entered into a license agreement entitled "Exclusive License Agreement for Selected Applications of Coated Nanocrystalline Particles," effective on June 18, 1997, having UC Agreement Control Number 1997-04-0671 ("License Agreement"), covering licensure to Licensee by The Regents of rights in certain inventions developed by Dr. Nir Kossovsky et al. at the University of California, Los Angeles, and covered by Patent Rights (as defined in the License Agreement);

Whereas, Licensee and The Regents amended the License Agreement effective October 26, 1999, ("First Amendment"), having UC Agreement Control No. 1997-04-0671A, to include additional terms into the License Agreement and to revise the minimum annual royalties schedule to a more financial and time feasible schedule;

Whereas, Licensee and The Regents amended the License Agreement by notice effective May 25, 2000, having UC Agreement Control No. 1997-04-067lB, to change the name of the company's name from Ben-Abraham Technologies to its current name;

Whereas, Licensee has requested The Regents to amend certain provisions in the License Agreement that pertains only to the field of Vaccine Adjuvant and a particular sublicensing arrangement, defined below as "Adjuvant Sublicense Agreement," between Licensee and a third party called Corixa Corporation;

Whereas, The Regents is willing to amend the License Agreement to reflect such request.

Now, Therefore, in consideration of the foregoing and the mutual promises and covenants contained herein, the parties hereto agree as follows:

1. Paragraph 1.2 (Definitions) of the License Agreement is deleted in its entirety and replaced with the following:

"1.2 "Patent Products" means:

i a Vaccine Adjuvant, Virus Vaccine Construct, or Drug Delivery System comprising a composition of matter, material, product, or Derived Product;

ii a Vaccine Adjuvant, Virus Vaccine Construct, or Drug Delivery System comprising a composition of matter, material, product, or Derived Product to be used in a manner requiring the performance of the Patent Method; or

iii a Vaccine Adjuvant, Virus Vaccine Construct, a Drug Delivery System comprising a composition of matter, material, product, or Derived Product produced by the Patent Method;

to the extent that the manufacture, use, or sale of such composition of matter, material, product, or Derived Product in a particular country, would be covered by or infringed, but for the license granted to Licensee pursuant to this Agreement, an unexpired claim of a patent or pending claim of a patent application were said claim issued in a patent under Patent Rights in that country. This definition of Patent Products also includes a service either used by Licensee or provided by Licensee to its customers when such service requires the practice of the Patent Method. For the avoidance of doubt, any product or service is deemed to be a Patent Product if such product or service contains a component that is a composition of matter, material, product, or Derived Product covered under Subparagraphs 1.2 i through 1.2 iii."

2. Paragraph 1.10 (Definitions) of the License Agreement is deleted in its entirety and replaced with the following:

"1.10 "Net Sales" means the gross invoice prices from the Final Sale of Patent Products by the Licensee or its sublicensee to one or more independent third parties for

cash or other forms of consideration in accordance with generally accepted accounting principles, less only the following deductions (if not already deducted from the gross invoice price and at rates customary within the industry):

1.10a allowances (actually paid and Limited to rejections, returns, and prompt payment and volume discounts granted to customers of Patent Products, whether in cash or Patent Products in lieu of cash);

1.10b freight, transport packing, insurance charges associated with transportation; and

1.10c taxes, tariff, or import/export duties based on sales when included in gross sales, but not value-added taxes or taxes assessed on income derived from such sales.

If the Licensee or its sublicensee distributes Patent Products for commercial end use to itself or to the other party (i.e., Licensee distributes Patent Products to its sublicensee or sublicensee distributes Patent Products to Licensee), then such distribution will be considered a Final Sale of Patent Products based on the price normally charged to independent third parties, and The Regents will be entitled to collect a royalty on such Final Sale at the rates and bases set forth in Article 4 (Royalties). Moreover, if Licensee or its sublicensee distributes a component that is claimed under Patent Rights to itself or to the other party (i.e., Licensee distributes a component to its sublicensee or sublicensee distributes a component to Licensee), and the receiving party includes such component in a Patent Product as defined in Paragraph 1.2, then the distribution of the entire Patent Product by the receiving party to its customers constitutes a Final Sale, and The Regents will be entitled to collect a royalty on such Final Sale at the rates and bases set forth in Article 4 (Royalties)."

