

BIOSANTE PHARMACEUTICALS INC
Form 10KSB40
March 28, 2002

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-KSB

(Mark one)

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

For the fiscal year ended December 31, 2001

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

For the transition period from _____ to _____

Commission file number 000-28637

BIOSANTE PHARMACEUTICALS, INC.

(Name of Small Business Issuer in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

58-2301143

(I.R.S. Employer Identification No.)

111 Barclay Boulevard, Suite 280 Lincolnshire,

Illinois

(Address of Principal Executive Offices)

60069

(Zip Code)

(847) 478-0500

(Issuer's Telephone Number, including Area Code)

Securities registered under Section 12(b) of the Exchange Act: **None**

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

Common Stock, \$0.0001 par value

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

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Check if there is no disclosure of delinquent filers pursuant to Item 405 of Regulation S-B contained in this Form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

The issuer's revenues for the fiscal year ended December 31, 2001 were \$1,921,802.

As of March 1, 2002, 63,218,798 shares of common stock of the registrant were outstanding, and the aggregate market value of the common stock of the registrant as of that date (based upon the last reported sale price of the common stock on that date as reported by the Over-the-Counter Bulletin Board), excluding outstanding shares beneficially owned by directors and executive officers, was \$22,333,603.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-KSB incorporates by reference information (to the extent specific sections are referred to herein) from the registrant's Proxy Statement for its 2002 Annual Meeting of Stockholders to be held May 21, 2002.

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

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Part I

This Form 10-KSB contains forward-looking statements. For this purpose, any statements contained in this Form 10-KSB that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as may, will, should, expects, anticipates, contemplates, estimates, plans, projected, predicts, potential or continue or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the heading Item 1. Business Certain Important Factors. These factors may cause our actual results to differ materially from any forward-looking statement.

As used in this Form 10-KSB, references to BioSante, the Company, we or us refer to BioSante Pharmaceuticals, Inc., unless the context otherwise indicates. We own or have the rights to use various trademarks, trade names or service marks, including BioSante, Bio-Vant, NanoVant, CAP-Oral, Bio-Air, Bio-T-Gel, Bio-E-Gel, Bio-E/P-Gel, LibiGel and LibiGel-E/T.

Item 1. DESCRIPTION OF BUSINESS

General

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

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

accelerate the development of our hormone replacement products;

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

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

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

Our primary focus is to build a pipeline of hormone replacement products for the treatment of human hormone deficiencies. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis.

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

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

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

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

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

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

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

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

Our CAP technology, which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call nanoparticles, as immune system boosters, for drug delivery and to purify the milk of transgenic animals. We have identified four potential initial applications for our CAP technology:

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

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

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

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown by selectively isolating biologically active therapeutic proteins from the transgenic milk.

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

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

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

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

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

Our company, which was initially formed as a corporation organized under the laws of the Province of Ontario on August 29, 1996, was continued as a corporation under the laws of the State of Wyoming on December 19, 1996 and reincorporated in Delaware on June 26, 2001. Our company is the continuing corporation resulting from an amalgamation, or consolidation, of three companies our company, which was previously named Ben-Abraham Technologies Inc., Structured Biologicals Inc., a corporation organized under the laws of the Province of Ontario, and 923934 Ontario Inc., a corporation organized under the laws of the Province of Ontario and a wholly owned subsidiary of Structured Biologicals. The amalgamation was approved by our stockholders on November 27, 1996 and the articles of arrangement were filed and became effective as of December 6, 1996. In November 1999, our stockholders approved the change of our corporate name from Ben-Abraham Technologies Inc. to BioSante Pharmaceuticals, Inc. In June 2001, our stockholders approved the reincorporation of our company to Delaware.

Business Strategy

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

Accelerate the development of our hormone replacement products. We are focused on building a pipeline of hormone replacement products for the treatment of human hormone deficiencies. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis. Human clinical trials have begun on four of our hormone replacement products, a necessary step in the process of obtaining FDA approval to market the products.

Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses. We are seeking opportunities to enter into business collaborations, joint ventures or sub-licenses with companies that have businesses or technologies complementary to our CAP technology business, such as vaccine and drug delivery pharmaceutical companies and transgenic milk companies. We believe that this partnering strategy will enable us to capitalize on our partners' strengths in product development, manufacturing and commercialization and thereby enable us to introduce into the market products incorporating our CAP technology sooner than which we otherwise would be able. In addition, we believe these collaborations would significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology.

