BIOSANTE PHARMACEUTICALS INC
Form SB-2
September 05, 2003

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As filed with the Securities and Exchange Commission on September 5, 2003

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIOSANTE PHARMACEUTICALS, INC.

(Name of Small Business Issuer in its Charter)

Delaware	**2836**	**58-2301143**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

111 Barclay Boulevard
Lincolnshire, Illinois 60069
Telephone No.: (847) 478-0500

(Address and Telephone Number of Principal Executive Offices)

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary
BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard
Lincolnshire, Illinois 60069
Telephone No.: (847) 478-0500

(Name, Address and Telephone Number of Agent for Service)

Copy to:
Amy E. Culbert, Esq.
Oppenheimer Wolff & Donnelly LLP
45 South Seventh Street, Suite 3300
Minneapolis, Minnesota 55402
(612) 607-7287

Approximate date of commencement of proposed sale to the public:

From time to time after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or reinvestment plans, check the following box: ý

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Number of shares to be registered(1)	Proposed maximum offering price per unit(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee(2)
Common Stock, par value $0.0001 per share	7,584,348	$2.75	$20,856,957	$1,687.33

(1) The amount to be registered hereunder consists of an aggregate of 7,584,348 shares of common stock to be sold by the selling stockholders named in this registration statement. Of the 7,584,348 shares of common stock, 4,791,982 are currently outstanding and beneficially owned by the selling stockholders and 2,792,366 shares are issuable upon the exercise of warrants held by the selling stockholders.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based upon the last sale of the registrant's common stock on September 4, 2003, as reported by the Over-the-Counter Bulletin Board.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

Subject to Completion, dated September 5, 2003

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

7,584,348 Shares

Common Stock

Selling stockholders of BioSante Pharmaceuticals, Inc. are offering 7,584,348 shares of common stock. BioSante will not receive any proceeds from the sale of shares offered by the selling stockholders.

The shares of common stock offered will be sold as described under the heading "Plan of Distribution," beginning on page 19.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol "BISP." On September 4, 2003, the last reported sale price of our common stock on the OTC Bulletin Board was $2.75 per share.

The common stock offered involves a high degree of risk. We refer you to "Risk Factors," beginning on page 6.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2003

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In this prospectus, references to "BioSante," the "company," "we," "our" or "us," unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, BioVant , NanoVant , CAP-Oral , BioAir , Bio-T-Gel , Bio-E-Gel , Bio-E/P-Gel , LibiGel and LibiGel-E/T .

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

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is accurate as of the date on the front cover. You should not assume that the information contained in this prospectus is accurate as of any other date.

SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. Therefore, you should also read the more detailed information contained in this prospectus, including the financial statements.

Our Company

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

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

The products we in-license from Antares Pharma, Inc. are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), combinations of estradiol and testosterone and estradiol and progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

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

Bio-T-Gel once daily transdermal bioidentical testosterone gel in clinical development for treatment of hypogonadism, or testosterone deficiency, in men.

Bio-E-Gel once daily transdermal bioidentical estrogen gel in clinical development for treatment of menopausal symptoms in women.

LibiGel once daily transdermal bioidentical testosterone gel in clinical development for treatment of female sexual dysfunction (FSD).

Bio-E/P-Gel once daily transdermal combination gel of bioidentical estrogen and a progestogen in clinical development for treatment of menopausal symptoms in women.

LibiGel-E/T once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone in development for treatment of FSD in menopausal women.

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

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

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

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

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

BioVant proprietary CAP adjuvant technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others.

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

BioAir proprietary technology using CAP as a delivery system for inhalable versions of proteins and other therapies that currently must be injected.

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

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

pursuing the development of our hormone therapy products;

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

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

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

We are also in the process of exploring strategic alternatives, which could include selling some or all of our assets or entering into a business combination, but we have not entered into any definitive agreements for such a strategic alternative.

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 was reincorporated under the laws of the State of Delaware on June 26, 2001.

