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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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FORM 10-KSB

(Mark one)

/x/ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2000

// TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER 000-28637

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BIOSANTE PHARMACEUTICALS, INC. (Name of Small Business Issuer in its Charter)

WYOMING

(State or Other Jurisdiction of Incorporation or Organization)

58-2301143 (I.R.S. Employer Identification No.)

175 OLDE HALF DAY ROAD, SUITE 247 LINCOLNSHIRE, ILLINOIS (Address of Principal Executive Offices) 60069 (Zip Code)

(847) 793-2458 (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, NO 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 /x/ NO //

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.  $/\mathrm{x}/$ 

The issuer's revenues for the fiscal year ended December 31, 2000 were  $\$227,718\,.$ 

As of March 1, 2001, 52,952,943 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 \$14,180,805.

# 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 2001 Annual Meeting to be held June 13, 2001.

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

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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 PHARMACEUTIALS, INC., UNLESS THE CONTEXT OTHERWISE INDICATES. WE OWN OR HAVE THE RIGHTS TO USE VARIOUS TRADEMARKS, TRADE NAMES OR SERVICE MARKS, INCLUDING THE BIOSANTE NAME.

#### ITEM 1. BUSINESS

#### GENERAL

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

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

- o accelerate the development of our hormone replacement products;
- o continue to develop our nanoparticle-based CAP platform technology and seek assistance in such development from corporate partners;
- o license or otherwise acquire other drugs that will add value to our current product portfolio; and
- o 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. (the entity that resulted from the merger of Permatec Technologie, AG with Medi-Ject Corporation), are gel formulations of testosterone, estradiol and a combination of estradiol and a progestogen. The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. We expect to begin human clinical trials on at least one of our hormone replacement products in 2001, continuing the process of obtaining United States Food and Drug Administration, or FDA, approval to market the product.

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 and for drug delivery. We have identified three

potential initial applications for our CAP technology:

- o 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;
- o the development of new, unique vaccines against diseases for which there currently are few or no effective methods of prevention (E.G., genital herpes); and
- o the creation of inhaled forms of drugs that currently must be given by injection (E.G., insulin).

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. 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 shareholders on November 27, 1996 and the articles of arrangement were filed and became effective as of December 6, 1996. In November 1999, our shareholders approved the change of our corporate name from Ben-Abraham Technologies Inc. to BioSante Pharmaceuticals, Inc.

# BUSINESS STRATEGY

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

- O 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.
- CONTINUE TO DEVELOP OUR NANOPARTICLE-BASED CAP PLATFORM TECHNOLOGY AND SEEK ASSISTANCE IN SUCH DEVELOPMENT FROM CORPORATE PARTNERS. 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. We are particularly interested in entering into product co-development and co-marketing arrangements with respect to our CAP technology with others for further development and marketing. We believe that this partnering strategy will enable us to capitalize on our partner's 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, such collaborations would significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology and thereby permit us to spend cash on accelerating the human clinical development of our hormone replacement products.
- 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 such 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.

O 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.

#### DESCRIPTION OF OUR HORMONE REPLACEMENT PRODUCTS

We are focused on building a pipeline of hormone replacement products to treat testosterone deficiency in men and estrogen deficiency in women.

Our hormone replacement products are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), 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 required amount of 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.

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 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 is often delivered through injections or dermal, or skin, patches. Delivery of testosterone through dermal patches were 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 is designed to deliver the required amount of testosterone without the pain of injections and the skin irritation and discomfort associated with dermal patches.

Estrogen deficiency in women can result in hot flashes, vaginal atrophy, decreased libido and osteoporosis. Hormone replacement in women decreases the chance the women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately twenty million women in the U.S. are currently 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 is designed to deliver the required amount of estrogen without the skin irritation associated with dermal

patches. We are also 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 may reduce the potential risks of uterine cancer and endometrial hyperplasia associated with estrogen therapy in these women.

We believe our hormone replacement products have a number of benefits, including the following:

- o estrogen and testosterone gels can be spread over large areas of skin where they dry rapidly and decrease the chance for skin irritation versus hormone patches;
- o estrogen and estrogen/progestogen gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;
- o adding progestogen to estrogen may reduce the potential risks of uterine cancer and endometrial hyperplasia when the uterus is intact:
- o testosterone gel has been shown to be absorbed evenly, thus allowing clinical testosterone levels to reach the systemic circulation; and
- o the clinical trials involving the hormone products will be relatively smaller requiring fewer patients than most drug development projects which will keep our costs, time and risks associated with the approval process down.

We expect to begin human clinical trials involving at least one of our hormone replacement products in 2001, which is required to obtain FDA approval to market the product.

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, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Australia, New Zealand, China, Malaysia, Indonesia and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada.

In September 2000, we sublicensed our female hormone replacement products to Paladin Labs Inc. for further development and sale in Canada.

#### 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.

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 performed 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 actually enhance the biological activity as compared to injection of the molecule alone in solution.

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:

- o 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;
- o it is fast, easy and inexpensive to manufacture, which will keep our costs down and potentially improve our profit margins;
- o the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays or inhalation instead of using painful injections; and
- o 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 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) new virus vaccines, including vaccines to treat or prevent disease such as Herpes viruses and (3) drug delivery systems, including a method of delivering proteins (e.g., insulin) through inhalation. 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 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.

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 "Item 1. Business - 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.

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 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., the entity that resulted from the merger of Permatec Technologie, AG with Medi-Ject Corporation, 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 will evaluate 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.

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 announced in August 2000, an option license agreement with Antex Biologics, Inc. to conduct preclinical tests of CAP in vaccines against CHLAMYDIA PNEUMONIAE and H. PYLORI.

NEW VACCINES. We believe our nanoparticle technology presents a new, and more effective and safer, approach to vaccine preparation. As with our vaccine adjuvant technology, we are continuing our own research and development in this area, but we also 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. We believe these collaborations may enable us to accelerate the development of potential improved vaccines for any products developed from our CAP technology. These arrangements also could include out-licenses of our CAP technology to vaccine companies and others for further development and marketing. We have begun discussions with other companies to out-license our adjuvant for use in those companies' new vaccine development.

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 stability 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. Our research and development efforts in this area are ongoing. 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.

#### SALES AND MARKETING

We currently do not have any 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 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 \$1,888,000 in 2000 and approximately \$661,000 in 1999 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues, other than interest revenues earned on available cash balances, these research and development costs must be financed by us. We estimate that we are currently spending approximately \$75,000 to \$100,000 per month on research and development activities. This amount is expected to increase as we begin to develop the hormone replacement product portfolio. These expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on 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 activities. 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. If, and when we are ready to commercially launch a product, 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.

# PATENTS, LICENSES AND PROPRIETARY RIGHTS

Our success depends and will continue to depend in part upon our ability 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 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 this technology 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.

The license agreement with Antares required us to make a \$1,000,000 payment of a license issue fee, which we have paid. Also pursuant to the terms of the Antares license agreement, we expect to:

- o pay royalties to Antares based on a percentage of the net sales of any products incorporating the licensed technology;
- accelerate the human clinical development of the hormone product portfolio, including;
  - >> testing proposed products;
  - >> conducting clinical trials;
  - >> obtaining government approvals; and
  - >> introducing products incorporating the licensed technology into the market.
  - enter into sub-license arrangements or agreements with other entities regarding development and commercialization of the technology covered by

UNIVERSITY OF CALIFORNIA. In June 1997, we entered into a licensing agreement with the Regents of the University of California 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 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 incorporating the licensed technology;
- o 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 (2013);

YEAR	MINIMUM ANNUAL ROYALTY DUE
2004 2005 2006 2007 2008 2009 2010 2011 2012 2013	\$ 50,000 \$ 100,000 \$ 150,000 \$ 200,000 \$ 400,000 \$ 600,000 \$ 800,000 \$ 1,500,000 \$ 1,500,000 \$ 1,500,000

- o 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;
- o payment of the costs of patent prosecution and maintenance of the patents included in the agreement which have amounted to \$11,722 in fiscal 2000 and which we estimate will equal approximately \$15,000 per year;
- o 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; 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

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 of California that we would not pursue the red blood cell surrogate use because we do not believe this will be proven an effective use of CAP. In October 1999, we signed an amendment to our license agreement with the University of California, 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 of California'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 of California, the University of California may terminate some projects included in the agreement.

PATENTS AND PATENT APPLICATIONS. Although we do not own any United States patents or foreign patents, on February 3, 2000, we filed a patent application with the U.S. Trademark and Patent Office relating to our development work with vaccine adjuvants, conventional DNA and RNA vaccines and drug delivery, including aerosol delivery into the lungs.

TRADEMARKS AND TRADEMARK APPLICATIONS. We have filed an intent-to-use application and received a notice of allowance for the mark BioSante. We currently have filed six intent-to-use applications in the United States and nine intent-to-use applications in foreign countries. The mark BioSante has been published in the European Community. We do not have any 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

Competition in the biopharmaceutical industry is intense both in hormone replacement therapy and the development of products 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 also 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. These institutions may also market competitive commercial products on their own or in collaboration with competitors and will compete with us in recruiting highly qualified scientific personnel.

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 any products we develop that incorporate our CAP technology. Several competing companies, including Wyeth-Ayerst Pharmaceuticals, Novartis, 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: SmithKline Beecham plc, Rhone-Poulenc S.A. (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. 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

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technologies. Competitive or comparable companies to us include Corixa Corporation, generally regarded as the 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 Food and Drug Administration 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:

- o preclinical laboratory and animal tests:
- o the submission to the FDA of an investigational new drug application, commonly known as an IND application;
- o 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;
- o the submission to the FDA of a new drug application, commonly known as an NDA; and
- o 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 successfully completed, 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, reevaluate, 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 seven full-time employees as of March 1, 2001, including four in research and development and three in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We consider our relationships with our employees to be good.

#### 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 our forward-looking statements. These factors, and their impact on the success of our operations and our ability to achieve our goals, include the following:

WE HAVE A HISTORY OF OPERATING LOSSES, EXPECT CONTINUING LOSSES AND MAY NEVER ACHIEVE PROFITABILITY.

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of \$3,437,195 for the year ended December 31, 2000, and as of December 31, 2000, our accumulated deficit was \$15,639,672.

All of our revenue to date has been derived from interest earned on invested funds. 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:

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

- o the absence of an operating history;
- o the lack of commercialized products;
- o insufficient capital;
- expected substantial and continual losses for the foreseeable future;
- o limited experience in dealing with regulatory issues;
- o the lack of manufacturing experience and limited marketing experience;
- an expected reliance on third parties for the development and commercialization of our proposed products;
- a competitive environment characterized by numerous, well-established and well-capitalized competitors; and
- o 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 STAGES AND WILL LIKELY NOT BE COMMERCIALLY INTRODUCED FOR SEVERAL YEARS, IF AT ALL.

Our proposed products are in the research 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:

- o be successfully developed;
- o prove to be safe and efficacious in clinical trials;
- meet applicable regulatory standards;
- o demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;
- o be capable of being produced in commercial quantities at reasonable costs; or
- o 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 for a number of years, 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, 2000 was \$2,611,755. We believe this cash will be sufficient to fund our operations through June 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 or products already on the market, and assist in the final development and commercialization of those products. 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.

While we have no current agreements or negotiations underway, if we purchase any products, we could issue common or preferred stock that would dilute our existing shareholders' percentage ownership, incur substantial debt or assume contingent liabilities. These purchases also involve numerous other risks, including:

- o problems assimilating the purchased products;
- o unanticipated costs associated with the purchase;
- o incorrect estimates made in the accounting for acquisitions; and
- o 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 distributed 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 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, at our own expense, 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 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 the target 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 can cause delay or termination of our clinical trials include:

- o slow patient enrollment;
- o longer treatment time required to demonstrate efficacy;
- adverse medical events or side effects in treated patients; and
- o 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 WOULD 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 DO NOT HAVE ANY FACILITIES APPROPRIATE FOR CLINICAL TESTING, WE LACK MANUFACTURING EXPERIENCE AND WE HAVE NO SALES AND MARKETING PERSONNEL. WE WILL, 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 do not have any 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 may also adversely affect our profit margins.

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 the right to 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, Antares and the University of California 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 license agreement could either, depending on 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.

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  $\frac{1}{2}$ 

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 technology. However, our owned and licensed patents and patent applications will not ensure the protection of our intellectual property for a number of other reasons:

- o We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease before others 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 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.
- o 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.
- o 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 that patent.
- We may also 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 is also 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. 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 are also 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:

- o result in costly litigation;
- o divert the time and attention of our technical personnel and management;
- cause product development delays;
- require us to develop non-infringing technology; or
- o require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry have often 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 are ultimately approved for sale, there can be no assurance that they will be commercially successful.

BECAUSE OUR INDUSTRY IS VERY COMPETITIVE AND 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 are also conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we are currently developing or will develop.

WE ARE DEPENDENT ON KEY PERSONNEL, MANY OF WHOM WOULD BE DIFFICULT TO REPLACE.