3. Paragraph 1.14 (Definitions) is added to the License Agreement as follows:

"1.14 "Derived Product" means any product that is made by using a composition of matter claimed under Patent Rights or by practicing the Patent Method to make a final product regardless of the number of steps in the process or the number and types of compositions of matter (e.g., intermediate compounds) that are involved in making the final product. A "Derived Product" also means any product that is made by using a composition of matter claimed under Patent Rights whether or not that composition of matter is directly incorporated or a part of the final product."

4. Paragraph 1.15 (Definitions) is added to the License Agreement as follows:

"1.l5 "Third Party" means Corixa Corporation, having a principle place of business at 1124 Columbia Street Suite 200, Seattle, Washington 98104-2040. Any reference to sublicensee under the terms of this Agreement is meant to include the Third Party, except when the terms of this Agreement conflict with those of the Second Amendment. In which case, the terms of the Second Amendment will control."

5. Paragraph 1.16 (Definitions) is added to the License Agreement as follows:

"1.16 "Adjuvant Sublicense Agreement" means a definitive agreement by and between the Licensee and Third Party involving the grant by Licensee to Third Party of one or more of the following rights: to make, use, sell, offer for sale, or import Patent Products in the Field, or to practice the Patent Method in the Field. Any reference to a sublicense or sublicense agreement under the terms of this Agreement is meant to include the Adjuvant Sublicense Agreement, except when the terms of this Agreement conflict with those of the Second Amendment. In which case, the terms of the Second Amendment will control."

6. Paragraph 1.17 (Definitions) is added to the License Agreement as follows:

"1.17 "Final Sale" means the point of sale or use of Patent Products, which sale or use is the last infringing act (but for the licenses granted herein) that is within the control of the Licensee or its sublicensee, whether or not the Licensee or sublicensee had control over prior infringing act(s). For the avoidance of doubt, this definition of Final Sale includes the sale of the entire Patent Product in which a component or intermediate claimed under Patent Rights is used to make such Patent Product or is a part thereof."

7. Last sentence of Paragraph 2.4 (Grant) of the License Agreement is deleted in its entirety and replaced with the following:

"Licensee may sublicense third party(s) any part, but not all of its rights that are granted to Licensee under Paragraph 2.1. To the extent certain rights are granted to a third party under a sublicense, such sublicense will include all of the corresponding rights and obligations due to The Regents that are contained in this Agreement including, but not limited to the following:

2.4a payment of royalties in sufficient amounts and at the appropriate times to permit Licensee to satisfy its royalty obligations owed The Regents at the rates, bases, and times set forth in Article 4 (Royalties);

2.4b disposition of Patent Products set forth in Article 11 (Disposition of Patent Products on Hand Upon Termination);

2.4c restrictions for use of names and trademarks set forth in Article 12 (Use of Names and Trademarks);

2.4d patent marking set forth in Article 15 (Patent Marking); and

2.4e indemnification set forth in Article 17 (Indemnification)."

8. Paragraph 3.2 (License Issue Fee) of the License Agreement is deleted in its entirety and replaced with the following:

"3.2 As further consideration for all rights granted by Licensee to the Third Party under the Adjuvant Sublicense Agreement, Licensee will pay to The Regents XXXXXXXXXX (XXX) of all consideration due or owing under the Adjuvant Sublicense Agreement (Sublicense Fee), including but not limited to, milestone payments and a Premium as defined in Paragraph 3.3 below. Licensee will pay The Regents any portion of the Sublicense Fee that had been received by the Licensee in the prior calendar quarter on or before the dates set forth in Paragraph 4.3." **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