Our principal executive offices are located at 111 Barclay Boulevard, Suite 280, Lincolnshire, Illinois 60069, and our telephone number is (847) 478-0500. Our web site is located at *www.biosantepharma.com*. Our web site, and the information contained on that site, or connected to that site, are not intended to be part of this prospectus.

Summary Financial Data

The summary statement of operations data shown below for the years ended December 31, 2000, 2001 and 2002 and the balance sheet data as of December 31, 2001 and 2002 are derived from our audited financial statements included elsewhere in this prospectus. The summary statement of operations data shown below for the period from August 29, 1996 (date of incorporation) to December 31, 1997 and for the years ended December 31, 1998 and 1999 and the balance sheet data as of December 31, 1998, 1999 and 2000 are derived from our audited financial statements not included elsewhere in this prospectus. The summary statement of operations data for the six months ended June 30, 2002 and 2003 and the balance sheet data as of June 30, 2003 has been derived from our unaudited financial statements included elsewhere in this prospectus, which, in the opinion of management, include all adjustments, consisting solely of normal recurring adjustments, necessary for a fair presentation of the financial information shown in these statements. The results for the six months ended June 30, 2002 and 2003 are not necessarily indicative of the results to be expected for the full year or for any future period. When you read this summary financial data, it is important that you also read the historical financial statements and related notes included in this prospectus, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations." Historical results are not necessarily indicative of future results.

	Period from August 29, 1996 (date of incorporation) to December 31, 1997	Year Ended December 31,					Six Months Ended June 30,	
		1998	1999	2000	2001	2002	2002	2003
	(in thousands, except per share data)							
Statement of Operations Data:								
Licensing income	$	$	$	$	$ 1,747	$ 2,770	$	$ 65
Interest income	197	123	199	228	174	64	30	30
Total income	197	123	199	228	1,921	2,834	30	95
Expenses:								
Research and development	336	1,400	661	1,888	2,142	4,787	1,632	1,742
General and administration	2,165	1,112	853	1,679	2,299	1,766	951	1,167
Depreciation and amortization	53	140	91	98	93	93	45	47
Loss on disposal of capital assets	28	130						
Total expenses	2,582	2,782	1,605	3,665	4,533	6,645	2,628	2,956
Loss before other expenses	(2,385)	(2,659)	(1,406)	(3,437)	(2,611)	(3,811)	(2,598)	(2,861)
Cost of acquisition of Structured Biologicals, Inc.	375							
Purchased in-process research and development	5,377							
Total other expenses	5,752							
Net loss	$ (8,137)	$ (2,659)	$ (1,406)	$ (3,437)	$ (2,611)	$ (3,811)	$ (2,598)	$ (2,861)
Basic and diluted net loss per share	$ (2.45)	$ (0.76)	$ (0.28)	$ (0.60)	$ (0.40)	$ (0.51)	$ (0.38)	$ (0.32)
Weighted average number of shares outstanding	3,316	3,487	4,942	5,754	6,485	7,503	6,788	9,057

As of December 31,					As of June 30,
1998	1999	2000	2001	2002	2003

	As of December 31,					As of June 30,
			(in thousands)			
Balance Sheet Data:						
Cash and cash equivalents	$ 2,841	$ 5,275	$ 2,612	$ 4,502	$ 4,884	$ 2,335
Working capital	2,099	5,004	1,735	3,666	4,292	1,734
Total assets	3,449	5,780	3,067	4,979	5,880	2,740
Convertible debenture current			500			
Stockholders' equity	2,631	5,451	2,126	4,051	4,624	2,019

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RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this prospectus, including the section entitled "Cautionary Statement Concerning Forward-Looking Statements" before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline, and you may lose part or all of your investment. These risks and uncertainties described below are not the only ones facing BioSante. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations and adversely affect the market price of our common stock.