Our success will be largely dependent upon the efforts of Stephen M. Simes, our 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. PROPERTIES

Our principal executive office is located in Lincolnshire, Illinois. We lease approximately 1,371 square feet of office space for approximately \$2,100 per month, which lease expires in December 2001. We plan to renew our lease for a one-year term. 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 on September 14, 2002. 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 September 14, 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, 2000.

#### ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers, their ages and the offices held, as of March 1, 2001, are as follows:

NAME	AGE	TITLE
Stephen M. Simes	49	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	40	Chief Financial Officer, Treasurer and Secretary
John E. Lee	51	Vice President, Commercial Development
Leah M. Lehman, Ph.D.	37	Vice President, Clinical Development
Steven J. Bell, Ph.D.	41	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. From 1993 to 1994, Mr. Donenberg was Controller of Molecular Geriatrics Corporation, a biotechnology corporation. Prior to Molecular Geriatrics Corporation, Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc. and Xtramedics, Inc.

JOHN E. LEE has served as our Vice President, Commercial Development since August 2000. Before joining our company, Mr. Lee was Vice President, Sales and Marketing at Questcor Pharmaceuticals (formerly Cypros Pharmaceuticals, Inc.) from March 1999 to May 2000. From 1996 to March 1998, Mr. Lee was Vice President, Commercial Development at Unimed Pharmaceuticals and has held various sales and marketing positions at G.D. Searle & Co.

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.

# 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 and in Canada on the Canadian Venture Exchange, formerly known as the Alberta Stock Exchange, under the symbol "BAI," since December 20, 1996. 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 Canadian Venture Exchange.

#### CANADIAN VENTURE EXCHANGE

2000	HIGH	LOW
First Quarter Second Quarter Third Quarter Fourth Quarter	\$1.38 \$1.07 \$1.01 \$0.95	\$0.22 \$0.46 \$0.71 \$0.49
1999		
First Quarter Second Quarter Third Quarter Fourth Quarter	\$0.24 \$0.50 \$0.37 \$0.48	\$0.15 \$0.21 \$0.23 \$0.45

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

2000	HIGH	LOW
Second Quarter	\$1.25	\$0.47
Third Quarter	\$1.03	\$0.80
Fourth Ouarter	\$0.92	\$0.52

# NATIONAL QUOTATION BUREAU ("PINK SHEETS")

2000	HIGH	LOW
First Quarter	\$1.50	\$0.28
1999	HIGH	LOW
Third Quarter	\$ 0.51	\$0.27
Fourth Quarter	\$1.125	\$.175

# NUMBER OF RECORD HOLDERS; DIVIDENDS

As of March 1, 2001, there were 1,578 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, 2000, we did not issue any securities without registration under the Securities Act.

# 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 testosterone deficiency in men and estrogen deficiency in women. We also are engaged in the development and commercialization of vaccine adjuvants or

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. Symptoms of these hormone deficiencies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

The new products we in-licensed are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), 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, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Australia, New Zealand, China, Malaysia, Indonesia and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of the hormone 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 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 our company's 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. Paladin may convert the debenture at any time after January 1, 2001. If Paladin does not convert the debenture by March 31, 2001, we may require it to be converted.

Our strategy with respect to our hormone replacement product portfolio is to initiate human clinical trials on at least one of our proposed hormone replacement products in 2001, which is required to obtain FDA approval to market the product in the United States.

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 and for drug delivery. We have identified three potential initial applications for our CAP technology:

- o the creation of improved versions of current vaccines by the "adjuvant" activity of our proprietary nanoparticles;
- o the development of new, unique vaccines against diseases for which there currently are few or no effective methods of prevention (e.g., genital herpes); and
- o the creation of inhaled forms of pharmaceutical compounds that currently must be given by injection (e.g., insulin).

Our strategy with respect to CAP over the next 12 months, is to continue development of our nanoparticle technology and to actively seek

collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the U.S. Food and Drug Administration to initiate a Phase I clinical trial of our proprietary calcium phosphate nanoparticles (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 and there was no apparent difference in side effect profile between CAP and placebo; statistical analysis is still in progress.

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

- o Accelerate the development of our hormone replacement products.
- o Continue to develop our nanoparticle-based CAP platform technology and seek assistance in such development from corporate partners.
- o License or otherwise acquire other drugs that will add value to our current product portfolio.
- Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

We currently do not expect any significant changes in the number of our employees unless we are able to enter into a business collaboration or joint venture to further develop and commercialize our hormone replacement products and products incorporating our CAP technology or in-license or otherwise acquire products in the late-stage human clinical development phase or products already on the market. Alternatively, if we are able to enter into business collaborations or joint ventures, in lieu of hiring additional employees, we may elect to enter into arrangements with third parties to accomplish the similar tasks of hired employees.

Since our inception, we have experienced significant operating losses, and we expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of \$3,437,195 for the year ended December 31, 2000, resulting in an accumulated deficit of \$15,639,672.

All of our revenue to date has been derived from interest earned on invested funds. We have not commercially introduced any products. We expect to incur substantial and continuing losses for the foreseeable future as we seek to in-license or otherwise acquire new products and 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:

- o the timing and cost of product development;
- o the progress and cost of preclinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of obtaining third party reimbursement; and
- o the costs of licensure or acquisition of new products.

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.

#### LIQUIDITY AND CAPITAL RESOURCES

To date, we, as well as our predecessor, Structured Biologicals, have consistently raised equity financing to fund our activities, and we expect to continue this practice to fund our ongoing activities. From inception through March 1, 2001, we have raised net proceeds of approximately \$9.2 million from private equity financings, class A and class C stock conversions and warrant exercises.

Our cash and cash equivalents were \$2,611,755 and \$5,274,552 at December 31, 2000 and 1999, respectively. The decrease in our cash balance is due to the increase in research, development and in- and out-licensing activities during the year ended December 31, 2000.

#### 2000 VERSUS 1999

We used cash in operating activities of \$3,207,604 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 \$588,045 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.

#### 1999 VERSUS 1998

We used cash in operating activities of \$1,787,822 for the year ended December 31, 1999 versus cash used in operating activities of \$3,041,425 for the year ended December 31, 1998. This change was driven by a reduction in both personnel-related expenses in research and development and, a similar reduction in general and administrative expenses during 1999. Net cash used in investing activities was \$4,219 for the year ended December 31, 1999 versus \$124,984 for the year ended December 31, 1998. The significant uses of cash in investing activities 1999 were capital expenditures for the purchase of office furniture and a computer. The significant uses of cash in investing activities for the year ended December 31, 1998 included capital expenditures for laboratory equipment and laboratory office furniture. Net cash provided by financing activities was \$4,225,343 for the year ended December 31, 1999 compared to \$4,257,328 for the year ended December 31, 1998. Net cash provided during 1999 was primarily the result of our private placement completed in May 1999. Net cash provided in 1998 was primarily the result of the conversion of class A and class C stock into shares of common stock.

# OUTLOOK

We expect to continue to incur significant expenses, primarily relating to our research and development activities. Management estimates that it is currently expending approximately \$75,000 to \$100,000 per month on research and development activities and approximately \$150,000 to \$200,000 per month in total expenses, including research and development activities. Our research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on the resources available and our development schedule. As we progress through the clinical development of our hormone replacement product portfolio or we are able to in-license or otherwise acquire additional drugs in the late-stage development phase or drugs already on the market, it is likely that our research and development and total expenses would increase

significantly. Results of studies, clinical trials, regulatory decisions and competitive developments also may influence our expenditures. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds for research and development activities. The capital equipment expenditures of \$43,238 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

#### COMMITMENTS

We have several financial commitments, including the following minimum annual lease payments:

YEAR	MINIMUM ANNUAL LEASE PAYMENTS		
2001 2002 2003	\$ 89,401 \$ 68,254 \$ 57,239		

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

o pay the following 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 (2013):

-	YEAR	M]	INIMUM ANNUAL ROYALTY DUE
	2004 2005 2006 2007 2008 2009 2010 2011		400,000 600,000 800,000 1,500,000
	2012 2013		1,500,000 1,500,000

- o 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
- o  $\,$  pay the costs of patent prosecution and maintenance of the patents included in the agreement.

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 and enter into additional licenses and collaborative agreements.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products or to carry out our business strategy or to meet the financial commitments described above. Therefore, we will likely need to raise substantial additional capital to fund our operations sometime in the future. We expect that our cash balance of \$2,611,755 as of December 31, 2000 will be sufficient to fund our operations through at least June 2002. We have based this estimate, however, on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. We cannot be certain that any financing will be available when needed. 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, 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:

- o preclinical studies and clinical trials;
- o research and development programs;
- o regulatory processes;

- o 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
- o 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 preclinical studies and clinical trials;
- o progress, timing and scope of our research and development programs;
- o time and cost necessary to obtain regulatory approvals;
- time and cost necessary to seek third party manufacturers to manufacture our products for us;
- o time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;
- o time and cost necessary to respond to technological and market developments;
- o changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- o new collaborative, licensing and other commercial relationships that we may establish.

# ITEM 7. FINANCIAL STATEMENTS

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Balance Sheets as of December 31, 2000 and 1999	31
Statements of Operations for the years ended December 31, 2000, 1999 and 1998 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2000	32
Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2000	33
Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998 and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2000	34
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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, 2000 and 1999 and the related statements of operations, stockholders' equity and cash flows for each of the two years ended December 31, 2000, and for the period from August 29, 1996 (date of incorporation) through December 31, 2000. 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 as of and for the year ended December 31, 1998 and 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 an 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, 2000 and 1999 and the results of its operations and its cash flows for each of the two years ended December 31, 2000, and for the period from August 29, 1996 (date of incorporation) through December 31, 2000 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 16, 2001 Chicago, Illinois INDEPENDENT AUDITORS' REPORT

Board of Directors BioSante Pharmaceuticals, Inc. (formerly Ben-Abraham Technologies Inc.)

We have audited the balance sheet of BioSante Pharmaceuticals, Inc. (formerly Ben-Abraham Technologies Inc.), a development stage company, as of December 31, 1998 and the related statements of operations, stockholders' equity and cash flows for the year ended December 31, 1998, and for the period from August 29, 1996 (date of incorporation) to December 31, 1998. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform an audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 1998 and the results of its operations and its cash flows for the year ended December 31, 1998, and for the period from August 29, 1996 (date of incorporation) through December 31, 1998 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

Chartered Accountants

Toronto, Ontario February 19, 1999

=======================================	=========	:========
	2000	1999
ACCETC		
ASSETS		
CURRENT ASSETS Cash and cash equivalents	\$2,611,755	\$5,274,552
Prepaid expenses and other sundry assets	64,341	
	2,676,096	5,333,546
PROPERTY AND EQUIPMENT, NET (Note 4)	390,821	446,083
	\$3,066,917	\$5,779,629
=======================================	=========	=========
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 11)	\$ 44,746	\$ 76,057
Accrued compensation	258,598	182,973
Other accrued expenses	137,919	45,085
Convertible debenture (Note 6) Due to licensor	500,000	25,000
	941,263	329,115
COMMITMENTS (Notes 10 and 12)		
STOCKHOLDERS' EQUITY (Note 7)		
Capital stock		
Issued and Outstanding 4,687,6(1999 - 4,807,865) Class C special stock	469	481
52,952,(1999 - 52,642,686) Common stock	17,782,857	
	17,783,326	
		2.,002,001
Deferred unearned compensation Deficit accumulated during the development stage	(18,000) (15,639,672)	- (12,202,477)
	2,125,654	5,450,514
	\$3,066,917	\$5,779,629

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998
AND THE CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO DECEMBER 31, 2000

	YEAR ENDED DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 1999	YEAR ENDED DECEMBER 31, 1998	CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO DECEMBER 31, 2000
REVENUE Interest income	\$ 227,718	\$ 198,683	\$ 123,061	\$ 746,536
EXPENSES  Research and development General and administration Depreciation and amortization Loss on disposal of capital assets Costs of acquisition of Structured Biologicals Inc. Purchased in-process research and development	1,887,832 1,678,581 98,500 -	660,588 853,389 90,965 - -	1,400,129 1,112,647 139,769 129,931	4,284,372 5,810,238 381,834 157,545 375,219 5,377,000
	3,664,913	1,604,942	2,782,476	16,386,208
NET LOSS	\$ (3,437,195)	\$ (1,406,259)	\$ (2,659,415)	\$ (15,639,672)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	\$ (0.06)	\$ (0.03)	\$ (0.08)	\$ (0.36)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	57,536,761 =======	49,424,140	34,858,243	42,914,244

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF STOCKHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998
AND THE CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION) TO
DECEMBER 31, 2000