9. Paragraph 3.3 (License Issue Fee) is added to the License Agreement as follows;

"3.3 If Licensee accepts an investment in equity or debt financing as consideration for the granting of rights to Third Party under the Adjuvant Sublicense Agreement, then Licensee and Third Party will determine by an arms length transaction, the portion of the equity or debt financing that should be attributed to the Adjuvant Sublicense Agreement (hereinafter referred to as "Premium"), and the fair market value of that equity or debt financing so that a dollar value can be assigned to such Premium. In accordance with Paragraph 3.2, Licensee will pay to The Regents XXXX of the Premium's determined value." **[Portions of this section have been omitted pursuant to a request for confidentiality under Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A copy of this Agreement with this section intact has been filed separately with the Securities and Exchange Commission.]**

10. Paragraph 3.4 (License Issue Fee) is added to the License Agreement as follows:

"3.4 The fees set forth in Paragraph 3.1 and 3.2 above will not be refunded, credited, or considered an advance against royalties, fee, Sublicense Fee or reimbursements for Patent Costs (as defined in Paragraph 14.5) due or owing The Regents under this Agreement."

11. Paragraph 4.1 (Royalties) of the License Agreement is deleted in its entirety and replaced with the following;

"4.1 As further consideration for all the rights and licenses granted to Licensee, Licensee and its sublicensees will pay to The Regents an earned royalty at the rate of four percent (4%) based on the Net Sales of Patent Products. If, however, Licensee has granted the right to manufacture and sell a Vaccine Adjuvant to any third party who manufactures and sells a pharmaceutical product, which pharmaceutical product is combined with the Vaccine Adjuvant, then Licensee may exchange the royalty rate paid to The Regents specified above for a royalty rate of two percent (2%) based on the Net Sales of the Patent Product comprising the pharmaceutical product and Vaccine Adjuvant. Notwithstanding the above, and with respect to only the Adjuvant Sublicense Agreement, Licensee may exchange the royalty rate paid to The Regents specified above

for a royalty rate of one percent (1%) based on the Net Sales of the Patent Product comprising the combination of a pharmaceutical product and Vaccine Adjuvant, which Patent Product can only be sold as a vaccine."

12. Paragraphs 4.2 (Royalties) of the License Agreement is deleted in its entirety and replaced with the following:

"4.2 Licensee will pay to The Regents royalties on Patent Products and Patent Methods covered by both pending applications and issued patents. Earned royalties will accrue in each country for the duration of The Regents' Patent Rights in that country and will be payable to The Regents when Patent Products are invoiced, or if not invoiced, when distributed by Licensee or sublicensee to itself, to the other party (i.e., Licensee distributes Patent Products to its sublicensee or sublicensee distributes Patent Products to Licensee), or to a third party for end use that constitutes a Final Sale. In such event, royalties will accrue to The Regents on the Net Sales in accordance with the terms of Paragraph 4.1 above."

13. Paragraphs 4.3 (Royalties) of the License Agreement is deleted in its entirety and replaced with the following:

"4.3 Royalties and Sublicense Fees accruing to The Regents will be paid to The Regents quarterly on or before the following dates of each calendar year:

February 28 for the calendar quarter ending December 31
May31 for the calendar quarter ending March 31
August 31 for the calendar quarter ending June 30
November 30 for the calendar quarter ending September 30"

14. Paragraph 14.5 (Patent Prosecution and Maintenance) of the License Agreement is deleted in its entirety amid replaced with the following;

"14.5 Licensee will reimburse The Regents for 1/n (where "n" means the total number of licensees and optionees of The Regents, excluding the United States Government) of all costs of preparing, filing, prosecuting, and maintaining all United States and foreign patent applications and patents covered by Patent Rights in Paragraph 1.1, including costs for interferences and opposition proceedings ('Patent Costs"). Licensee will reimburse The Regents for all Patent Costs within 30 days following Licensee's receipt of an itemized invoice from The Regents stating such costs."