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies. We intend to seek opportunities to enter into business collaborations or joint ventures with entities that have businesses or technology complementary to our business. We are particularly interested in entering into product co-development and co-marketing arrangements.

License or otherwise acquire other drugs that will add value to our current product portfolio. We intend to seek opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. In seeking these opportunities, we intend to target products that cover therapeutic areas treated by a limited number of physicians and drugs that are in or require human clinical trials that involve a

limited number of patients and not a significant amount of time and cost needed to complete them. We believe that targeting these products that are currently in or ready for human clinical trials would decrease the risks associated with product development and would likely shorten the time before we can introduce the products into the market. In addition to late-stage development products, we intend to seek opportunities to in-license or otherwise acquire products that (1) have FDA approval, (2) have been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience, and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have a full portfolio in development.

Description of Our Hormone Replacement Products

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

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

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

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

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

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

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

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone may also experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Approximately five million men in the United States, primarily in the over age 40 male population group, have lower than normal levels of testosterone. Testosterone replacement therapy has been shown to restore levels of testosterone with minimal side effects.

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

and the skin irritation and discomfort associated with dermal patches. We are aware of one gel testosterone product for men currently on the market in the United States and several in development.

Estrogen deficiency in women can result in hot flashes and flushes, vaginal atrophy, decreased libido and osteoporosis. Hormone replacement in women decreases the chance that women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately twenty million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone replacement therapy.

Estrogen is most commonly given orally in pill or tablet form. There are several potential side effects, however, with the use of oral estrogen, including insufficient absorption by the circulatory system, gallstones and blood clots. Although dermal patches have been shown to avoid some of these problems, delivery of estrogen through dermal patches, like testosterone patches, can result in skin irritation. Our estrogen formulated gel product, Bio-E-Gel, is designed to deliver estrogen without the skin irritation associated with, and the physical presence of, dermal patches.

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product. Women whose uterus is intact often use a combined hormone replacement therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial cancer and endometrial hyperplasia associated with estrogen therapy in these women.

We are also developing a testosterone formulated gel product for women, LibiGel. Though generally characterized as a male hormone, testosterone also is present in women and its deficiency has been found to cause low libido or sex drive. Studies have shown that testosterone replacement therapy can boost sexual desire and pleasure, increase bone density, raise energy levels and improve mood. Similarly, we are developing a combination gel product of testosterone and estradiol for women, LibiGel-E/T, for low libido or sex drive.

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

- our transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus hormone patches;

- our transdermal gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;

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

- our transdermal gels have been shown to be absorbed evenly, thus allowing clinical hormone levels to reach the systemic circulation;

- hormone replacement therapy using gels may allow for better dose adjustment than either patches or oral pills or capsules; and

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

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

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

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

On August 7, 2001, we entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay paid us an initial payment of \$2.5 million (\$1.7 million net of the related payments due to Antares and Paladin) and has agreed to make future milestone payments and pay escalating sales-based royalties. Solvay is responsible for all costs of development and marketing of the estrogen/progestogen combination transdermal hormone replacement gel product. We have retained co-promotion rights to the product and will be compensated for sales we generate over and above those attributable to Solvay's marketing efforts.

Description of Our CAP Technology and CAP Technology Products

We believe our CAP technology will serve as an effective vehicle for delivering drugs and vaccines and enhancing the effects of vaccines. The key component, calcium phosphate, or CAP, is on the FDA's GRAS (Generally Regarded as Safe) list. Our nanoparticles have successfully passed the first stage of toxicity studies for administration orally, into muscles, under the skin, and into the lungs by inhalation.

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

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

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

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

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

Research and development involving our CAP technology originated in a project set up under an agreement dated April 6, 1989 between the University of California and our predecessor company, Structured Biologicals, relating to viral protein surface absorption studies. The discovery research was funded by Structured Biologicals at UCLA School of Medicine and was based, in essence, on the use of extremely small, solid, uniform particles as components that could increase the stability of drugs and act as systems to deliver drugs into the body.

These ultra fine particles are made from inert, biologically acceptable materials, such as ceramics, pure crystalline carbon or biodegradable calcium phosphate. The size of the particles is in the nanometer range. A nanometer is one millionth of a millimeter and typically particles measure approximately 1,000 nanometers (nm). For comparison, a polio virus particle is about 27 nm in diameter, a herpes virus particle has a central core measuring 100 nm in diameter, contained in an envelope measuring 150-200 nm, while a tuberculosis bacterium is rod-shaped, about 1,200 nm long by 300 nm across. Because the size of these particles is measured in nanometers, we use the term "nanoparticles" to describe them.