Shares Amount Shares Amount Shares Amount Compe	erred earned
Shares Amount Shares Amount Compe  BALANCE, AUGUST 29, 1996, DATE OF INCORPORATION - \$- \$ \$- \$-  Issuance of Class "C" shares August 29, 1996	
DATE OF INCORPORATION - \$	ensation
Issuance of Class "C" shares August 29, 1996	
August 29, 1996	\$ -
(\$0.0001 per Share) - 4,130,000 413	
Issuance of Class "A" shares	-
September 23, 1996 (\$0.0001 per share) 20,000,000 2,000	-
Issuance of common shares  September 23, 1996 4,100,000 4,100,000	_
Financing fees accrued (410,000) November 27, 1996 - issued as	-
consideration	
upon acquisition of SBI (Note 3) 7,434,322 4,545,563 Exercise of Series "X" warrants (Note 7) 215,714 275,387	-
Exercise of Series "Z" warrants (Note 7) 1,428 2,553 Net loss	-
Conversion of shares	-
January 13, 1997 (282,850) (28) 282,850 70,741 January 13, 1997 (94,285) (9) 94,285 23,580	-
December 2, 1997 (106,386) (11) 106,386 26,607	-
December 2, 1997 (100,000) (10) 100,000 25,010  Exercise of Series "V" warrants (Note 7) 24,000 36,767	-
Exercise of Series "X" warrants (Note 7) 28,571 36,200	-
Exercise of Series "W" warrants (Note 7) 20,000 25,555  Adjustment for partial shares issued	-
upon amalgamation 130 -	-
Financing fees reversed 410,000 Net loss	-
BALANCE, DECEMBER 31, 1997 20,000,000 2,000 3,566,479 357 12,407,686 9,167,963 Conversion of shares	-
March 4, 1998 (20,000) (2) 20,000 5,002 March 16, 1998 (10,000) (1) 10,000 2,501	-
May 8, 1998 (15,000,000) (1,500) 15,000,000 3,751,500	-
June 1, 1998 (1,000,000) (100) 1,000,000 250,100 June 1, 1998 (1,000,000) (100) 1,000,000 250,100	-
Return of shares to treasury	
May 8, 1998 (1,468,614) (147)	-
Net loss	-
BALANCE, DECEMBER 31, 1998 1,531,386 153 3,286,479 329 29,437,686 13,427,166	-
Conversion of shares February 2, 1999 (10,000) (1) 10,000 2,501	-
Private placement of common shares, net  May 6, 1999 23,125,000 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 Net loss	-
BALANCE, DECEMBER 31, 1999 4,807,865 481 52,642,686 17,652,510 Conversion of shares	-
March 17, 2000 (10,000) (1) 10,000 2,501	-
March 24, 2000 (31,840) (3) 31,840 7,963 June 12, 2000 (50,000) (5) 50,000 12,505	-
July 13, 2000 (28,341) (3) 28,341 7,088	-
Issuance of common shares  July 18, 2000 190,076 58,000	-
Issuance of warrants for services received 42,290 (42,	290)
	290
Net loss	-
BALANCE, DECEMBER 31, 2000 - \$ - 4,687,684 \$ 469 52,952,943 \$17,782,857 \$(18,	

Deficit Accumulated During the Development Stage Total

BALANCE, AUGUST 29, 1996, DATE OF INCORPORATION

Issuance of Class "C" shares August 29, 1996		
(\$0.0001 per share)	-	415
Issuance of Class "A" shares September 23, 1996 (\$0.0001 per share)	· -	2,000
Issuance of common shares September 23, 1996 Financing fees accrued November 27, 1996 - issued as consideration	-	4,100,000 (410,000)
upon acquisition of SBI (Note 3) Exercise of Series "X" warrants (Note 7) Exercise of Series "Z" warrants (Note 7) Net loss	- - (6,246,710)	4,545,563 275,387 2,553 (6,246,710)
BALANCE, DECEMBER 31, 1996		2 260 209
Conversion of shares	(6,246,710)	
January 13, 1997 January 13, 1997 December 2, 1997 December 2, 1997	- - -	70,713 23,571 26,596 25,000
Exercise of Series "V" warrants (Note 7)	-	36,767
Exercise of Series "X" warrants (Note 7) Exercise of Series "W" warrants (Note 7)	-	36,200 25,555
Adjustment for partial shares issued		20,000
upon amalgamation Financing fees reversed	-	410,000
Net loss	(1,890,093)	(1,890,093)
BALANCE, DECEMBER 31, 1997	(8,136,803)	1,033,517
Conversion of shares March 4, 1998	_	5,000
March 16, 1998	-	2,500
May 8, 1998	-	3,750,000
June 1, 1998 June 1, 1998	-	250,000 250,000
Return of shares to treasury		200,000
May 8, 1998	-	(147)
May 8, 1998 Net loss	(2,659,415)	(25) (2,659,415)
BALANCE, DECEMBER 31, 1998	(10,796,218)	2.631.430
Conversion of shares	(==,:==,	
February 2, 1999 Private placement of common shares, net	-	2,500
May 6, 1999	-	4,197,843
Share redesignation July 13, 1999	-	_
Issuance of common shares		05.000
August 15, 1999 Net loss	(1,406,259)	25,000 (1,406,259)
DALANCE DECEMBED 21 1000		
BALANCE, DECEMBER 31, 1999 Conversion of shares	(12,202,477)	5,450,514
March 17, 2000	-	2,500
March 24, 2000 June 12, 2000	-	7,960 12,500
July 13, 2000	-	7,085
Issuance of common shares July 18, 2000	_	58,000
Issuance of warrants for services received	-	-
Amortization of deferred unearned compensatio	- (2 427 405)	24, 290
Net loss	(3,437,195)	(3,437,195)
DALANCE DECEMBED 04 0000		
BALANCE, DECEMBER 31, 2000	\$(15,639,672)	\$2,125,654

See accompanying notes to the finanual statements.

	YEAR ENDED DECEMBER 31, 2000	YEAR ENDED DECEMBER 31, 1999	YEAR ENDED DECEMBER 31, 1998	CUMULATIVE PERIOD FROM AUGUST 29, 1996 (DATE OF INCORPORATION)TO DECEMBER 31, 2000
CACH FLOWS HOLD IN ODERATING ACTIVITIES				
CASH FLOWS USED IN OPERATING ACTIVITIES  Net loss  Adjustments to reconcile net loss to  net cash used in operating activities	\$ (3,437,195)	\$ (1,406,259)	\$ (2,659,415)	\$ (15,639,672)
Depreciation and amortization Amortization of deferred unearned compensation Purchased in-process research and development	98,500 24,290	90,965 - -	139,769	381,834 24,290 5,377,000
Loss on disposal of equipment Changes in other assets and liabilities	-	-	129,931	157,545
affecting cash flows from operations Prepaid expenses and other sundry assets Accounts payable and accrued expenses Due to licensor	(5,347) 137,148 (25,000)		(53,376) (598,334)	
Due from SBI		(102,017)	-	(128,328)
NET CASH USED IN OPERATING ACTIVITIES		(1,787,822)	(3,041,425)	(10,187,628)
CASH FLOWS USED IN INVESTING ACTIVITIES Purchase of capital assets	(43,238)	(4,219)	(124,984)	(896,090)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture (Conversion) issuance of Class "A" shares (Conversion) issuance of Class "C" shares	500,000 - (12)	-	(1,847) (28)	· -
Proceeds from sale or conversion of shares	88,057	4,225,343	4,259,203	
NET CASH PROVIDED BY FINANCING ACTIVITIES	588,045	4,225,343	4,257,328	13,695,473
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,662,797)	2,433,302	1,090,919	2,611,755
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,274,552	2,841,250	1,750,331	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD		\$ 5,274,552		\$ 2,611,755
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION Acquisition of SBI				
Purchased in-process research and development Other net liabilities assumed	\$ -	\$ -	\$ -	\$ 5,377,000 (831,437)
Less: subordinate voting shares issued therefor	- - r -	-	- - -	4,545,563 4,545,563
	\$ -	\$ -	\$ -	\$ - ====================================
Income tax paid	\$ -	\$ -	\$ -	\$ -
	<del></del>			

See accompanying notes to the financial statements.

#### 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 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 testosterone deficiency in men and estrogen deficiency in women. 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

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### CASH AND CASH EQUIVALENTS

For purposes of reporting cash flows, the Company considers all instruments with original maturities of three months or less to be cash equivalents.

# PROPERTY AND EQUIPMENT

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation of computer, office and laboratory equipment is computed primarily by accelerated methods over estimated useful lives of seven years. Leasehold improvements are amortized on a straight-line basis over the terms of the leases, plus option renewals.

### 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 continuing to apply APB No. 25, SFAS No. 123, "Accounting for Stock-Based Compensation," requires certain additional disclosures of the pro forma compensation expense arising from the Company's fixed and performance stock compensation plans. The expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected

# 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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 8 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.

### INTEREST INCOME

Interest income on invested cash is recorded as earned following the accrual basis of accounting.

# NEW STATEMENTS OF FINANCIAL ACCOUNTING STANDARDS

In June 1998, the FASB issued SFAS No. 133, ACCOUNTING FOR DERIVATIVES INSTRUMENTS AND HEDGING ACTIVITIES. 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. The Company adopted this statement effective January 1, 2001. No cumulative transition adjustment was required.

#### ACOUISITION

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 3 1/2 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 Other	\$5,377,000 37,078
	5,414,078
LIABILITIES Current liabilities Due to directors Due to the Company	679, 498 60, 689 128, 328
	868,515
Net assets acquired	\$4,545,563
CONSIDERATION Common stock	\$4,545,563

# 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:

- O 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.
- o The estimated additional research and development expenditures required before FDA approval was \$26.5 million, to be incurred over 8 to 10 years.
- o Future cash flows were estimated based on estimated market size, with costs determined based on industry norms, an estimated annual growth rate of 3%.
- o The cash flows were discounted at 25%. The rate was preferred due to the high-risk nature of the biopharmaceutical business.
- o The Company is continuing to develop the technology related to five of the six indications.
- o 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. PROPERTIES AND EQUIPMENT

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

	2000	1999
Computer equipment Office equipment Laboratory equipment Leasehold improvements- Laboratory	\$ 61,643 34,208 103,012 474,294	\$23,951 32,862 103,012 470,094
Accumulated depreciation and amortization	,	629,919 (183,836)  \$446,083

## 5. INCOME TAXES

The components of the Company's net deferred tax asset at December 31, 2000, 1999 and 1998 were as follows:

	2000	1999	1998
•			
Net operating loss carryforwards	\$ \$ 3,886,495	\$ 2,367,292	\$ 1,778,246
Amortization of intangibles	1,468,699	1,613,942	1,759,186
Research & development credits	191,358	235,310	144,310
Other .	60,993	38,794	16,594
-			
	5,607,545	4,255,338	3,698,336
Valuation allowance	(5,607,545)	(4,255,338)	(3,698,336)
•	\$ -	\$ -	\$ -

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2000, the Company had approximately \$10,500,000 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 2011-2020. 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 \$191,000 of research and development credits available to reduce future income taxes through the year 2014.

# INCOME TAXES (CONTINUED)

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:

	2000	0 	1999		19	98
Tax at U.S. federal statutory rate State taxes, net of federal benefit Change in valuation allowance Other, net	(:	160,388) 195,854) 352,207 4,035	<u>5</u> 56	0,799) .,015) 6,972 8,842	\$	(904,201) (90,810) 986,730 8,281
	\$ ======	- ====== =:	\$ =======	- :==== =	\$	- ======

## 6. 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 does not bear interest and is due September 1, 2001, unless converted into shares of the Company's common stock. If the debenture is not converted and not paid in full by September 1, 2001, then any unpaid principal shall bear interest at a rate of 10 percent from September 1, 2001 forward, until paid in full. The debenture is convertible at the conversion price of \$1.05 per share, subject to adjustment in certain situations, at the option of Paladin at anytime after January 1, 2001. The Company can declare the debenture mandatorily convertible in full at any time after March 31, 2001 if Paladin has not previously converted the debenture.

# 7. 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, 2000.

# 7. STOCKHOLDERS' EQUITY (CONTINUED)

### 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.
- 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 3 1/2 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.

- 7. STOCKHOLDERS' EQUITY (CONTINUED)
- >> 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.

# 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, 2000.

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, 2000, 125,000 of these shares were exercisable. The Company recognized expense in 2000 of approximately \$18,000 for this warrant grant, and will recognize a similar amount in 2001.