15. Paragraph 14.6 (Patent Prosecution and Maintenance) of the License Agreement is deleted in its entirety and replaced with the following:

"14.6 Licensee's obligation to underwrite and pay for Patent Costs incurred by The Regents will continue until three months after expiration or termination of this Agreement. The Licensee will reimburse The Regents for all Patent Costs incurred during the term of the Agreement and for three months thereafter whether or not invoices for such costs are received during the three-month period after expiration or termination

of this Agreement. The Licensee may terminate its obligations with respect to any particular patent application or patent in any or all designated countries three months after giving written notice to The Regents. The Regents may continue prosecution and/or maintenance of such application(s) or patent(s) at its sole discretion and expense, provided, however, that the Licensee will have no further right or licenses thereunder."

16. Paragraph 18.1 (Notices) of the License Agreement is deleted in its entirety and replaced with the following:

"18.1 Any notice or payment required to be given to either party will be deemed to have been properly given and to be effective:

18.la on the date of delivery if delivered in person;

18.lb on the date of mailing if mailed by first-class certified mail, postage paid; or

18.1c on the date of mailing if mailed by any global express carrier service that requires the recipient to sign the documents demonstrating the delivery of such notice of payment;

to the respective addresses given below, or to another address as designated in writing by the party changing its prior address.

In the case of Licensee:
BioSante Pharmaceuticals, Inc.
175 Olde Half Day Road, Suite 247
Lincolnshire, Illinois 60069
Telephone: (847) 793-2434
Facsimile: (847) 793-2435
Attention: Stephen M. Simes
President & CEO

In the case of The Regents:
The Regents of the University of California
Office of the President
Office of Technology Transfer
111 Franklin Street, 5th Floor
Oakland, California 94607-5200
Telephone: (510) 587-6000
Facsimile: (510) 587-6090
Attention: Executive Director,
Office of Technology Transfer
Referring to: UC Case No, 89-204"

In witness whereof, both The Regents and the Licensee have executed this Second Amendment, in duplicate originals, by their respective officers hereunto duly authorized, on the day and year hereafter written.

BIOSANTE PHARMACEUTICALS, INC. **THE REGENTS OF THE**

UNIVERSITY OF CALIFORNIA

By /s/ Stephen M. Simes
(Signature)

Name Stephen M. Simes

Title President & CEO

Date 4/18/01

By /s/ Alan B. Bennett
(Signature)

Name Alan B. Bennett

Title Executive Director,
Research Administration
and Technology Transfer

Date May 7, 2001

Approved as to legal form: /s/ P. Martin Simpson, Jr. 3/22/01
P. Martin Simpson, Jr. Date
University Counsel
Office of General Counsel

SEPARATION AGREEMENT AND MUTUAL RELEASES

THIS SEPARATION AGREEMENT ("Agreement") is entered into effective this 1st day of February, 2002, by and between John E. Lee ("Employee") and BioSante Pharmaceuticals, Inc. ("Employer") (collectively referred to as the "Parties"), to resolve all issues related to or arising out of Employee's former full-time employment with Employer and Employee's September 28, 2001 separation. In consideration of the mutual covenants contained herein, the sufficiency of which the Parties acknowledge, the Parties agree as follows:

1. Separation Date. Employee's last day of full-time employment with Employer was September 28, 2001.

2. Payments at Separation. On September 28, 2001, Employer tendered to Employee: (a) a check in the amount of $7,083.33, less normal tax withholding, that was for Employee's regular salary through September 28, 2001; and (b) a check in the amount of $4,740.93, less normal tax withholding, that was the equivalent of Employee's accrued but unused vacation through September 28, 2001. On October 7, 2001, Employer tendered to Employee: (a) a check in the amount of $14,166.66 less, normal tax withholding, pursuant to Section V(C) of Employee's Employment Agreement dated August 1, 2000 (the "Employment Agreement"); (b) a check in the amount of $170,000.00 less normal tax withholding, pursuant to Section V(C)2)(i) of the Employment Agreement; and (c) a check in the amount of $402.83 as reimbursement for Employee's out-of-pocket expenses through September 28, 2001.