We use the nanoparticles as the basis of a delivery system by applying a layer of a bonding coating of cellobiose or another carbohydrate derivative. The critical property of these coated nanoparticles is that biologically active molecules, proteins, peptides or pharmacological agents, for example, vaccine components like bacterial or viral antigens or proteins like insulin, attached to them retain their activity and can be protected from natural alterations to their molecular structure by adverse environmental conditions. It has been shown in studies conducted by us that when these combinations are injected into animals, the attachment can enhance the biological activity as compared to injection of the molecule alone.

A major immune response that is triggered by these combination particles is the creation of antibody molecules, which can then specifically counteract an invading virus or bacterium. Similarly, a drug will produce an effect on an organ system only if it can attach to specific receptors on the surface of target cells (*e.g.*, tumor cells). The stabilizing and slow release capabilities of a drug carrier and delivery system based on this discovery can lead to significant advances towards finding more effective and less toxic or harmful molecules to seek out and attach to such receptors.

We believe our CAP technology has a number of benefits, including the following:

- it is biodegradable (capable of being decomposed by natural biological processes) and non-toxic and therefore potentially safe to use and introduce into the human body;

- it is fast, easy and inexpensive to manufacture, which will keep our costs down and potentially improve our profit margins;

- the nanometer (one-millionth of a millimeter) size range makes it ideal for delivering drugs through aerosol sprays, inhalation or orally, instead of using often painful and inconvenient injections; and

- it has excellent loading capacity the amount of molecules that can bond with the nanoparticles thereby potentially decreasing the dose needed to be taken by patients while enhancing the release capabilities.

Research in these areas has resulted in the issuance of a number of patents that we license from the University of California.

We have completed a Phase I human clinical trial of CAP as a vaccine adjuvant and delivery system, a necessary step in the process of obtaining FDA approval to market the product. The Phase I trial was a double blind, placebo controlled trial, in 18 subjects to determine the safety of CAP as a vaccine adjuvant. The trial results showed that there was no apparent difference in side-effect profile between CAP and placebo.

We plan to develop commercial applications of our CAP technology and any proprietary technology developed as a result of our ongoing research and development efforts. Initially, we plan to pursue the development of (1) vaccine adjuvants, (2) drug delivery systems, including a method of delivering proteins (*e.g.*, insulin) through inhalation, orally and subcutaneous routes of administration, and (3) the purification of the milk of transgenic animals. Our pre-clinical research team in our laboratory in Smyrna, Georgia is currently pursuing the development of our CAP technology.

Vaccine adjuvants. We believe that our CAP nanoparticles may offer a means of preparing new improved formulations of current vaccines that are equal or better in their safety and immunogenicity, that is, in their capacity to elicit an immune response, compared to alum-formulated and non-adjuvanted vaccines but may be injected in lower concentrations and less often which could result in certain benefits, including cost savings and improved patient compliance. Also, we believe that CAP will allow for creation of safe and effective vaccines for diseases and conditions for which no vaccines currently exist.

We intend to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in vaccine development, co-development and co-marketing arrangements. We believe these collaborations may enable us to accelerate the development of potential improved vaccines. These arrangements also could include out-licenses of our CAP technology to vaccine companies and others for further development and marketing.

Our nanoparticles when combined with vaccine antigens have been shown in animal studies conducted by us and others to possess an ability to elicit a higher immune response than non-adjuvanted vaccines and an immune response of the same magnitude as alum-formulated vaccines but up to 100 times lower concentrations. These preclinical studies also have shown that our CAP nanoparticles also may sustain higher antibody levels over a longer time period than both alum-formulated vaccines and non-adjuvanted vaccines. Because our CAP nanoparticles are made of calcium phosphate, which has a chemical nature similar to normal bone material and therefore is natural to the human body, as opposed to aluminum hydroxide, or alum, which is not natural to the human body, we believe that our nanoparticles may be safer to use than alum. In our animal studies, we observed no material adverse reactions when our CAP nanoparticles were administered at effective levels.

We filed an investigational new drug, or IND, application with the FDA in July 2000 to commence a Phase I human clinical trial. We completed our Phase I human clinical trial in October 2000. As discussed in more detail under the heading Government Regulation, the purpose of a Phase I trial is to evaluate the metabolism and safety of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. The Phase I trial of our CAP specifically looked at safety parameters, including local irritation and blood chemistry changes. The trial was completed and there was no apparent difference in the side effects profile between CAP and placebo.