# 8. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 7,000,000 shares of common stock have been reserved for issuance. Options for 5,263,125 shares of common stock have been granted as of December 31, 2000 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:

	2000	1999	1998
Net loss			
As reported	\$(3,437,195)	\$(1,406,259)	\$(2,659,415)
Pro forma	\$(3,960,210)	\$(1,713,693)	
rio ioima	Ψ(3,900,210)	Φ(1,713,093)	Ψ(2,771,391)
Basic and diluted net loss			
per share	#(0,0C)	<b>#</b> (0,00)	<b>#</b> (0.00)
As reported	\$(0.06)	\$(0.03)	\$(0.08)
Pro forma	\$(0.07)	\$(0.03)	\$(0.08)
Cumulative net loss			
As reported	\$(15,639,672)		
Pro forma	\$(16,817,160)		
Cumulative basic and diluted net loss per share			
As reported	\$(0.36)		
Pro forma	\$(0.39)		
	\$(0.00)		

# B. STOCK OPTIONS (CONTINUED)

The weighted average fair value of the options at the date of the grant for options granted during 2000, 1999 and 1998 was \$0.90, \$0.33 and \$0.44 was estimated using the Cox Rubinstein binomial model and the Black-Scholes option-pricing model with following weighted average assumptions:

	2000	1999	1998
Expected option life (years) Risk free interest rate Expected stock price volatility Dividend yield	10 6.03% 157.06%	5 4.59% 238.08% -	5 5.05% 350.00%

The following table summarizes the Company's stock option activity:

	2000	Weighted Average Excercise Price	1999	Weighted Average Excercise Price	1998	Weighted Average Excersice Price
Options outstanding,						
Beginning of period	4,973,125	\$ 0.30	2,465,000	\$ 0.37	250,000	\$ 1.07
Options granted	510,000	\$ 0.91	3,068,125	\$ 0.24	2,225,000	\$ 0.29
Options cancelled/expired	(220,000)	\$ 1.00	(560,000)	\$ 0.31	(10,000)	\$ 0.29
Options exercised	- · · · · · · · · · · · · · · · · · · ·	\$ -	-	\$ -	-	\$ -
Options outstanding,						
End of period	5,263,125	\$ 0.33	4,973,125	\$ 0.30	2,465,000	\$ 0.37
Options exercisable,						
End of year	3,865,025	\$ 0.28	2,117,113	\$ 0.35	674,500	\$ 0.60

# 8. STOCK OPTIONS (CONTINUED)

The following table summarizes information about stock options outstanding at December 31, 2000:

	Outstandi	ng Options		Options Ex	ercisable
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	3.2 YEARS	\$ 0.23	1,680,692	\$ 0.23
\$0.28 - \$0.29 \$0.75 - \$1.04	2,325,000 560,000	3.1 YEARS 9.4 YEARS	\$ 0.28 \$ 0.92	2,046,833 137,500	\$ 0.28 \$ 0.96
-	5,263,125		-	3,865,025	

### 9. 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 2000, 1999 and 1998 totaled \$26,296, \$23,899 and \$21,799, respectively.

### 10. LEASE ARRANGEMENTS

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

2001 2002	\$89,401 68,254	
2002 2003 THEREAFTER	57, 239	
	\$214,894	

Rent expense amounted to \$82,069, \$89,110 and \$134,788 for the years ended December 31, 2000, 1999 and 1998, 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.

# 11. RELATED PARTY TRANSACTIONS

2000 1999 1998

Management fees paid to a company controlled by a former member of management, who was also a shareholder and was a member of the Board of Directors

\$ - \$ - \$94,200

Included in current liabilities are \$379, \$5,588, and \$133,901 which represent amounts due to directors and officers of the Company as of December 31, 2000, 1999 and 1998, 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 7.

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.

# 12. COMMITMENTS

# UNIVERSITY OF CALIFORNIA LICENSE

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

- o Payment of royalties to the University based on a percentage of the net sales of any products incorporating the licensed technology;
- Payment of minimum annual royalties on February 28 of each year beginning in the year 2004 in the amounts set forth below, to be credited against earned royalties, for the life of the agreement (2013);

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

- Development of products incorporating the licensed technology until a product is introduced to the market;
- o Payment of the costs of patent prosecution and maintenance of the patents included in the agreement which for the year ended December 31, 2000 have amounted to \$11,722 and which management estimates will equal approximately \$15,000 per year;

# 12. COMMITMENTS (CONTINUED)

- o 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;
  - o Testing proposed products;
  - o Obtaining government approvals;
  - o Conducting clinical trials; and
  - Introducing products incorporating the licensed technology into the market.
- o Entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.
- O 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 (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. 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.

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

None

ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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 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 2001 Proxy Statement 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 2001 Proxy Statement is incorporated herein by reference.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information under the caption "Principal Shareholders and Beneficial Ownership of Management" in our 2001 Proxy Statement is incorporated herein by reference.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information under the caption "Certain Transactions" in our 2001 Proxy Statement is incorporated herein by reference.

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### ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

#### (a) EXHIBITS

The exhibits to this Report are listed on the Exhibit Index on pages 53-57 below. 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., 175 Olde Half Day Road, Suite 247, Lincolnshire, Illinois 60069, Attn: Shareholder 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 (filed herewith electronically).
- 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. Stock Option Agreement, dated December 8, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes (incorporated by reference to Exhibit 10.6 to BioSante's Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 0-28637)).
- D. Stock Option Agreement, dated December 8, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes (incorporated by reference to Exhibit 10.7 to BioSante's Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 0-28637)).
- E. Stock Option Agreement, dated March 30, 1999, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes (incorporated by reference to Exhibit 10.8 to BioSante's Amendment No. 1 to the Registration Statement on Form 10-SB (File No. 0-28637)).
- F. Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended (incorporated by reference to Exhibit 10.16 to BioSante's Registration Statement on Form 10-SB (File No. 0-28637)).
- G. 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)).

- H. Employment Agreement, dated August 1, 2000, between BioSante Pharmaceuticals, Inc. and John E. Lee (filed herewith electronically).
- Employment Agreement, dated December 15, 2000, between BioSante Pharmaceuticals, Inc. and Leah Lehman, Ph.D. (filed herewith electronically).
- (B) REPORTS ON FORM 8-K

None.

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# SIGNATURES

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

Dated: March 15, 2001 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 15, 2001 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.	Chairman of the Board
Avi Ben-Abraham, M.D.	Director
/s/ Victor Morgenstern Victor Morgenstern	Director
/s/ Edward C. Rosenow, III, M.D. Edward C. Rosenow, III, M.D.	Director
/s/ Fred Holubow Fred Holubow	Director
/s/ Ross Mangano Ross Mangano	Director
/s/ Angela Ho Angela Ho	Director
/s/ Peter Kjaer	Director

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Peter Kjaer

# BIOSANTE PHARMACEUTICALS, INC. EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-KSB FOR THE YEAR ENDED DECEMBER 31, 2000

EXHIBIT NO		METHOD OF FILING
2.1	Arrangement Agreement, dated October 23, 1996, between Structured Biologicals Inc. and BioSante Pharmaceuticals, Inc	
		reference to Exhibit 2.1 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
3.1	Articles of Continuance of BioSante Pharmaceuticals, Inc., as amended	Incorporated by reference to Exhibit 3.1 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
3.2	Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.2 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
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)
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)
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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	Filed herewith electronically
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	Stock Option Agreement, dated December 8, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.6 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.6	Stock Option Agreement, dated December 8, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.7 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.7	Stock Option Agreement, dated March 30, 1999, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes	Incorporated by reference to Exhibit 10.8 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
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10.8	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)
10.9	Voting Agreements, dated May 6, 1999, between BioSante Pharmaceuticals, Inc., Avi Ben-Abraham, M.D. and certain shareholders of BioSante	
	Pharmaceuticals, Inc	Incorporated by reference to Exhibit 10.11 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.10	Shareholders' Agreement, dated May 6, 1999, between BioSante Pharmaceuticals, Inc., Avi Ben-Abraham, M.D. and certain shareholders of BioSante	
	Pharmaceuticals, Inc	Incorporated by reference to Exhibit 10.12 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.11	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)
10.12	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)

10.13	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)
10.14	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)
10.15	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)
10.16	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)
10.17	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)
10.18	Employment Agreement, dated August 1, 2000, between BioSante Pharmaceuticals, Inc. and John E. Lee	Filed herewith electronically
10.19	Employment Agreement, dated December 15, 2000, between BioSante Pharmaceuticals, Inc. and Leah Lehman, Ph.D	Filed herewith electronically
23.1	Consent of Deloitte & Touche LLP	Filed herewith electronically
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(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.

#### BIOSANTE PHARMACEUTICALS, INC. AMENDED AND RESTATED 1998 STOCK OPTION PLAN

(As amended through March 15, 2001)

#### PURPOSE OF PLAN.

The purpose of the BioSante Pharmaceuticals, Inc. 1998 Stock Option Plan (the "Plan") is to advance the interests of BioSante Pharmaceuticals, Inc. (the "Company") and its shareholders by enabling the Company and its Subsidiaries to attract and retain persons of ability to perform services for the Company and its Subsidiaries by providing an incentive to such individuals through equity participation in the Company and by rewarding such individuals who contribute to the achievement by the Company of its objectives, as the Board of Directors describes them.

# DEFINITIONS.

- 2.1 "CVE" means the Canadian Venture Exchange.
- 2.2 "CVE REQUIREMENTS" means the by-laws, rules, circulars and policies of the CVE.
  - 2.3 "BOARD" means the Board of Directors of the Company.
- 2.4 "BROKER EXERCISE NOTICE" means a written notice pursuant to which a Participant, upon exercise of an Option, irrevocably instructs a broker or dealer to sell a sufficient number of shares or loan a sufficient amount of money to pay all or a portion of the exercise price of the Option and/or any related withholding tax obligations and remit such sums to the Company and directs the Company to deliver stock certificates to be issued upon such exercise directly to such broker or dealer.
- 2.5 "CHANGE IN CONTROL" means an event described in Section 9.1 of the Plan.  $\,$ 
  - 2.6 "CODE" means the Internal Revenue Code of 1986, as amended.
- $2.7\,$  "COMMITTEE" means the group of individuals administering the Plan, as provided in Section 3 of the Plan.
- 2.8 "COMMON STOCK" means the common stock of the Company, no par value, or the number and kind of shares of stock or other securities into which such Common Stock may be changed in accordance with Section 4.3 of the Plan.
- 2.9 "DISABILITY" means the disability of the Participant such as would entitle the Participant to receive disability income benefits pursuant to the long-term disability plan of the Company or Subsidiary then covering the Participant or, if no such plan exists or is applicable to

the Participant, the permanent and total disability of the Participant within the meaning of Section 22(e)(3) of the Code.

- 2.10 "ELIGIBLE RECIPIENTS" means all employees of the Company or any Subsidiary and any non-employee directors, officers, consultants and independent contractors of the Company or any Subsidiary.
- 2.11 "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.
- 2.12 "FAIR MARKET VALUE" means, with respect to the Common Stock, as of any date (or, if no shares were traded or quoted on such date, as of the next preceding date on which there was such a trade or quote) (a) the mean between the reported high and low sale prices of the Common Stock if the Common Stock is listed, admitted to unlisted trading privileges or reported on any foreign or national securities exchange or on the Nasdaq National Market or an equivalent foreign market on which sale prices are reported; (b) if the Common Stock is not so listed, admitted to unlisted trading privileges or reported, the closing bid price as reported by the Nasdaq SmallCap Market, OTC Bulletin Board or the National Quotation Bureau, Inc. or other comparable service; or (c) if the Common Stock is not so listed or reported, such price as the Committee determines in good faith in the exercise of its reasonable discretion.
- 2.13 "INCENTIVE STOCK OPTION" means a right to purchase Common Stock granted to an Eligible Recipient pursuant to Section 6 of the Plan that qualifies as an "incentive stock option" within the meaning of Section 422 of the Code.
- 2.14 "NON-STATUTORY STOCK OPTION" means a right to purchase Common Stock granted to an Eligible Recipient pursuant to Section 6 of the Plan that does not qualify as an Incentive Stock Option.
- 2.15 "OPTION" means an Incentive Stock Option or a Non-Statutory Stock Option.
- $2.16\,$  "PARTICIPANT" means an Eligible Recipient who receives one or more Options under the Plan.
- 2.17 "PREVIOUSLY ACQUIRED SHARES" means shares of Common Stock or any other shares of capital stock of the Company that are already owned by the Participant or, with respect to any Option, that are to be issued upon the exercise of such Option.
- 2.18 "RETIREMENT" means termination of employment or service pursuant to and in accordance with the regular (or, if approved by the Board for purposes of the Plan, early) retirement/pension plan or practice of the Company or Subsidiary then covering the Participant, provided that if the Participant is not covered by any such plan or practice, the Participant will be deemed to be covered by the Company's plan or practice for purposes of this determination.
  - 2.19 "SECURITIES ACT" means the Securities Act of 1933, as amended.
- 2.20 "SUBSIDIARY" means any entity that is directly or indirectly controlled by the Company or any entity in which the Company has a significant equity interest, as determined by the Committee.

 $2.21\,$  "TAX DATE" means the date any withholding tax obligation arises under the Code or other applicable tax statute for a Participant with respect to an Option.