3. Settlement Amount. In consideration for the agreements and releases by the Employee set forth below, including Employee's agreement to provide marketing liason services to Employer as more fully described below, Employer agrees that within five business days after the revocation period described in Paragraph 18, below, with no revocation of this Agreement by Employee, Employer will provide Employee with the following (which Employee acknowledges is more than Employee would receive if Employee did not sign this Agreement): (a) $12,000 per month, subject to normal tax withholding, for a period of eight months commencing February 1, 2002 (or as soon thereafter as possible based upon Employee's acceptance of this Agreement and the expiration of the revocation period described in Paragraph 19, below) through and including September 1, 2002. Said payments shall be made by payroll check on the 15th and last day of each month and mailed to Employee on or before those dates; (b) a check in the amount of $3,937.50 which is equivalent to the net amount of Employer's 2001 matching 401(k) contribution for Employee; and (c) a check in the amount of $1,731.84 to "gross up" Employee's moving expenses. Employer shall make its payments to Employee under paragraphs 3(b) and (c) no later than ten (10) days after Employee signs and delivers this Agreement to Employer's counsel. If Lee dies or becomes disabled prior to September 30, 2002, any remaining salary payments due under this Agreement shall be paid (in a lump sum, less applicable tax withholding) to any person or persons designated by Lee in writing, or if he fails to make such designation, to Lee's estate.

4. Continuation of Benefits. Employee, pursuant to Sections V(C)(2)(ii) and (iii) of the Employment Agreement, shall be allowed to participate, at the Company's expense, in Employer's health, dental disability insurance and term life insurance programs until the earlier of September 28, 2002 or Employee becoming eligible to participate in another employer's corresponding health and disability plans. In the event Employer's insurance company refuses to allow Employee's continued participation in said plans, Employer agrees, in consultation with

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Employee, to provide Employee with the most comparable coverage available in the marketplace, at Employer's sole expense. Employee acknowledges that Employee's participation in and entitlement to any and all other compensation, fringe benefits, employee benefit plans and stock option plans of Employer ceased as of Employee's separation date except that Employee's ability to exercise his 500,000 vested options of Employee's common stock shall be extended until November 30, 2003.

5. Employee's Obligation to Provide Services. Employee agrees that from the date of execution of this Agreement through and including September 30, 2002, Employee will make himself available to perform marketing liaison services for Employer. These services may include, but are not limited to, follow-up at Employer's request with any third party with which Employee had contact, on Employer's behalf, prior to September 28, 2001, (subject to his availability and reasonable notice of need from Employer), but in any event shall not exceed a maximum of 20 hours per month, unless mutually agreed upon in writing by Employer and Employee. Employer shall also reimburse Employee for all expenses reasonably incurred in the performance of his Employer-designated activities during the period he performs these services. The scheduling and scope of such services, and the time required to perform such services, must be reasonable, and cannot unreasonably interfere with Employee's other employment or business activities. Employer agrees and acknowledges that Employee may accept full or part-time time employment with another employer and/or engage in any other business activities at any time, and there shall be no restrictions on such activities. Except as otherwise specifically provided herein, such employment shall not affect, reduce or terminate Employer's obligations under this Agreement or Employee's rights under this Agreement, including without limitation, Employer's obligations to timely make the payments as provided in Paragraph 3, above.