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

Our outlicensing activities with respect to our adjuvant, which we call Bio-Vant, for use in other companies' vaccines have to date included meeting with target companies and, in some cases, agreeing that the target company will test our adjuvant in their animal models. Thereafter, the target company may send to us its vaccine antigen or DNA which we will then formulate with our nanoparticles and return for use in the target company's animal models. Once this is completed, if the results are positive, we would negotiate an out-license agreement with the target company.

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

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

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

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

Drug delivery systems. The third field of use in which we are exploring applying our CAP technology involves creating novel and improved forms of delivery of drugs, including proteins (*e.g.*, insulin). The attachment of drugs to CAP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We believe we may have successfully created a formulation for the inhaled delivery of insulin, which we call Bio-Air. We are in the process of contacting and meeting the insulin manufacturers and companies with devices for inhalation of drugs to pursue collaborations for this development. Furthermore, we have shown pre-clinical efficacy in the oral delivery of insulin in diabetic mouse models. In the oral insulin mouse models, our product, which we call CAP-Oral, has shown an 80% reduction of glucose levels for 12 hours versus 20-30% glucose reduction for five hours for free insulin. Our research and development efforts in this area are ongoing.

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

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

Sales and Marketing

We currently have very limited sales and marketing personnel to sell on a commercial basis any of our proposed products. If and when we are ready to commercially launch a product, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner to assist us with this function.

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately \$2,142,000 in 2001 and \$1,888,000 in 2000 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues from the sale of our products, these research and development costs must be financed by us. We estimate that we are currently spending approximately \$200,000 to \$250,000 per month on research and development activities. These expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon the resources available and our development schedule. Results of preclinical studies, clinical trials, regulatory decisions and competitive developments may significantly influence the amount of our research and development expenditures. In addition, we expect that our spending on product development will increase if we are successful at in-licensing or otherwise acquiring other late-stage development products.

Manufacturing

We currently do not have any facilities suitable for manufacturing on a commercial scale basis any of our proposed products nor do we have any experience in volume manufacturing. We will either find our own manufacturing facilities, hire additional personnel with manufacturing experience and comply with the extensive Good Manufacturing Practices, or GMP, regulations of the FDA and other regulations applicable to such a facility or we will more likely rely upon third-party manufacturers to manufacture our proposed products in accordance with these regulations.

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

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

Patents, Licenses and Proprietary Rights

Our success depends and will continue to depend in part upon our ability to maintain our exclusive licenses, to maintain patent protection for our products and processes, to preserve our proprietary information and trade secrets and to operate without infringing the proprietary rights of third parties. Our

policy is to attempt to protect our technology by, among other things, filing patent applications or obtaining license rights for technology that we consider important to the development of our business.

Antares Pharma, Inc. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares has granted us an exclusive license to four hormone replacement products for the treatment of testosterone deficiency in men and women and estrogen deficiency in women, including rights to sublicense the hormone replacement technology, in order to develop and market the hormone replacement technology in certain territories. Antares has an issued patent for these technologies in the United States and has filed patent applications for this licensed technology in several foreign jurisdictions, including Argentina, Australia, Canada, Europe, Italy, Japan, Korea, New Zealand, South Africa, and Taiwan.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the single entity estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately \$600,000 of manufacturing and formulation services and a license for a transdermal hormone replacement gel combination of testosterone and estradiol.

The license agreement with Antares required us to pay a \$1,000,000 up-front license fee to Antares, which we paid in June 2000. Also pursuant to the terms of the Antares license agreement, we expect to:

- pay royalties to Antares based on a percentage of the net sales of any products we sell incorporating the licensed technology;

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

 - testing proposed products;

 - conducting clinical trials;

 - obtaining government approvals;

 - introducing products incorporating the licensed technology into the market; and

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

University of California. In June 1997, we entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted us an exclusive license to nine United States patents owned by the University, including rights to sublicense such patents, in fields of use initially pertaining to: (1) vaccine adjuvants; (2) vaccine constructs or combinations for use in immunization against herpes virus; (3) drug delivery systems; and (4) red blood cell surrogates. The University of California has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan.