### PLAN ADMINISTRATION.

THE COMMITTEE. The Plan will be administered by the Board or by a committee of the Board. So long as the Company has a class of its equity securities registered under Section 12 of the Exchange Act, any committee administering the Plan will consist solely of two or more members of the Board who are "non-employee directors" within the meaning of Rule 16b-3 under the Exchange Act and, if the Board so determines in its sole discretion, who are "outside directors" within the meaning of Section 162(m) of the Code. Such a committee, if established, will act by majority approval of the members (but may also take action with the written consent of all of the members of such committee), and a majority of the members of such a committee will constitute a quorum. As used in the Plan, "Committee" will refer to the Board or to such a committee, if established. To the extent consistent with corporate law, the Committee may delegate to any officers of the Company the duties, power and authority of the Committee under the Plan pursuant to such conditions or limitations as the Committee may establish; provided, however, that only the Committee may exercise such duties, power and authority with respect to Eligible Recipients who are subject to Section 16 of the Exchange Act. The Committee may exercise its duties, power and authority under the Plan in its sole and absolute discretion without the consent of any Participant or other party, unless the Plan specifically provides otherwise. Each determination, interpretation or other action made or taken by the Committee pursuant to the provisions of the Plan will be final, conclusive and binding for all purposes and on all persons, including, without limitation, the Company, the shareholders of the Company, the participants and their respective successors-in-interest. No member of the Committee will be liable for any action or determination made in good faith with respect to the Plan or any Option granted under the Plan.

### 3.2 AUTHORITY OF THE COMMITTEE.

- (a) In accordance with and subject to the provisions of the Plan, the Committee will have the authority to determine all provisions of Options as the Committee may deem necessary or desirable and as consistent with the terms of the Plan, including, without limitation, the following: (i) the Eligible Recipients to be selected as Participants; (ii) the nature and extent of the Options to be made to each Participant (including the number of shares of Common Stock to be subject to each Option, the exercise price and the manner in which Options will become exercisable) and the form of written agreement, if any, evidencing such Option; (iii) the time or times when Options will be granted; (iv) the duration of each Option; and (v) the restrictions and other conditions to which the Options may be subject. In addition, the Committee will have the authority under the Plan in its sole discretion to pay the economic value of any Option in the form of cash, shares of Common Stock, shares of any capital stock of the Company, or any combination of both.
- (b) The Committee will have the authority under the Plan to amend or modify the terms of any outstanding Option in any manner, including, without limitation, the authority to modify the number of shares or other terms and conditions of an Option,

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extend the term of an Option, accelerate the exercisability or otherwise terminate any restrictions relating to an Option, accept the surrender of any outstanding Option or, to the extent not previously exercised or vested, authorize the grant of new Options in substitution for surrendered Options; provided, however that the amended or modified terms are permitted by the Plan as then in effect and that any Participant adversely affected by such amended or modified terms has consented to such amendment or modification. No amendment or modification to an Option, however, whether pursuant to this Section 3.2 or any other provisions of the Plan, will be deemed to be a re-grant of such Option for purposes of this Plan.

(c) In the event of (i) any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, extraordinary dividend or divestiture (including a spin-off) or any other similar change in corporate structure or shares, (ii) any purchase, acquisition, sale or disposition of a significant amount of assets or a significant business, (iii) any change in accounting principles or practices, or (iv) any other similar change, in each case with respect to the Company or any other entity whose performance is relevant to the grant or vesting of an Option, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation) may, without the consent of any affected Participant, amend or modify the conditions to the exercisability of any outstanding Option that is based in whole or in part on the financial performance of the Company (or any Subsidiary or division thereof) or such other entity so as equitably to reflect such event, with the desired result that the criteria for evaluating such financial performance of the Company or such other entity will be substantially the same (in the sole discretion of the Committee or the board of directors of the surviving corporation) following such event as prior to such event; provided, however, that the amended or modified terms are permitted by the Plan as then in effect.

# 4. SHARES AVAILABLE FOR ISSUANCE.

- 4.1 MAXIMUM NUMBER OF SHARES AVAILABLE. Subject to Section 4.4 below and adjustment as provided in Section 4.3 of the Plan, the maximum number of shares of Common Stock that will be available for issuance under the Plan will be 7,000,000 shares of Common Stock, plus any shares of Common Stock which, as of the date the Plan is approved by the shareholders of the Company, are reserved for issuance under the Company's existing Stock Option Plan and which are not thereafter issued or which have been issued but are subsequently forfeited and which would otherwise have been available for further issuance under such plan.
- 4.2 ACCOUNTING FOR OPTIONS. Shares of Common Stock that are issued under the Plan or that are subject to outstanding Options will be applied to reduce the maximum number of shares of Common Stock remaining available for issuance under the Plan. Any shares of Common Stock that are subject to an Option that lapses, expires, is forfeited or for any reason is terminated unexercised and any shares of Common Stock that are subject to an Option that is settled or paid in cash or any form other than shares of Common Stock will automatically again become available for issuance under the Plan.

- 4.3 ADJUSTMENTS TO SHARES AND OPTIONS. 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 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) will make appropriate adjustment (which determination will be conclusive) as to the number and kind of securities or other property (including cash) available for issuance or payment under the Plan and, in order to prevent dilution or enlargement of the rights of Participants, the number and kind of securities or other property (including cash) subject to, and the exercise price of, outstanding Options.
- 4.4 CVE REQUIREMENTS. So long as the Common Stock of the Company is listed on the CVE and the Company has not been exempted from the CVE Requirements the number of shares of Common Stock that may be reserved for issuance pursuant to the Plan and any other stock option plan, stock purchase plan or for remuneration for any service performed for or on behalf of the Company to any one party shall not exceed five percent of the outstanding shares of Common Stock, on a non-diluted basis.

#### PARTICIPATION.

Participants in the Plan will be those Eligible Recipients who, in the judgment of the Committee, have contributed, are contributing or are expected to contribute to the achievement of objectives as determined by the Board of the Company or its Subsidiaries. Eligible Recipients may be granted from time to time one or more Options as may be determined by the Committee in its sole discretion. Options will be deemed to be granted as of the date specified in the grant resolution of the Committee, which date will be the date of any related agreement with the Participant.

#### OPTIONS.

- GRANT. An Eligible Recipient may be granted one or more Options under the Plan, and such Options will be subject to such terms and conditions, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion. The Committee may designate whether an Option is to be considered an Incentive Stock Option or a Non-Statutory Stock Option. To the extent that any Incentive Stock Option granted under the Plan ceases for any reason to qualify as an "incentive stock option" for purposes of Section 422 of the Code, such Incentive Stock Option will continue to be outstanding for purposes of the Plan but will thereafter be deemed to be a Non-Statutory Stock Option.
- Articipant upon exercise of an Option will be determined by the Committee in its discretion at the time of the Option grant; provided, however, that (a) such price will not be less than 100% of the Fair Market Value of one share of Common Stock on the date of grant with respect to an Incentive Stock Option (110% of the Fair Market Value if, at the time the Incentive Stock Option is granted, the Participant owns, directly or indirectly, more than 10% of the total combined voting power of all classes of stock of the Company or any parent or subsidiary corporation of the Company), and (b) such price will not be less than 85% of the Fair Market Value of one share of Common Stock on the date of

grant with respect to a Non-Statutory Stock Option. NOTWITHSTANDING THE FOREGOING, SO LONG AS THE COMMON STOCK OF THE COMPANY IS LISTED ON THE CVE AND THE COMPANY HAS NOT BEEN EXEMPTED FROM THE CVE REQUIREMENTS IN THIS REGARD, THE EXERCISE PRICE PER SHARE OF AN OPTION SHALL NOT BE LESS THAN THE PRICE PER SHARE PERMITTED BY THE CVE REQUIREMENTS.

- 6.3 EXERCISABILITY AND DURATION. An Option will become exercisable at such times and in such installments as may be determined by the Committee in its sole discretion at the time of grant; provided, however, that no Incentive Stock Option may be exercisable after 10 years from its date of grant (five years from its date of grant if, (a) at the time the Incentive Stock Option is granted, the Participant owns, directly or indirectly, more than 10% of the total combined voting power of all classes of stock of the Company or any parent or subsidiary corporation of the Company or (B) THE COMMON STOCK OF THE COMPANY IS THEN LISTED ON THE CVE AND THE COMPANY HAS NOT BEEN EXEMPTED FROM THE CVE REQUIREMENTS IN THIS REGARD).
- 6.4 PAYMENT OF EXERCISE PRICE. The total purchase price of the shares to be purchased upon exercise of an Option must be paid entirely in cash (including check, bank draft or money order); provided, however, that the Committee, in its sole discretion and upon terms and conditions established by the Committee, may allow such payments to be made, in whole or in part, by tender of a Broker Exercise Notice, Previously Acquired Shares, a promissory note (on terms acceptable to the Committee in its sole discretion) or by a combination of such methods.
- ANNER OF EXERCISE. An Option may be exercised by a Participant in whole or in part from time to time, subject to the conditions contained in the Plan and in the agreement evidencing such Option, by delivery in person, by facsimile or electronic transmission or through the mail of written notice of exercise to the Company (Attention: Chief Financial Officer) at its principal executive office in Lincolnshire, Illinois and by paying in full the total exercise price for the shares of Common Stock to be purchased in accordance with Section 6.4 of the Plan.
- 6.6 AGGREGATE LIMITATION OF STOCK SUBJECT TO INCENTIVE STOCK OPTIONS. To the extent that the aggregate Fair Market Value (determined as of the date an Incentive Stock Option is granted) 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 a Participant 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 Options will be treated as Non-Statutory Stock Options. The determination will be made by taking incentive stock options into account in the order in which they were granted. If such excess only applies to a portion of an Incentive Stock Option, the Committee, in its discretion, will designate which shares will be treated as shares to be acquired upon exercise of an Incentive Stock Option.
- 7. EFFECT OF TERMINATION OF EMPLOYMENT OR OTHER SERVICE.
- 7.1 TERMINATION DUE TO DEATH, DISABILITY OR RETIREMENT. Unless otherwise provided by the Committee in its sole discretion in the agreement evidencing an Option:

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- (a) In the event a Participant's employment or other service with the Company and all Subsidiaries is terminated by reason of death or Disability, all outstanding Options then held by the Participant 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 expiration date of any such Option).
- (b) In the event a Participant's employment or other service with the Company and all Subsidiaries is terminated by reason of Retirement, all outstanding Options then held by the Participant 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 expiration date of any such Option).

# 7.2 TERMINATION FOR REASONS OTHER THAN DEATH, DISABILITY OR RETIREMENT.

- (a) Unless otherwise provided by the Committee in its sole discretion in the agreement evidencing an Option, in the event a Participant's employment or other service is terminated with the Company and all Subsidiaries for any reason other than death, Disability or Retirement, or a Participant is in the employ or service of a Subsidiary and the Subsidiary ceases to be a Subsidiary of the Company (unless the Participant continues in the employ or service of the Company or another Subsidiary), all rights of the Participant under the Plan and any agreements evidencing an Option will immediately terminate without notice of any kind, and no Options then held by the Participant will thereafter be exercisable; provided, however, that if such termination is due to any reason other than termination by the Company or any Subsidiary for "cause," all outstanding Options then held by such Participant 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 expiration date of any such Option).
- (b) For purposes of this Section 7.2, "cause" (as determined by the Committee) will be as defined in any employment or other agreement or policy applicable to the Participant or, if no such agreement or policy exists, will mean (i) dishonesty, fraud, misrepresentation, embezzlement or deliberate injury or attempted injury, in each case related to the Company or any Subsidiary, (ii) any unlawful or criminal activity of a serious nature, (iii) any intentional and deliberate breach of a duty or duties that, individually or in the aggregate, are material in relation to the Participant's overall duties, or (iv) any material breach of any employment, service, confidentiality or non-compete agreement entered into with the Company or any Subsidiary.
- 7.3 MODIFICATION OF RIGHTS UPON TERMINATION. Notwithstanding the other provisions of this Section 7, upon a Participant's termination of employment or other service with the Company and all Subsidiaries, the Committee may, in its sole discretion (which may be exercised at any time on or after the date of grant, including following such termination), cause Options (or any part thereof) then held by such Participant to become or continue to become exercisable and/or remain exercisable following such termination of employment or service; provided, however, that no Option may remain exercisable beyond its expiration date.

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- 7.4 EXERCISE OF INCENTIVE STOCK OPTIONS FOLLOWING TERMINATION. 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.
- 7.5 DATE OF TERMINATION OF EMPLOYMENT OR OTHER SERVICE. Unless the Committee otherwise determines in its sole discretion, a Participant's employment or other service will, for purposes of the Plan, be deemed to have terminated on the date recorded on the personnel or other records of the Company or the Subsidiary for which the Participant provides employment or other service, as determined by the Committee in its sole discretion based upon such records.

#### PAYMENT OF WITHHOLDING TAXES.

- 8.1 GENERAL RULES. The Company is entitled to (a) withhold and deduct from future wages of the Participant (or from other amounts that may be due and owing to the Participant from the Company or a Subsidiary), or make other arrangements for the collection of, all legally required amounts necessary to satisfy any and all foreign, federal, state and local withholding and employment-related tax requirements attributable to an Option, including, without limitation, the grant or exercise of an Option or a disqualifying disposition of stock received upon exercise of an Incentive Stock Option, or (b) require the Participant promptly to remit the amount of such withholding to the Company before taking any action, including issuing any shares of Common Stock, with respect to an Option.
- 8.2 SPECIAL RULES. The Committee may, in its sole discretion and upon terms and conditions established by the Committee, permit or require a Participant to satisfy, in whole or in part, any withholding or employment-related tax obligation described in Section 8.1 of the Plan by electing to tender Previously Acquired Shares, a Broker Exercise Notice or a promissory note (on terms acceptable to the Committee in its sole discretion), or by a combination of such methods.