6. Releases.

A. Except for Employee's breach of this Agreement, to the maximum extent permitted by applicable law, Employer and Employer's Releasees **RELEASE AND FOREVER DISCHARGE** Employee and Employee's agents, immediate family members, attorneys, including, but not limited to, Bankhead Nesthus & Scalone LLP, employees, representatives, trustees, administrators, fiduciaries, heirs, successors and assigns (Employee and all of the foregoing being hereinafter collectively referred to as the "Employee's Releasees"), of and from, and does hereby **WAIVE** any and all rights, contracts, torts, claims, damages, actions, causes of action, and suits, whether or not now known, suspected, or claimed, which it ever had, now has or claims, or might hereafter have or claim against Employee's Releasees, and each of them, based upon, arising out of, or relating to, directly or indirectly, any matter or thing occurring, in whole or in part, from the beginning of the world through the date hereof, including, without limitation, any and all rights, claims, or causes of action which Employer has, had, or may have against Employee's Releasees, and each of them, relating directly or indirectly to Employee's employment with Employer and the cessation of this employment as of the date of this Agreement. Further, Employer agrees to fully defend and indemnify Employee as a former officer of BioSante, as required by Illinois law, including, but not limited to, in the event that Employee is named in any claim arising from or relating to Employer's alleged wrongful taking or use of proprietary material of any third party or arising out of the alleged illegal or tortious conduct of any of Employer's employees or agents, provided that Employer's obligations to indemnify and defend as described in this Section 6A do not apply to any illegal or intentionally tortious conduct by Employee that is found not to have arisen within the scope of Employee's duties or from Employee's obedience to Employer's direction. Consistent with the

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foregoing, if Employee is found to have engaged in any illegal or intentionally tortious conduct that is found not to have arisen within the scope of Employee's duties or from obedience to Employer's direction, Employee shall reimburse Employer for any and all sums expended by Employer to indemnify or defend Employee.

Employer **REPRESENTS AND WARRANTS** that that Employer and/or Employer's Releasees are the sole owner of all of the claims against Employee released under this Section 6A, and that it has not heretofore assigned or transferred to any person or entity any of the matters released under this Section 6A. Except for purposes of enforcement of this Agreement, Employer covenants not to sue or file any claims against Employee's Releasees, or any of them, for any of the matters released under this Section 6A.

B. Except for Employer's breach of this Agreement and Employer's obligations to defend and indemnify Employee and as provided in Section 6A, to the maximum extent permitted by applicable law, Employee and Employee's Releasees **RELEASE AND FOREVER DISCHARGE** Employer and any of its affiliated businesses, partners, and joint ventures, and its/their predecessors, successors, heirs and assigns, and its/their past, present and future directors, shareholders, officers, including, but not limited to, Stephen Simes, Phillip Donenberg, Leah Lehman and Victor Morgenstern, agents, attorneys, including, but not limited to, Ungaretti & Harris, employees, representatives, trustees, administrators, and fiduciaries, jointly and severally, in their individual, fiduciary and corporate capacity (Employer and all of the foregoing being hereinafter referred to as the "Employer's Releasees") of and from, and does hereby **WAIVE**, any and all rights, contracts, torts, claims, damages, actions, causes of action, and suits, whether or not now known, suspected or claimed, which Employee ever had, now has or claims, or might hereafter have or claim against Employer's Releasees, and each of them, based upon, arising out of, or relating to, directly or indirectly, any matter or thing occurring, in whole or in part, from the beginning of the world through the date hereof, including, without limitation, any and all rights, claims, or causes of action which Employee has, had or may have against Employer's Releasees, and each of them, relating directly or indirectly to Employee's employment with Employer and the cessation of this employment as of the date of this Agreement.

Without limiting the foregoing terms, this Agreement specifically includes and extinguishes all claims for age discrimination, sex discrimination or discrimination on any other basis; any and all wage claims; breach of contract; wrongful discharge; detrimental reliance; retaliatory discharge; infliction of emotional distress; any other tort; and any and all claims Employee or Employee's Releasees have arising from any alleged violation by or on behalf of the Released Parties, of any federal, state or local constitution, statute, regulation, ordinance, order, public policy or common law, including, but not limited to, the Age Discrimination in Employment Act of 1967, as amended, Title VII of the Civil Rights Act of 1964, as amended, the Civil Right Act of 1991, the Americans With Disabilities Act 42 U.S.C.§ 1981, and any other similar Illinois law prohibiting employment discrimination.