Risks Relating to Our Company

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

We have incurred losses in each year since our amalgamation in 1996 and expect to incur substantial and continuing losses for the foreseeable future. We incurred a net loss of $3,810,690 for the year ended December 31, 2002, and as of December 31, 2002, our accumulated deficit was 22,061,723. We incurred a net loss of $2,860,781 for the six months ended June 30, 2003, and as of June 30, 2003, our accumulated deficit was $24,922,504.

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

the timing and cost of product development;

the progress and cost of preclinical and clinical development programs;

the costs of licensure or acquisition of new products;

the timing and cost of obtaining necessary regulatory approvals; and

the timing and cost of obtaining third party reimbursement.

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

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

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Therefore, we will need to raise substantial additional capital to fund our operations sometime in the future. We cannot be certain that any financing will be available when needed. If we fail to raise additional financing as we need it, we may have to delay or terminate our 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 June 30, 2003 was $2,334,937 and on August 4, 2003, we closed a private placement financing raising approximately $9.7 million in net proceeds. We believe this cash will be sufficient to fund our operations through December 2004. We have based this estimate on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. Any additional equity financings may be dilutive to our existing stockholders and involve the issuance of securities that may have rights, preferences or privileges senior to those possessed by our current stockholders. A debt financing, if available, may involve restrictive covenants on our business which could limit our operational and financial flexibility, and the amount of debt incurred could make us more vulnerable to economic downturns and limit our ability to compete. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. In addition, insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

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

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

the absence of an operating history;

the lack of commercialized products;

insufficient capital;

expected substantial and continual losses for the foreseeable future;

limited experience in dealing with regulatory issues;

the lack of manufacturing experience and limited marketing experience;

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

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

reliance on key personnel.

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

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

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

be successfully developed;

prove to be safe and efficacious in clinical trials;

meet applicable regulatory standards;

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

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

be successfully marketed.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the trading price of our shares.

In July 2002, the National Institutes of Health released data from its Women's Health Initiative study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The National Institutes of Health announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed hormone therapy products differ from the products used in the Women's Health Initiative study and the primary products observed in the National Cancer Institute and United Kingdom studies. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

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

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

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

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

As part of the FDA approval process, we must conduct preclinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of preclinical studies and clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform

multiple preclinical studies using various doses and formulations before we can begin clinical trials, which could result in delays in our ability to obtain any regulatory approvals or to market

any of our products. Furthermore, even if we obtain favorable results in preclinical studies on animals, the results in humans may be different.

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

slow patient enrollment;

longer treatment time required to demonstrate efficacy;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

We license the technology underlying most of our proposed hormone therapy products and most of our CAP technology from third parties and may lose the rights to license them.

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

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

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

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

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

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

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

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

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

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

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

It also is unclear whether our trade secrets will provide useful protection. While we use reasonable efforts to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

result in costly litigation;

divert the time and attention of our technical personnel and management;

cause product development delays;

require us to develop non-infringing technology; or

require us to enter into royalty or licensing agreements.

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

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

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

Risks Relating to Our Industry

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

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

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

Our success will be largely dependent upon the efforts of Stephen M. Simes, our Vice Chairman, President and Chief Executive Officer, and other key employees. Our future success also will depend in

large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel, could make it more difficult for us to manage our business and meet key objectives, such as the timely introduction of our proposed products, which would harm our business, financial condition and operating results.

Risks Relating to Our Common Stock

Because our common stock is traded on the OTC Bulletin Board, your ability to sell your shares in the secondary trading market may be limited.

Our common stock currently is traded on the over-the-counter market on the OTC Bulletin Board. Consequently, the liquidity of our common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions, and coverage by security analysts and the news media, if any, of our company. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock was quoted on the Nasdaq Stock Market or traded on a national securities exchange, like The New York Stock Exchange or American Stock Exchange.

Because our shares are "penny stocks," you may have difficulty selling them in the secondary trading market.