#### CHANGE IN CONTROL.

- 9.1 CHANGE IN CONTROL. For purposes of this Section 9, a "Change in Control" of the Company will mean the following:
  - (a) the sale, lease, exchange or other transfer, directly or indirectly, of substantially all of the assets of the Company (in one transaction or in a series of related transactions) to a person or entity that is not controlled by the Company;
  - (b) the approval by the shareholders of the Company of any plan or proposal for the liquidation or dissolution of the Company;
  - (c) any person becomes after the effective date of the Plan the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of (i) 20% or more, but not 50% or more, of the combined voting power of the Company's outstanding securities ordinarily having the right to vote at elections of directors, unless the transaction resulting in such ownership has been approved in advance by the Continuity Directors (as defined in Section 9.2 below), or (ii) 50% or more of the

combined voting power of the Company's outstanding securities ordinarily having the right to vote at elections of directors (regardless of any approval by the Continuity Directors);

- (d) a merger or consolidation to which the Company is a party if the shareholders of the Company immediately prior to effective date of such merger or consolidation have "beneficial ownership" (as defined in Rule 13d-3 under the Exchange Act), immediately following the effective date of such merger or consolidation, of securities of the surviving corporation representing (i) more than 50%, but less than 80%, of the combined voting power of the surviving corporation's then outstanding securities ordinarily having the right to vote at elections of directors, unless such merger or consolidation has been approved in advance by the Continuity Directors, or (ii) 50% or less of the combined voting power of the surviving corporation's then outstanding securities ordinarily having the right to vote at elections of directors (regardless of any approval by the Continuity Directors);
- (e) the Continuity Directors cease for any reason to constitute at least a majority of the Board; or
- (f) any other change in control of the Company of a nature that would be required to be reported pursuant to Section 13 or 15(d) of the Exchange Act, whether or not the Company is then subject to such reporting requirement.
- 9.2 CONTINUITY DIRECTORS. For purposes of this Section 9, "Continuity Directors" of the Company will mean any individuals who are members of the Board on the effective date of the Plan and any individual who subsequently becomes a member of the Board whose election, or nomination for election by the Company's shareholders, was approved by a vote of at least a majority of the Continuity Directors (either by specific vote or by approval of the Company's proxy statement in which such individual is named as a nominee for director without objection to such nomination).
- 9.3 ACCELERATION OF EXERCISABILITY. Without limiting the authority of the Committee under Sections 3.2 and 4.3 of the Plan, if a Change in Control of the Company occurs, then, unless otherwise provided by the Committee in its sole discretion either in the agreement evidencing an Option at the time of grant or at any time after the grant of an Option, all outstanding Options will become immediately exercisable in full and will remain exercisable for the remainder of their terms, regardless of whether the Participant to whom such Options have been granted remains in the employ or service of the Company or any Subsidiary.
- 10. RIGHTS OF ELIGIBLE RECIPIENTS AND PARTICIPANTS; TRANSFERABILITY.
- 10.1 EMPLOYMENT OR SERVICE. Nothing in the Plan will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment or service of any Eligible Recipient or Participant at any time, nor confer upon any Eligible Recipient or Participant any right to continue in the employ or service of the Company or any Subsidiary.
- $10.2\,$  RIGHTS AS A SHAREHOLDER. As a holder of Options, a Participant will have no rights as a shareholder unless and until such Options are exercised for, or paid in the form of, shares of

Common Stock and the Participant becomes the holder of record of such shares. Except as otherwise provided in the Plan, no adjustment will be made for dividends or distributions with respect to such Options as to which there is a record date preceding the date the Participant becomes the holder of record of such shares, except as the Committee may determine in its discretion.

- 10.3 RESTRICTIONS ON TRANSFER. Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by the Plan (unless approved by the Committee in its sole discretion and the CVE, if necessary), no right or interest of any Participant in an Option prior to the exercise of such Option will be assignable or transferable, or subjected to any lien, during the lifetime of the Participant, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise. A Participant will, however, be entitled to designate a beneficiary to receive an Option upon such Participant's death, and in the event of a Participant's death, payment of any amounts due under the Plan will be made to, and exercise of Options (to the extent permitted pursuant to Section 7 of the Plan) may be made by, the Participant's legal representatives, heirs and legatees.
- 10.4 BREACH OF CONFIDENTIALITY OR NON-COMPETE AGREEMENTS.

  Notwithstanding anything in the Plan to the contrary, in the event that a Participant 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 such Participant's employment or other service with the Company or any Subsidiary, the Committee in its sole discretion may immediately terminate all rights of the Participant under the Plan and any agreements evidencing an Option then held by the Participant without notice of any kind.
- 10.5 NON-EXCLUSIVITY OF THE PLAN. Nothing contained in the Plan is intended to modify or rescind any previously approved compensation plans or programs of the Company or create any limitations on the power or authority of the Board to adopt such additional or other compensation arrangements as the Board may deem necessary or desirable.

#### 11. SECURITIES LAW AND OTHER RESTRICTIONS.

Notwithstanding any other provision of the Plan or any agreements entered into pursuant to the Plan, the Company will not be required to issue any shares of Common Stock under this Plan, and a Participant may not sell, assign, transfer or otherwise dispose of shares of Common Stock issued pursuant to Options granted under the Plan, unless (a) there is in effect with respect to such shares a registration statement under the Securities Act and any applicable state or foreign securities laws or an exemption from such registration under the Securities Act and applicable state or foreign securities laws, 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 shares of Common Stock, as may be deemed necessary or advisable by the Company in order to comply with such securities law or other restrictions.

### 12. PLAN AMENDMENT, MODIFICATION AND TERMINATION.

The Board may suspend or terminate the Plan or any portion thereof at any time, and may amend the Plan from time to time in such respects as the Board may deem advisable in order that Options under the Plan will conform to any change in applicable laws or regulations or in any other respect the Board may deem to be in the best interests of the Company; provided, however, that no amendments to the Plan will be effective without approval of the shareholders of the Company if shareholder approval of the amendment is then required pursuant to Section 422 of the Code or the rules of any stock exchange or Nasdaq or similar regulatory body. No termination, suspension or amendment of the Plan may adversely affect any outstanding Option without the consent of the affected Participant; provided, however, that this sentence will not impair the right of the Committee to take whatever action it deems appropriate under Sections 3.2, 4.3 and 9 of the Plan.

### 13. EFFECTIVE DATE AND DURATION OF THE PLAN.

The Plan is effective as of December 8, 1998, the date it was adopted by the Board. The Plan will terminate at midnight on December 8, 2008 and may be terminated prior to such time to by Board action, and no Option will be granted after such termination. Options outstanding upon termination of the Plan may continue to be exercised in accordance with their terms.

### 14. MISCELLANEOUS.

- 14.1 GOVERNING LAW. The validity, construction, interpretation, administration and effect of the Plan and any rules, regulations and actions relating to the Plan will be governed by and construed exclusively in accordance with the laws of the State of Wyoming, notwithstanding the conflicts of laws principles of any jurisdictions.
- $14.2\,$  SUCCESSORS AND ASSIGNS. The Plan will be binding upon and inure to the benefit of the successors and permitted assigns of the Company and the Participants.

August 1, 2000

Mr. John E. Lee 2507 Saffron Glen Escondido, CA 92029

Dear John:

I am pleased to confirm our agreement with you concerning your employment by BioSante Pharmaceuticals, Inc. (the "Company") which is subject to review, approval, and ratification by the Company's Board of Directors (the "Board").

I. EMPLOYMENT. Subject to the terms and conditions described in this Employment Agreement (the "Agreement"), the Company agrees to employ you as the Vice President, Commercial Development of the Company, and you accept this employment on the following terms and conditions.

#### II. DUTIES.

- A. You agree to devote, on a full time basis, all of your business hours to the Company's business. You will diligently perform the duties of your position, within guidelines to be determined by Stephen Simes, the Company's Chief Executive Officer (the "CEO"), consistent with the policies of the Board. Said responsibilities shall include, but not be limited to, the following specific areas: commercialization of all products, in-licensing of additional products and technologies, out-licensing and partnering of CAP technologies and new hormone products, budgeting in the areas of product sales and marketing, and forecasting and analysis of current and future BioSante markets and competition in those markets. You will report to the CEO, who will be responsible for evaluating your job performance in accordance with the Company's annual performance review process.
- B. While you are employed by the Company, except as otherwise expressly permitted by the Company's Conflict of Interest policy or this Agreement, you will not engage in any business activity or outside employment that conflicts with the Company's interests or adversely affects the performance of your duties for the Company.

- C. You shall be based at, and shall perform your duties at an office located in, Lincolnshire, Illinois, or the surrounding suburban area, where the corporate headquarters of the Company are located. The Company agrees that the other officers and executives of the Company except for those who are directly involved in the research and development activities of the Company that are currently conducted in Atlanta, Georgia shall also be located in the same corporate headquarters. However, you shall also travel to other locations at such times as may be appropriate for the performance of your duties under this Agreement.
- III. TERM. This Agreement is effective August 1, 2000 (the "Effective Date"), and will terminate on July 31, 2003, unless earlier terminated pursuant to Section V of this Agreement (the "Base Term"). Commencing August 1, 2003, and on each August 1st thereafter, the term of your employment will be automatically extended for three (3) additional years unless on or before June 1st immediately preceding any such extension, either party gives written notice to the other of the cessation of further extensions, in which case no further automatic extensions will occur. In the event that the Company elects not to renew this Agreement other than for "cause" as defined herein, you will be paid the amount described in Section V.C.2 below.

#### IV. COMPENSATION.

- A. BASE SALARY. The Company agrees to pay you an annual base salary of One Hundred Seventy Thousand Dollars (\$170,000) in accordance with the Company's standard payroll practices ("Base Salary"). In subsequent years, the CEO or the Board shall have the sole discretion to establish your Base Salary, except that, at a minimum, it shall be adjusted upward consistent with changes to the Consumer Price Index.
- B. ANNUAL BONUS. You will be eligible to receive an annual performance bonus not to exceed 30% of your Base Salary in effect during the year under review. The amount of said bonus shall be determined in the sole discretion of the CEO or the Compensation Committee and approved by the Board.

# C. OPTIONS.

1. Upon the execution of this Agreement, the Company will grant you five hundred thousand (500,000) stock options to purchase Common Shares of stock of the Company at the lowest permissible price when this agreement is executed, 50,000 of which shall vest (but cannot be sold for four months pursuant to CDNX requirements) at the time of the grant. The remainder shall vest in twelve equal quarterly installments over the three year period starting on the Effective Date of this Agreement with

the first installment vesting on November 1, 2000. The remaining unvested options shall vest immediately upon a termination without cause by the Company, a substantial reduction in job responsibilities, a Change in Control as defined in Section IX or a change of greater than 50 miles of the geographical location of the corporate headquarters.

2. In the event the Company issues a stock dividend, or effectuates a stock split or exchange of any shares of the Company, whether by way of reorganization, reclassification, conversion or other means, the Company shall make appropriate adjustment to the terms of the Option in order to prevent dilution or enlargement of your rights.

In the event that your employment is terminated by the Company other than for cause (as hereinafter defined), or if the Company elects not to renew this Agreement, all outstanding stock options and shares held by you or your estate will immediately become exercisable and all restrictions against disposition, if any, which have not otherwise lapsed shall immediately lapse, and the period within which they may be exercised will be one year following such termination of employment.

- D. BENEFITS. In addition to the other compensation to be paid under this Section IV, you will be entitled to participate in all benefit plans available to all full-time eligible employees hereafter established by the Company, in accordance with the terms and conditions of such plans, which the Company shall adopt promptly following the date hereof. These plans shall include, but are not limited to, the following: a 401(k) plan; group hospitalization, health, dental, and term life and disability insurance.
- E. EIMBURSEMENT OF BUSINESS EXPENSES. In addition to payment of compensation under this Section IV, the Company agrees to reimburse you for all reasonable out-of-pocket business expenses incurred by you on behalf of the Company, provided that you properly account to the Company for all such expenses in accordance with the rules and regulations of the Internal Revenue Service promulgated under the Internal Revenue Code of 1986, as amended, and in accordance with the standard policies of the Company relating to reimbursement of business expenses.
- F. AUTOMOBILE ALLOWANCE. The Company shall provide you with a monthly stipend of six hundred dollars (\$600) for your automobile use.
- G. VACATION. You are entitled to three (3) weeks of paid vacation per calendar year.