Employee **REPRESENTS AND WARRANTS** that Employee is the sole owner of all of the claims against Employer released under this Section 6B and that Employee has not heretofore assigned, transferred or reconveyed to any person or entity any of the matters released under this Section 6B. Except for purposes of enforcement of this Agreement, Employee covenants not to sue or file any claims against Employer's Releasees, or any of them, for any of the matters released under this Section 6B.

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7. Confidentiality of Agreement. Except as may be specifically required by law, neither party shall disclose, publish, indicate, or communicate any term or provision of this Agreement to any person or entity other than such party's spouse, attorney, or (solely to the extent necessary to allow preparation of such party's tax returns) accountant/financial advisor. Prior to any such disclosure, the disclosing party will inform each such person to whom disclosure is to be made that the terms of this Agreement are confidential and secure the agreement of each such person to maintain the confidentiality of all terms of this Agreement. If Employee is specifically required by law to disclose any of the terms or provisions of this Agreement, Employee will if not prohibited by law, before making any such disclosure, provide prompt written notice to BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Suite 280, Lincolnshire, Illinois 60069, Attention: Phillip Donenberg, in which Employee shall describe the reason for, and the scope, nature, and timing of, any such legally required disclosure. If Employer is specifically required by law to disclose any of the terms or provisions of this Agreement, Employer will if not prohibited by law, before making any such disclosure, provide prompt written notice to John E. Lee, 1857 Cardinal Lane, Long Grove, Illinois 60047, in which Employer shall describe the reason for, and the scope, nature, and timing of, any such legally required disclosure. By signing below, each party confirms that he/it has honored the terms of this paragraph through the date on which each party signed this Agreement.

8. No Encouragement of Claims. Neither party will encourage any person to file a lawsuit, claim, or complaint against any of the Released Parties. Neither party will assist any person who has filed a lawsuit, claim, or complaint against any of the Released Parties unless such party is required to render such assistance pursuant to a lawful subpoena or other legal obligation.

9. Return of Property. Employee agrees that Employee has or will return to Employer all of its property that is in Employee's possession or control, including, without limitation, any disc, including all copies, containing information from any third-party obtained during Employee's employment with Employer, all keys, computer hardware, materials, papers, books, files, documents, records, policies, customer information and lists, sales and marketing information, data base information and lists, mailing lists, notes, computer software and programs, data, and any other property or information, that Employee may have relating to Employer, its customers, employees, policies, or practices (whether those materials are in paper or computer-stored form). Employee represents and warrants that regarding any disc, including all copies, containing information from any third party, Employee will return to Employer said disc and copies prior to Employee's receipt of the first payment described in Section 3, and that Employee shall not retain any copy or copies of any disc containing information of any third party obtained during Employee's employment with Employer. Employer agrees that it promptly will return to Employee all of Employee's personal property in Employer's possession or control, including without limitation, Employee's artwork, telephone, books and binders, and rolodex/Microsoft Outlook information (whether those materials are in paper or computer-stored form) containing information that Employee had in his possession prior to his employment with Employer. Employer further agrees to promptly forward to Employee all personal calls, emails and personal mail.

10. Confidential Information. Employee acknowledges that during the term of Employee's employment with Employer, Employee was obligated to retain the confidentiality of certain confidential and proprietary information disclosed to Employee and the security of Employer's property entrusted to Employee. Nothing contained in this Agreement is intended to relieve Employee of these obligations, as set forth in Section VII of the Employment Agreement

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which is incorporated herein by reference. Therefore, at all times during and subsequent to Employee's employment by Employer, Employee will regard and preserve all confidential information and will not disclose such information to others and will refrain from harming any Employer property.

11. Non-disparagement. Employee and Employer agree that neither party will defame, disparage or denigrate, the other party or any of such party's Released Parties and/or related persons or any of its/their business products or services. In the event that inquiries are made of Employer seeking confirmation of Employee's employment by, or an evaluation of Employee's performance while in the employ of, or concerning the circumstances surrounding Employee's separation from full-time employment with Employer, Employer shall provide only Employee's positions and dates of employment, provided, that if asked for the reason for such a limited response, Employer shall be permitted to state that it has a policy not to comment further. The parties agree that all inquiries regarding Employee's employment are to be directed to Phillip Donenberg.