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

- payment of royalties to the University based on a percentage of the net sales of any products we sell incorporating the licensed technology;

payment of minimum annual royalties on February 28 of each year beginning in the year 2004 in the amounts set forth below, to be credited against earned royalties, for the life of the agreement;

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

maintaining an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market;

payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which amounted to \$11,358 in fiscal 2001;

meeting performance milestones relating to:

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

testing proposed products;

conducting clinical trials;

obtaining government approvals;

introducing products incorporating the licensed technology into the market; and

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

The license agreement further provides that we have the right to abandon any project in any field of use without abandoning our license to pursue other projects in that or other fields of use covered by the agreement. In May 1999, we notified the University that we would not pursue the red blood cell surrogate use because we did not believe it will be proven an effective use of CAP. In October 1999, we signed an amendment to our license agreement with the University, which removed the red-blood cell surrogate use from the agreement. In addition, under the terms of the amendment, the University agreed to make other changes we suggested to the license agreement, including delaying minimum royalty payments until 2004 and limiting the University's rights to terminate the agreement in cases where we do not perform under the agreement. If we violate or fail to perform any term or covenant of the license agreement and fail to cure this default within 60 days after written notice from the University, the University may terminate some projects included in the agreement. In May 2001, we signed a second amendment to our license agreement with the University to amend certain provisions of the license agreement for sublicensing arrangements with third parties.

Patents and patent applications. We own one United States patent and no foreign patents. In June 1999, we filed a patent for our advanced method of selectively isolating biologically active therapeutic proteins from transgenic milk. This patent was issued in February 2001. In February 2000, we filed a patent application with the U.S. Patent and Trademark Office relating to our development work with vaccine adjuvants, conventional DNA and RNA vaccines and drug delivery, including aerosol delivery into the lungs. In addition, there are two other patent applications pending for products in development.

Trademarks and trademark applications. We have filed trademark applications in the U. S. for the mark BIOSANTE for vaccines and vaccine adjuvants and for hormone replacement products. Both applications have been allowed for registration and will register upon submission of proof of use. We have also filed U.S. trademark applications and received Notices of Allowance for the marks BIOVANT, BIOAIR, NANOVANT and LIBIGEL. Two other U. S. trademark applications are pending for BIO E GEL and BIO-T-GEL for products in development. The BIOSANTE mark is registered in the European Union and Israel, and BIO-E-GEL and BIO-T-GEL are registered in Mexico. In addition, there are 17 other applications pending in the European Union and other countries for marks including the BIOSANTE mark. We do not have any other registered trademarks.

Confidentiality and assignment of inventions agreements. We require our employees, consultants and advisors having access to our confidential information to execute confidentiality agreements upon commencement of their employment or consulting relationships with us. These agreements generally provide that all confidential information we develop or make known to the individual during the course of the individual's employment or consulting relationship with us must be kept confidential by the individual and not disclosed to any third parties. We also require all of our employees and consultants who perform research and development for us to execute agreements that generally provide that all inventions conceived by these individuals will be our property.

Competition

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

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

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

We expect our products, if and when approved for sale, to compete primarily on the basis of product efficacy, safety, patient convenience, reliability and patent position. In addition, the first product to reach

the market in a therapeutic or preventative area is often at a significant competitive advantage relative to later entrants in the market.

We are aware of certain programs and products under development by others which may compete with our hormone replacement products and products we may develop that incorporate our CAP technology. Several competing companies, including Wyeth-Ayerst Pharmaceuticals, Novartis AG, Solvay Pharmaceuticals, Inc., Noven Pharmaceuticals, Inc. and Berlex Laboratories, Inc., dominate the international hormone replacement industry. The international vaccine industry is dominated by three companies: GlaxoSmithKline, Aventis (through its subsidiaries, including Institut Merieux International, Pasteur Merieux Serums et Vaccins, Connaught Laboratories Limited and Connaught Laboratories, Inc.) and Merck & Co., Inc.

There are several firms currently marketing or developing transdermal hormone replacement products. They include The Proctor & Gamble Company, Noven Pharmaceuticals, Inc., Novavax, Inc., Cellegy Pharmaceuticals, Inc., Auxilium A2, Inc., Watson Pharmaceuticals Inc. and Solvay Pharmaceuticals, Inc.

With regard to our CAP technology, the larger, better known pharmaceutical companies have generally focused on a traditional synthetic drug approach, although some have substantial expertise in biotechnology. During the last decade, however, significant research activity in the biotechnology industry has been completed by smaller research and development companies, like us, formed to pursue new technologies. Competitive or comparable companies to us include Corixa Corporation, generally regarded as a leader in vaccine adjuvant development, ID Biomedical Corporation and Antex Biologicals Inc., which both develop sub-unit vaccines from mycobacteria and other organisms.

Governmental Regulation

Pharmaceutical products intended for therapeutic use in humans are governed by extensive FDA regulations in the United States and by comparable regulations in foreign countries. Any products developed by us will require FDA approvals in the United States and comparable approvals in foreign markets before they can be marketed. The process of seeking and obtaining FDA approval for a previously unapproved new human pharmaceutical product generally requires a number of years and involves the expenditure of substantial resources.