# V. TERMINATION.

- A. EARLY TERMINATION. Subject to the respective continuing obligations of the parties pursuant to Sections VI, VII and VIII, this Section sets forth the terms for early termination of this Agreement.
- B. TERMINATION FOR CAUSE. The Company may terminate this Agreement and your employment immediately for cause. For this purpose, "cause" means any of the following: (1) fraud, (2) theft or embezzlement of the Company's assets or other act of dishonesty, (3) a violation of law involving moral turpitude, (4) your repeated and willful failure to follow instructions of the Board provided that the conduct has not ceased or the offense cured within thirty (30) days following written warning from the Company that sets forth in reasonable detail the facts claimed to provide the basis for such termination. In the event of termination for cause pursuant to this Section V.B., you will be paid, at the usual rate, your annual Base Salary, car allowance, and any out-of-pocket expenses, through the date of termination specified in any notice of termination and any amounts to which you are entitled under any Company benefit plan in accordance with the terms of such plan.
- C. TERMINATION WITHOUT CAUSE. Either you or the Company may terminate this Agreement and your employment without cause on thirty (30) days written notice. In the event of termination of this Agreement and of employment pursuant to this Section V.C., compensation shall be paid as follows:
  - If the termination is by you without cause, you will be paid, at the usual rate, your annual Base Salary, car allowance, and any out-of-pocket expenses incurred on behalf of the Company and accounted for pursuant to Section IV.E through the date of termination specified in such notice (but not to exceed thirty (30) days from the date of such notice); or
  - 2. Notwithstanding any provision to the contrary contained herein, in the event your employment is terminated by the Company at any time for any reason other than for cause, disability or death, the Company shall:
    - (i.) pay you a severance benefit, in a lump sum payable no later than the fifth business day following the date of termination, an amount equal to your total compensation over the preceding twelve months;
    - (ii.) continue to provide you, at the Company's expense, with term life insurance, as provided herein until the earlier of (A) the expiration of the "Severance Period" (which shall mean the shorter of these two periods: one year from the

date of termination or the remaining term of this Agreement), or (B) your attaining full-time employment, elsewhere; but in no event shall the Company provide you with term life insurance for a period of longer than one year;

- (iii.)continue to allow you to participate, at the Company's expense, in the Company's group health, dental and disability insurance programs until the earlier of (A) the expiration of the Severance Period, or (B) your becoming eligible to participate in another employer's corresponding group insurance and disability plans;
- (iv.) provide you with outplacement services at a qualified agency selected by mutual agreement between you and the Company and the use of an office and reasonable secretarial support for one year (unless you become otherwise employed within such a period) all expenses of services described in this paragraph not to exceed \$10,000;
- (v.) reimburse out-of-pocket expenses incurred by you on the behalf of the Company prior to termination and accounted pursuant to Section IV.E; and
- (vi.) reimburse you for any and all unused vacation days accrued to the date of such termination.
- D. TERMINATION FOR GOOD REASON. You may terminate this Agreement upon thirty (30) days written notice to the Company for good reason. For this purpose, "good reason" means: (i) the assignment to you of any duties that constitute a significant adverse change in the nature, scope or level of your positions, duties, responsibilities and status with the Company as of the date hereof, (ii) the failure of the Company to continue in effect any fringe benefit or compensation plan, retirement plan, life insurance plans, health or disability plan in which you were participating (except as such change is prompted in good faith by a change in the law), or the taking of any action by the Company, which could reasonably be expected to adversely affect your participation in or materially reduce your benefits under any such plans or deprive you of any material fringe benefit enjoyed by you, (iii) the reduction of your salary or car allowance or failure to increase such salary as is provided in Section IV.A above, or any other breach of this Agreement by the Company which has not been cured within thirty (30) days following written warning from you, or (iv) the occurrence of a Change of Control as defined in Section IX and at which time your employment is terminated. In any such

case the Company will pay you the amounts, and provide you the benefits, all as set forth in Section V.C.2 above.

- E. TERMINATION IN THE EVENT OF DEATH OR PERMANENT DISABILITY. This Agreement and your employment will terminate in the event of your death or permanent disability.
  - In the event of your death, Base Salary and car allowance will be terminated as of the end of the month in which death occurs.
  - 2. For the purposes of this Agreement, the term "disability" shall mean your inability, due to an illness, accident or any other physical or mental incapacity, to substantially perform your duties for a period of four (4) consecutive months or for a total of six (6) months (whether or not consecutive) during any twelve (12) month period during the term of this Agreement.

#### F. ENTIRE TERMINATION PAYMENT.

- 1. The compensation provided for in Sections V.B, V.C, V.D, and V.E for early termination of this Agreement will constitute your sole remedy for such termination. You will not be entitled to any other termination or severance payment which might otherwise be payable to you under any other agreement between you and the Company or under any policy of the Company. This Section F.1. will not have any effect on distributions to which you may be entitled at termination from any qualified tax plan or any other plan (other than a severance payment or similar plan).
- 2. Notwithstanding any other provisions of this Agreement or any other agreement, contract or understanding heretofore or hereafter entered into between you and the Company, if any "payments" (including, without limitation, any benefits or transfers of property or the acceleration of the vesting of any benefits) in the nature of compensation under any arrangement this is considered contingent on a Change in Control for purposes of Section 280g of the Internal Revenue Code of 1986, as amended (the "Code"), together with any other payments that you have the right to receive from the Company or any corporation that is a member of an "affiliated group" (as defined in Section 1504(a) of the Code without regard to Section 1504(b) of the Code) of which the Company is a member, would constitute a "parachute payment" (as defined in Section 280G of the Code), such payments will be reduced to the largest amount as will result in no portion of such payments being subject to the excise tax imposed by Section 4999 of the Code; provided, however, that you

will be entitled to designate those payments that will be reduced or eliminated in order to comply with the forgoing provision.

- G. REQUIRED RESIGNATIONS UPON EARLY TERMINATION OR EXPIRATION. You agree that upon any termination of your employment with the Company or expiration under this Agreement will automatically and without further action be deemed to constitute your simultaneous resignation from all director officer, trustee, agent and any other positions within the Company, all of its affiliates (including but not limited to any entity that is a shareholder of the Company and any subsidiaries and any parent of the Company), the Company's employee benefit plans, trusts, and foundations (charitable or otherwise) or any other similar positions associated with the Company. Simultaneously upon such termination of employment or expiration of this employment agreement, you agree to execute and deliver to the Company any and all documents, agreements, certificates, letters or other written instruments confirming all such resignations.
- H. If for any reason, other than for Termination Without Cause, you are not employed by the Company 15 months from the effective date of this Agreement, you will reimburse the Company for all costs paid by the Company to relocate you to the Chicago area.

#### VI. INVENTIONS.

- A. You agree that all Inventions (as defined below) you make, conceive, reduce to practice or author (either alone or with others) during or within one year after the term of this Agreement will be the Company's sole and exclusive property. You 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 you are 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 you hereby assign) to the Company all of your rights to the Invention, any applications you make 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 the Invention against forfeiture, abandonment, or loss and to obtain and maintain patents and/or copyrights on the Invention to vest the entire right and title to the Invention to the Company.
- B. "Inventions," as used in this Section, 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 term of this Agreement, (ii) result from any work you perform for the Company; (iii) use the Company's equipment, supplies, facilities or trade secret information, or (iv) you develop during any time that Section II above obligates you to perform your employment duties.

The requirements of this Section do not apply to an Invention for which no equipment, supplies, facility or trade secret information of the Company was used and which was developed entirely on your own time, and which neither (1) relates directly to the Company's business or to the Company's actual and demonstrably anticipated research or development, nor (2) results from any work you performed for the Company. Except as previously disclosed to the Company in writing, you do not have, and will not assert, any claims to or rights under any Inventions as having been made, conceived, authored or acquired by you prior to your employment by the Company.

# VII. PROPRIETARY INFORMATION.

- A. Except as required in your duties to the Company, you will never, either during or after your employment by the Company, use or disclose Proprietary Information to any person not authorized by the Company to receive it. When your employment with the Company ends, you will promptly turn over to the Company all records and any compositions, articles, devices, apparatus and other items that disclose, describe or embody Proprietary Information, including all copies, reproductions and specimens of the Proprietary Information in your possession, regardless of who prepared them.
- B. "Proprietary Information," as used in this Section VII, means any nonpublic information concerning the Company, including information relating to the Company's research, product development, engineering, purchasing, product costs, accounting, leasing, servicing, manufacturing, sales, marketing, administration and finances. This information includes, without limitation: (i) trade secret information about the Company and its products; (ii) "Inventions," as defined in Section VI.B; (iii) information concerning any of the Company's past, current or possible future products. Proprietary Information also includes any information which is not generally disclosed and which is useful or helpful to the Company and/or which would be useful or helpful to competitors. More specific examples include financial data, sales figures for individual projects or groups of projects, planned new projects or planned advertising programs, areas where the Company intends to expand, lists of suppliers, lists of customers, wage and salary data, capital investment plans, projected earnings, changes in management or policies of the Company, testing data, manufacturing methods, suppliers' prices to us, or any plans we may have for improving any of our products. Information is Proprietary Information regardless of its form, e.g. oral, written, electronic or

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other, and whether or not it is labeled as "proprietary" or "confidential." The Company's Proprietary Information includes our information and that of our affiliates and third parties concerning or relating to us.

# VIII. COMPETITIVE ACTIVITIES.

- A. You agree that during your employment with the Company, you will not alone, or in any capacity with another person or entity, (i) directly or indirectly engage in any employment or activity that competes with the Company's business at the time of your employment with the Company ends, within any state in the United States or within Canada, or (ii) in any way interfere or attempt to interfere with the Company's relationships with any of its current or potential customers.
- B. You agree that during your employment with the Company, you will not, directly or indirectly, whether for your 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 (or, but for the violation of this Agreement, would have been employed by) the Company and any clients of the Company or (ii) otherwise interfere with the relationship between any such person, the Company and any clients of the Company.
- C. You also agree that for a period of one year after the termination of this Agreement for any one of the following reasons: (i) for "cause" as defined above, (ii) voluntarily by you without "good reason" as defined above; or (iii) in the event of a non-renewal of the Agreement by you other than for "good reason", you will abide by Sections VIII.A and B above.

#### IX. CHANGE IN CONTROL.

- A. For purposes of this Agreement, a "Change in Control" of the Company will mean the following:
  - the sale, lease, exchange or other transfer, directly or indirectly, of all or substantially all of the assets of the Company (in one transaction or in a series of related transactions) to a person or entity that is not controlled by the Company;
  - the approval by the shareholders of the Company of any plan or proposal for the liquidation or dissolution of the Company; or
  - 3. a change in control of the Company of a nature that would be required to be reported in response to Item 5(f) of Schedule 14A of Regulation 14A or to Item 1 of Form 8-K promulgated under the Securities

Exchange Act of 1934, as amended (the "Act"); provided that, without limitation, a Change in Control shall be deemed to have occurred if (i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Act) is or shall become the beneficial owner, directly or indirectly, of securities of the Company representing 30% or more of the Company" then outstanding securities; or (ii) during any period of twenty-four (24) consecutive months, individuals who at the beginning of such period constitute the entire Board of Directors shall cease for any reason to constitute a majority thereof unless the election, or the nomination for election by the Company's stockholders, of each new director was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of the period.

- B. If a Change in Control occurs, all stock options held by you will become immediately exercisable in full and will remain exercisable for the remainder of their terms, regardless of whether you remain in the employ or service of the Company.
- C. For purposes of this Section IX, you shall be entitled to the severance benefits provided in Section V.D if the date of termination occurs either (i) while there is to the Company's knowledge actively pending a proposed transaction, which, if consummated, could reasonably be expected to result within one (1) year in a Change of Control; unless, in the case of either (i) or (ii), your employment is terminated or this Agreement is not renewed because of death or disability or by the Company for "cause" or voluntarily by you other than for "good reason".

# X. MISCELLANEOUS.

- A. NO ADEQUATE REMEDY. You understand that if you fail to fulfill your obligations under this Agreement, the monetary damages to the Company as a result of your failure would be very difficult to determine. Therefore, if the Company shall institute any action or proceeding to enforce such provisions, you waive the defense that there is an adequate remedy at law and agree not to interpose the claim or defense that such remedy exists at law. Therefore, without limiting any other rights or remedies available to the Company at law, in equity, or by statute, you hereby consent to the specific enforcement of this Agreement by the Company through an injunction, restraining order or other equitable relief in any such action.
- B. GOVERNING LAW AND JURISDICTION. The internal laws of Illinois (as opposed to the conflict of law provisions) will govern the validity, construction, and

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performance of this Agreement and the parties submit to the jurisdiction of the state or federal courts located in Illinois.

C. ARBITRATION. Any and all disputes which arise concerning the rights, duties or obligations of either party under any provision of this Agreement shall be resolved exclusively by binding arbitration in accordance with the following terms and conditions. The party seeking arbitration shall commence a proceeding in arbitration in Chicago, Illinois under the Rules of the American Arbitration Association. The arbitrator shall render his or her decision and award in writing with ninety (90) days from the initiation of the arbitration.

There shall be no appeal from arbitrator's decision and award which shall be final and binding on the parties and may be entered in any court having jurisdiction thereof.