12. Non-Admission. This Agreement does not constitute an admission by any of the Released Parties, and Employer specifically denies, that any action that any of the Released Parties has taken or has failed to take with respect to Employee was or is wrongful, unlawful, in violation of any local, state or federal act, statute or constitution or susceptible of inflicting any damages or injury upon Employee.

13. Applicable Law. This Agreement shall be governed by, construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Agreement shall be governed by, the laws of the State of Illinois without giving effect to that State's principles regarding conflict of laws. The parties agree that venue will lie solely with the federal or state courts located in Cook County, Illinois and submit to the jurisdiction of federal or state courts located in Cook County, Illinois.

14. Severability. In the event that any provision of this Agreement is found by any court or tribunal of competent jurisdiction to be invalid or unenforceable, the remaining provisions shall remain valid and enforceable.

15. Entry to Employer's Property. Employee agrees that Employee will not enter the premises of Employer without Employer's prior written consent which consent only may be given by Phillip Donenberg, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Suite 280, Lincolnshire, Illniois 60069.

16. Entire Agreement. This Agreement contains the entire agreement and understanding between Employee and Employer concerning the matters described herein and supercedes all prior agreements, discussions, negotiations, understandings and proposals of the parties. The terms of this Agreement cannot be changed except in a subsequent document signed by Employee and Chief Executive Officer of Employer. This Agreement binds and is for the benefit of Employee and Employer as well as his/her/its respective heirs, personal representatives, successors and assigns.

17. Revocation Period. Employee has the right to revoke this Agreement during a period of seven days after Employee signs it. To revoke this Agreement, Employee must sign and send a written notice of Employee's decision to revoke the Agreement, addressed to Phillip Donenberg, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Suite 280, Lincolnshire,

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Illinois 60069, and that written notice must be received at that address no later than seven days after the Employee signed this Agreement. If Employee exercises Employee's right to revoke this Agreement, Employee will not be entitled to any of the money, benefits and other consideration from Employer described in paragraph 3, and must immediately repay to Employer any consideration that Employee already has received from Employer under that paragraph.

18. Knowing and Voluntary Waiver. Employee acknowledges that Employee: (a) has completely read this Agreement and fully understands its meaning; (b) has had the opportunity of twenty-one (21) days to review this agreement before signing it; (c) has had the full opportunity to investigate all matters pertaining to Employee's claims and fully understands its terms and contents, including the rights and obligations hereunder; (d) **has been informed of the right to consult an attorney before signing this document**; (e) is entering into this Agreement knowingly and voluntarily; and (f) the only consideration Employee is receiving for signing this Agreement is described herein, and no other promises or representations of any kind have been made by any person or entity to cause Employee to sign this Agreement.

READ CAREFULLY.
THIS DOCUMENT CONTAINS A GENERAL RELEASE OF ALL
KNOWN AND UNKNOWN CLAIMS

BIOSANTE PHARMACEUTICALS, INC.

/s/ John E. Lee
John E. Lee

By: /s/ Stephen M. Simes
Its: Chief Executive Officer

Date Signed by Employee

Date Signed by BioSante Pharmaceuticals, Inc.

Exhibit 23.1

INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in Registration Statement No. 333-53384 of BioSante Pharmaceuticals, Inc. (BioSante) on Form S-8 and Registration Statement No. 333-64218 of BioSante on Form SB-2 of our report dated February 15, 2002 (which report expresses an unqualified opinion and includes an explanatory paragraph referring to the developmental stage nature of BioSante), appearing in this Annual Report on Form 10-KSB of BioSante Pharmaceuticals, Inc. for the year ended December 31, 2001.

/s/ Deloitte & Touche LLP

Chicago, Illinois
March 27, 2002