Following drug discovery, the steps required before a drug product may be marketed in the United States include:

preclinical laboratory and animal tests;

the submission to the FDA of an investigational new drug application, commonly known as an IND application;

clinical and other studies to assess safety and parameters of use;

adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug product;

the submission to the FDA of a new drug application, commonly known as an NDA; and

FDA approval of the NDA prior to any commercial sale or shipment of the product.

Typically, preclinical studies are conducted in the laboratory and in animals to gain preliminary information on a proposed product's uses and physiological effects and harmful effects, if any, and to identify any potential safety problems that would preclude testing in humans. The results of these studies, together with the general investigative plan, protocols for specific human studies and other information, are submitted to the FDA as part of the IND application. The FDA regulations do not, by their terms, require FDA approval of an IND. Rather, they allow a clinical investigation to commence if the FDA does not notify the sponsor to the contrary within 30 days of receipt of the IND. As a practical matter, however, FDA approval is often sought before a company commences clinical investigations. That approval may come within 30 days of IND receipt but may involve substantial delays if the FDA requests additional information.

The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

Phase II trials are designed to evaluate the effectiveness of the product in the treatment of a given disease and involve people with the disease under study. These trials often are well controlled, closely monitored studies involving a relatively small number of subjects, usually no more than several hundred. The optimal routes, dosages and schedules of administration are determined in these studies. If Phase II trials are completed successfully, Phase III trials are often commenced, although Phase III trials are not always required.

Phase III trials are expanded, controlled trials that are performed after preliminary evidence of the effectiveness of the experimental product has been obtained. These trials are intended to gather the additional information about safety and effectiveness that is needed to evaluate the overall risk/benefit relationship of the experimental product and provide the substantial evidence of effectiveness and the evidence of safety necessary for product approval. Phase III trials usually include from several hundred to several thousand subjects.

A clinical trial may combine the elements of more than one Phase and typically two or more Phase III studies are required. A company's designation of a clinical trial as being of a particular Phase is not necessarily indicative that this trial will be sufficient to satisfy the FDA requirements of that Phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one Phase notwithstanding the designation of the trial as being of a particular Phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to complete Phase I, II and III studies with respect to a given product.

Upon the successful completion of clinical testing, an NDA is submitted to the FDA for approval. This application requires detailed data on the results of preclinical testing, clinical testing and the composition of the product, specimen labeling to be used with the drug, information on manufacturing methods and samples of the product. The FDA typically takes from six to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further,

there is no assurance that the FDA will ultimately approve an NDA. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

All facilities and manufacturing techniques used to manufacture products for clinical use or sale in the United States must be operated in conformity with current good manufacturing practice regulations, commonly referred to as GMP regulations, which govern the production of pharmaceutical products. We currently do not have manufacturing capability. In the event we undertake any manufacturing activities or contract with a third-party manufacturer to perform our manufacturing activities, we intend to establish a quality control and quality assurance program to ensure that our products are manufactured in accordance with the GMP regulations and any other applicable regulations.

Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. We intend to seek and utilize foreign partners to apply for foreign approvals of our products.

Employees

We had eight full-time employees as of December 31, 2001, including six in research and development and two in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We believe we have an excellent relationship with our employees.

Certain Important Factors

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

We have a history of operating losses, expect continuing losses and may never achieve profitability.

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of \$2,611,361 for the year ended December 31, 2001, and as of December 31, 2001, our accumulated deficit was \$18,251,033.

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

the timing and cost of product development;

the progress and cost of preclinical and clinical development programs;

the costs of licensure or acquisition of new products;

the timing and cost of obtaining necessary regulatory approvals; and

the timing and cost of obtaining third party reimbursement.

In order to generate revenues, we must successfully develop and commercialize our own proposed products or products in the late-stage human clinical development phase or already on the market that we may in-license or otherwise acquire, or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

We are a development stage company with a short operating history, making it difficult for you to evaluate our business and your investment.

We are in the development stage and our operations and the development of our proposed products are subject to all of the risks inherent in the establishment of a new business enterprise, including:

the absence of an operating history;

the lack of commercialized products;

insufficient capital;

expected substantial and continual losses for the foreseeable future;

limited experience in dealing with regulatory issues;

the lack of manufacturing experience and limited marketing experience;

an expected reliance on third parties for the development and commercialization of some of our proposed products;

a competitive environment characterized by numerous, well-established and well-capitalized competitors; and

reliance on key personnel.