- D. RIGHTS IN THE EVENT OF DISPUTE. If, with respect to any alleged failure by the Company to comply with any of the terms of this Agreement, you hire legal counsel with respect to this Agreement or institute any negotiations or institute or respond to legal action to assert or defend the validity of, enforce your rights under, or recover damages for breach of this Agreement, the Company shall pay, as they are incurred, your actual expenses for attorneys' fees and disbursements, together with such additional payments, if any, as may be necessary so that the net-after-tax payments to you equal such fees and disbursements up to a maximum aggregate of \$10,000, provided that, in regard to such matters, you have not acted in bad faith or with no colorable claim of success. Further, if the Company is the prevailing party in any action brought by you to enforce the terms of this Agreement, such payments shall be reimbursed by you to the Company.
- E. MITIGATION. You are not required to mitigate the amount of any payments to be made pursuant to this Agreement by seeking other employment or otherwise, nor shall the amount of any payments provided for in the Agreement be reduced by any compensation earned by you as the result of your self-employment or your employment by another employer after the date of termination of your employment with the Company.
- F. CONSTRUCTION. Wherever possible, each provision of this agreement will be interpreted so that it is valid under the applicable law. If any provision of this agreement is to any extent invalid under the applicable law, that provision will still be effect to the extent it remains valid under the applicable law. The remainder of this Agreement also will continue to be valid, and the entire Agreement will continue to be valid in other jurisdictions.

- G. WAIVERS. No failure or delay by either the Company or you in exercising any right or remedy under this Agreement will waive any provision of the Agreement. Nor will any single or partial exercise by either the Company or you for any right or remedy under this agreement preclude either the Company or you from otherwise or further exercising these rights or remedies, or any other rights or remedies granted by any law or any related document.
- H. ENTIRE AGREEMENT. This Agreement is the entire agreement between the parties and replaces all other oral negotiations, commitments, writings and understandings between the parties concerning the matters in this agreement. The Agreement can only be modified by mutual written consent of the parties. You acknowledge that you have been advised to seek legal counsel to review this Agreement with you before you sign it.
- I. SUCCESSORS AND ASSIGNS. Except as otherwise provided in Section IX, this Agreement will be binding upon and inure the benefit of the successors and assigns of the Company whether by way of merger, consolidation, operation of law, purchase or other acquisition of substantially all of the assets or business of the Company, and any such successor or assign will absolutely and unconditionally assume all of the Company's obligations under this Agreement. You are not permitted to assign your rights or obligations under this Agreement.
- J. NOTICES. All notices, requests and demands given to or made pursuant hereto will, except as otherwise specified herein, be in writing and be delivered or mailed to any such party at its address which:
  - A. In the case of the Company will be:

BioSante Pharmaceuticals, Inc. 175 Olde Half Day Road Lincolnshire, IL 60069 Attn: Chief Executive Officer

B. In the case of the employee will be:

John E. Lee 2507 Saffron Glen Escondido, CA 92029

Any party may, by notice to the other party, designate a changed address. Any notice, if mailed properly addressed, postage prepaid, registered or certified mail, will be deemed dispatched on the registered date or that date stamped on the certified mail receipt, and will be deemed received within the

second business day thereafter or when it is actually received, whichever is sooner.

- K. CAPTIONS. The various headings or captions in this Agreement are for convenience only and will not affect the meaning or interpretation of this agreement.
- L. REASONABLE LIMITATIONS. The parties hereto stipulate and agree that each of the terms of this Agreement including, but not limited to, the scope of the activities prohibited and the time limitations are 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 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.

Would you please confirm that this Agreement is in accordance with your understanding and that you have received a copy of this letter by signing and dating where indicated below, and returning an executed copy for our records.

Very truly yours,

BioSante Pharmaceuticals, Inc.

By: /s/ Stephen Simes

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Stephen Simes

Its: Chief Executive Officer

By signing below, you warrant and represent that: (1) you have been represented by legal counsel of your choice in connection with the review, approval and execution of this Agreement or have elected not to engage legal counsel after having been informed of your right to do so; (2) you understand that this Agreement is a legally binding contract; (3) you have read and understand the terms of this Agreement; (4) that you understand its terms which are fair, reasonable and enforceable; (5) you have had ample opportunity to negotiate with the Company with regard to all of the Agreement's terms; (6) you have entered into this Agreement freely and voluntarily without fraud, duress, or coercion; (7) you have the full right, power, authority and capacity to enter into and execute this Agreement; and (8) you intend to be bound by each provision of this Adreement.

Agreed to and confirmed as of August 1, 2000:

/s/ John E. Lee

John E. Lee

# EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this "AGREEMENT") is made as of this 15th day of December, 2000 (the "EFFECTIVE DATE"), by and between BioSante Pharmaceuticals, Inc. (the "COMPANY") and Leah Lehman, Ph.D. ("EMPLOYEE").

#### RECTTALS

WHEREAS, the Company desires to employ Employee and Employee desires to accept Employment with the Company pursuant to the terms of 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 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 January 1, 2001, and ending on December 31, 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 thirty (30) days prior written notice prior to the end of either the Initial Term or any Renewal Term of her 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 she has no other commitments or obligations of any kind to anyone else which would hinder or interfere with her acceptance of her obligations hereunder, or the exercise of her 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, in

furtherance thereof, such duties and responsibilities as the Company's president and chief executive officer (the "CEO"), shall from time to time assign her. Employee shall be Vice President of 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"). Employee shall initially report to the CEO. Thereafter, Employee shall report to the person designated by the CEO. Employee shall be based at, and shall perform her duties at, an office located in Lincolnshire, Illinois, or the surrounding suburban areas. Employee shall travel to other locations at such times as may be appropriate to her performance of her duties and responsibilities under this Agreement.

(c) During the Employment Term, Employee agrees to devote, on a full time basis, all of her 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 Eighty Thousand and 00/100 Dollars (\$180,000.00), 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. Commencing on January 1, 2002, 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, up to a maximum of 30% of Employee's annual base salary.
- 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 her 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-PERSON INSURANCE POLICY. During the Employment Term, the Company may, in its sole discretion, maintain "key-person" 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 her a reasonable period of time to elect to continue the coverage for her 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 Six Hundred and 00/100 Dollars (\$600.00) 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 3.2; (c) election by the Company to terminate Employee for Cause, as defined in SECTION 3.4; (d) election by the Company (whether for Cause or not) during the first six months of the Initial Term; (e) by either the Company or Employee for any reason (whether for Cause or not) upon the expiration of thirty (30) days from the date when the terminating party gives written notice to the other party; or (f) election by Employee to terminate this Agreement for Good Reason, as defined in SECTION 3.9 of this Agreement.
- 3.2. 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 her regular duties as an employee of the Company for a period (whether continuous or periodic) of six (6) months during any twelve (12) month period, 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 and paid by Employee, one selected and paid by the Company and the third selected by the two physicians so selected with the cost of such third physician being borne equally by Employee and the Company.
- 3.3. 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 pay Employee or Employee's estate all amounts due through the date of termination and shall owe Employee, or Employee's estate, no further amounts under this Agreement.

- 3.4. 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 of thirty (30) days after written notice thereof from the Company to Employee;
  - (c) The commission of an act or acts by Employee in the performance of her 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, or guilty or nolo contendre plea to, or confession of, a Class A-type felony or a felony involving moral turpitude.
- 3.5. EFFECT OF TERMINATION FOR CAUSE. In the event Employee is terminated for Cause, this Agreement shall immediately terminate and the Company shall pay Employee all amounts due through the date of termination and shall owe Employee no further amounts under this Agreement.
- 3.6. EFFECT OF TERMINATION OTHER THAN FOR CAUSE, UPON DEATH OR FOR LEGAL DISABILITY DURING THE FIRST SIX MONTHS OF THE INITIAL TERM. In the event Employee is terminated (with or without Cause) during the first six months of the Initial Term, this Agreement shall immediately terminate and the Company shall pay Employee all amounts due through the date of termination and shall owe Employee no further amounts under this Agreement.
- 3.7. EFFECT OF TERMINATION OTHER THAN FOR CAUSE, UPON DEATH OR FOR LEGAL DISABILITY DURING THE FINAL SIX MONTHS OF THE INITIAL TERM. In the event Employee is terminated other than for Cause during the final six months of the Initial Term or if this Agreement is not renewed after the Initial Term, 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 or returns to consulting (such period is the "INITIAL TERM SEVERANCE PERIOD"); (ii) continue to allow Employee to participate during the Initial Term Severance Period, at the Company's expense, in the Company's group health and dental 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 3.7 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.

- 3.8. EFFECT OF TERMINATION OTHER THAN FOR CAUSE, UPON DEATH OR FOR LEGAL DISABILITY FOR ANY RENEWAL TERM. In the event Employee is terminated other than for Cause during any Renewal Term or if this Agreement is not renewed after any Renewal Term, the Company shall (i) pay Employee a severance benefit equal to Employee's base salary for the shorter of (A) twelve months or (B) the date upon which Employee obtains full-time employment or returns to consulting (such period is the "RENEWAL TERM SEVERANCE PERIOD"); (ii) continue to allow Employee to participate during the Renewal Term Severance Period, at the Company's expense, in the Company's group health and dental 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 3.8 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.
- TERMINATION FOR GOOD REASON. Notwithstanding any other provisions of this Agreement, Employee shall be entitled to terminate this Agreement upon thirty (30) days written notice to the Company for Good Reason, as defined in this SECTION 3.9. "Good Reason" means: (i) the Company's exclusion or removal of Employee from participation in any fringe benefit or compensation plan, retirement plan, life insurance plan, health or disability plan available to other personnel of the Company holding comparable positions to that of Employee; provided; however, that nothing in this SECTION 3.9 shall prevent the Company from discontinuing or altering any fringe benefit so long as Employee is not treated differently than other employees of the Company holding comparable positions, (ii) the reduction of her base salary or car allowance so long as such reduction in base salary or car allowance (A) is not required of other personnel of the Company holding comparable positions to that of Employee or (B) is not related to a material adverse change in the Company's business, financial condition, results of operations or prospects. If Employee terminates this Agreement for Good Reason, the Company will pay Employee the amounts, and provide her with the following benefits: if such termination is effective during the final six months of the Initial Term under this Agreement, the severance benefit and other benefits described in SECTION 3.7 of this Agreement, and if such termination is effective during any Renewal Term, the severance benefit and other benefits described in SECTION 3.8 of this Agreement.
- 3.10. PROPERTY OF THE COMPANY. Upon termination of her employment with the Company, Employee shall surrender to the Company any and all material, including, but not limited to, manuals, reports, documents, protocols, INDs, preclinical and clinical results, 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 she has in her 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 her of her 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 or rule, or any compulsory process of any agency of a governmental body). 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 known by Employee prior to the beginning of the Initial Term of employment hereunder, or which becomes known to Employee from a third person or other source not under a duty of confidentiality, or which is disclosed on a non-confidential basis to another party by an employee or other agent of the Company in a manner which does not involve a breach of a duty of confidentiality by the disclosing party, or 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 one year thereafter, 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 including, but not limited to, calcium phosphate adjuvant or hormone replacement gel products.

- 4.4. NON-SOLICITATION OF EMPLOYEES. Employee agrees that, during her employment and for a period of one year 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, but for the violation of this Agreement, would have been employed by 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 (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 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 her obligations under 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. REASONABLE 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 time that Employee is obligated to perform her 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:

Leah Lehman, Ph.D. 14308 West Braemore Close Libertyville, Illinois 60048

# with a copy to:

Hoogendoorn, Talbot, Davids, Godfrey & Milligan 122 South Michigan Avenue Suite 1220 Chicago, Illinois 60603 Attention: Richard M. Sawdey

# If to the Company:

BioSante Pharmaceuticals, Inc. 175 Olde Half Day Road Lincolnshire, Illinois 60069 Attention: Stephen M. Simes 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. In the event that the Company brings an action to enforce this Agreement including, but not limited to, Sections 4.3 and 4.4, and is the prevailing party in such action, Employee shall reimburse the Company for the reasonable costs and expenses, including attorneys' fees, so incurred by the Company.
- 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]

COMPANY:

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes

Name: Stephen M. Simes Its: Chief Executive Officer

EMPLOYEE:

/s/ Leah Lehman, PH.D.

Leah Lehman, Ph.D.

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# INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in Registration Statement No. 333-53384 of BioSante Pharmaceuticals, Inc. on Form S-8 of our report dated February 16, 2001, appearing in this Annual Report on Form 10-KSB of BioSante Pharmaceuticals. Inc. for the year ended December 31, 2000.

/s/ Deloitte & Touche LLP

Chicago, Illinois March 28, 2001

# INDEPENDENT AUDITORS' CONSENT

We consent to the incorporation by reference in Registration Statement No. 333-53384 of BioSante Pharmaceuticals, Inc. on Form S-8 of our report dated February 19, 1999, appearing in this Annual Report on Form 10-KSB of BioSante Pharmaceuticals, Inc. for the year ended December 31, 2000.

/s/ Deloitte & Touche LLP

Chartered Accountants

Toronto, Ontario March 28, 2001