Because we are subject to these risks, you may have a difficult time evaluating our business and your investment in our company.

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

Our proposed products are in the research and development stages and will require further research and development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. We cannot assure you that any of our proposed products will:

be successfully developed;

prove to be safe and efficacious in clinical trials;

meet applicable regulatory standards;

demonstrate substantial protective or therapeutic benefits in the prevention or treatment of any disease;

be capable of being produced in commercial quantities at reasonable costs; or

be successfully marketed.

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

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we may need to raise substantial additional capital to fund our operations sometime in the future. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our own product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business.

Our cash on hand as of December 31, 2001 was \$4,502,387. We believe this cash will be sufficient to fund our operations through December 2002. We have based this estimate on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. Any additional equity financings may be dilutive to our existing shareholders, and debt financing, if available, may involve restrictive covenants on our business. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

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

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

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

problems assimilating the purchased products;

unanticipated costs associated with the purchase;

incorrect estimates made in the accounting for acquisitions; and

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

If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed, we will be unable to generate revenue from the sale of our products.

We must obtain regulatory approval to sell any of our products in the United States and abroad. In the United States, we must obtain the approval of the FDA for each product or drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products to be commercialized abroad are subject to similar foreign government regulation.

Generally, only a very small percentage of newly discovered pharmaceutical products that enter preclinical development are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our proposed products could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our management's credibility, the value of our company and our operating results and liquidity would be adversely affected.

To obtain regulatory approval to market our products, costly and lengthy preclinical studies and clinical trials may be required, and the results of the studies and trials are highly uncertain.

As part of the FDA approval process, we must conduct preclinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of preclinical studies and clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform multiple preclinical studies using various doses and formulations before we can begin clinical trials, which could result in delays in our ability to obtain any regulatory approvals or to market any of our products. Furthermore, even if we obtain favorable results in preclinical studies on animals, the results in humans may be different.

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

slow patient enrollment;

longer treatment time required to demonstrate efficacy;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

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

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

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

We license our hormone replacement products from Antares Pharma, Inc. and our CAP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license our hormone replacement products or CAP technology could harm our business and future operating results. For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone replacement products or CAP technology for a license fee, the termination of the main license agreement with Antares Pharma, Inc. or the University of California could either, depending upon the terms of the outlicense agreement, cause us to breach our obligations under the outlicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the outlicense fees.

We do not have any facilities appropriate for clinical testing, we lack significant manufacturing experience and we have very limited sales and marketing personnel. We may, therefore, be dependent upon others for our clinical testing, manufacturing, sales and marketing.

Our current facilities do not include accommodation for the testing of our proposed products in animals or in humans for the clinical testing required by the FDA. We do not have a manufacturing facility that can be used for full-scale production of our products. In addition, at this time, we have very limited sales and marketing personnel. In the course of our development program, we will therefore be required to enter into arrangements with other companies or universities for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If we are unable to retain third parties for these purposes on acceptable terms, we may be unable to successfully develop, manufacture and market our proposed products. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our proposed products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise impair our competitive position. Our dependence on third

parties for the development, manufacture, sale and marketing of our products also may adversely affect our profit margins.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, upon our ability to obtain, enjoy and enforce protection for any products we develop or acquire under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties.

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

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

Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention before us or may claim that we are infringing on their patents and therefore we cannot use our technology as claimed under our patent. Competitors may also contest our patents by showing the patent examiner that the invention was not original or novel or was obvious.

We are in the research and development stage and are in the process of developing proposed products. Even if we receive a patent, it may not provide much practical protection. If we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent. Even if the development of our proposed products is successful and approval for sale is obtained, there can be no assurance that applicable patent coverage, if any, will not have expired or will not expire shortly after this approval. Any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our proposed product.

Enforcing patents is expensive and may require significant time by our management. In litigation, a competitor could claim that our issued patents are not valid for a number of reasons. If the court agrees, we would lose those patents.

We also may support and collaborate in research conducted by government organizations or universities. We cannot guarantee that we will be able to acquire any exclusive rights to technology or products derived from these collaborations. If we do not obtain required licenses or rights, we could encounter delays in product development while we attempt to design around other patents or we may be prohibited from developing, manufacturing or selling products requiring these licenses. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties.

It also is unclear whether our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is

unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our gross margins. In addition, we cannot be sure that the necessary licenses would be available to us on satisfactory terms, or that we could redesign our products or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing, manufacturing and selling some of our products, which could harm our business, financial condition and operating results.

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

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

Because our industry is very competitive and many of our competitors have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us, we may not succeed in developing our proposed products and bringing them to market.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors will not succeed in developing similar technologies

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

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

Our success will be largely dependent upon the efforts of Stephen M. Simes, our Vice Chairman, President and Chief Executive Officer, and other key employees. We are not the stated beneficiary of key person life insurance on any of our key personnel. Our future success also will depend in large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, could make it more difficult for us to manage our business and meet key objectives, such as the timely introduction of our proposed products, which would harm our business, financial condition and operating results.

Item 2. DESCRIPTION OF PROPERTY

Our principal executive office is located in Lincolnshire, Illinois. In September 2001, we entered into a new lease agreement for approximately 4,034 square feet of office space for approximately \$6,200 per month, which lease expires in December 2003. Our CAP research and development operations are located in Smyrna, Georgia where we lease approximately 11,840 square feet of laboratory space for approximately \$5,400 per month. This lease expires in October 2003. We also lease approximately 2,600 square feet of office space in Atlanta, Georgia for approximately \$3,500 per month. This lease expires in mid-September 2002 and will not be renewed. In September 1999, we entered into a sublease agreement for the Atlanta office space under which we receive approximately \$3,400 per month from the sub-tenant through mid-September 2002. Management of our company considers our leased properties suitable and adequate for our current and immediately foreseeable needs.

Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

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

No matter was submitted to a vote of our security holders during the fourth quarter ended December 31, 2001.

Item 4A. EXECUTIVE OFFICERS OF THE COMPANY

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

Name	Age	Title
Stephen M. Simes	50	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	41	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	38	Vice President, Clinical Development
Steven J. Bell, Ph.D.	42	Vice President, Research and Pre-Clinical Development

Information regarding the business experience of the executive officers is set forth below.

Stephen M. Simes has served as our Vice Chairman, President and a director of our company since January 1998 and Chief Executive Officer since March 1998. From October 1994 to January 1997, Mr. Simes was President, Chief Executive Officer and a Director of Unimed Pharmaceuticals, Inc., a company with a product focus on infectious diseases, AIDS, endocrinology and oncology. From 1989 to 1993, Mr. Simes was Chairman, President and Chief Executive Officer of Gynex Pharmaceuticals, Inc., a company which concentrated on the AIDS, endocrinology, urology and growth disorders markets. In 1993, Gynex was acquired by Bio-Technology General Corp., and from 1993 to 1994, Mr. Simes served as Senior Vice President and director of Bio-Technology General Corp. Mr. Simes' career in the pharmaceutical industry started in 1974 with G.D. Searle & Co.

Phillip B. Donenberg, CPA has served as our Chief Financial Officer, Treasurer and Secretary since July 1998. Before joining our company, Mr. Donenberg was Controller of Unimed Pharmaceuticals, Inc. from January 1995 to July 1998. Prior to Unimed Pharmaceuticals, Inc., Mr. Donenberg held similar positions with other pharmaceutical companies, including Gynex Pharmaceuticals, Inc., Molecular Geriatrics Corporation and Xtramedics, Inc.

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

Steven J. Bell, Ph.D. has served as our Vice President, Research and Pre-Clinical Development since October 2000 and served as a Director of Research and Development of BioSante from July 1997 to October 2000. Prior to joining our company, Dr. Bell held various positions with Boehringer Mannheim, Hoffman-LaRoche, The Upjohn Company and Boehringer Ingelheim.

PART II

Item 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**Market Price**

Our common stock has traded in the United States in the over-the-counter market on the OTC Bulletin Board, under the symbol BTPH, since May 5, 2000. Our common stock traded in Canada on the Canadian Venture Exchange, formerly known as the Alberta Stock Exchange, under the symbol BAI, from December 20, 1996 to July 20, 2001. From September 10, 1999 to May 4, 2000, our common stock was traded in the United States on the National Quotation Bureau, commonly referred to as the Pink Sheets, under the symbol BTPH.

The following table sets forth, in U.S. dollars and in dollars and cents (in lieu of fractions), the high and low sales prices for each of the calendar quarters indicated, as reported by the OTC Bulletin Board and the Pink Sheets. The prices in the table may not represent actual transactions. These quotations reflect inter-dealer prices, without retail mark up, mark down or commissions and may not represent actual transactions.

OTC Bulletin Board

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

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

National Quotation Bureau (Pink Sheets)

2000	High	Low
First Quarter	\$1.50	\$0.28