Federal regulations under the Securities Exchange Act of 1934 regulate the trading of so-called "penny stocks," which are generally defined as any security not listed on a national securities exchange or Nasdaq, priced at less than $5.00 per share and offered by an issuer with limited net tangible assets and revenues. Since our common stock currently trades on the OTC Bulletin Board at less than $5.00 per share, our common stock is a "penny stock" and may not be traded unless a disclosure schedule explaining the penny stock market and the risks associated therewith is delivered to a potential purchaser prior to any trade.

In addition, because our common stock is not listed on Nasdaq or any national securities exchange and currently trades at less than $5.00 per share, trading in our common stock is subject to Rule 15g-9 under the Exchange Act. Under this rule, broker-dealers must take certain steps prior to selling a "penny stock," which steps include:

obtaining financial and investment information from the investor;

obtaining a written suitability questionnaire and purchase agreement signed by the investor; and

providing the investor a written identification of the shares being offered and the quantity of the shares.

If these penny stock rules are not followed by the broker-dealer, the investor has no obligation to purchase the shares. The application of these comprehensive rules will make it more difficult for broker-dealers to sell our common stock and our stockholders, therefore, may have difficulty in selling their shares in the secondary trading market.

Sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus and under other registration statements, could lower our stock price and impair our ability to raise funds in new stock offerings.

Future sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus, under other registration statements and shares available for resale under Rule 144(k) under the Securities Act purchased under our May 1999 and April 2001 private placements, or the perception that such sales could occur, could adversely affect the

prevailing market price of our common stock and could make it more difficult for us to raise additional capital through the sale of equity securities. We filed this registration statement pursuant to an investor rights agreement with the holders of the common stock and warrants purchased in our August 2003 private placement. We are required under this investor rights agreement to use our reasonable best efforts to cause this registration statement to remain effective until the earlier of (1) the sale of all the shares of our common stock covered by this registration statement; or (2) such time as the selling stockholders named in this registration statement become eligible to resell the shares of BioSante common stock and the shares of BioSante common stock issuable upon exercise of warrants pursuant to Rule 144(k) under the Securities Act.

Our stock price may be volatile and your investment in our common stock could suffer a decline in value.

Our common stock has been listed on the OTC Bulletin Board since May 2000. The market price of our common stock may fluctuate significantly in response to a number of factors, some of which are beyond our control. These factors include:

progress of our products through the regulatory process;

results of preclinical studies and clinical trials;

announcements of technological innovations or new products by us or our competitors;

government regulatory action affecting our products or our competitors' products in both the United States and foreign countries;

developments or disputes concerning patent or proprietary rights;

actual or anticipated fluctuations in our operating results;

changes in our financial estimates by securities analysts;

general market conditions for emerging growth and pharmaceutical companies;

broad market fluctuations; and

economic conditions in the United States or abroad.

We may incur significant costs from class action litigation due to our expected stock volatility.

In the past, following periods of large price declines in the public market price of a company's stock, holders of that stock occasionally have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring this type of lawsuit against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. The lawsuit also could divert the time and attention of our management, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

authorizing the issuance of "blank check" preferred that could be issued by our Board of Directors to increase the number of outstanding shares and thwart a takeover attempt;

prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; and

advance notice provisions in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

We refer you to "Description of Securities Undesignated Preferred Stock; Anti-Takeover Provisions of Delaware Law" for more information on the specific provisions of our certificate of incorporation, our bylaws and Delaware law that could discourage, delay or prevent a change of control of our company.

Our directors and executive officers own a sufficient number of shares of our capital stock to control our company, which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Our directors and executive officers own or control approximately 31.6% of our outstanding voting power. Accordingly, these stockholders, individually and as a group, may be able to influence the outcome of stockholder votes, involving votes concerning the election of directors, the adoption or amendment of provisions in our certificate of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

Exercise of outstanding options and warrants will dilute stockholders and could decrease the market price of our common stock.

As of August 7, 2003, we had issued and outstanding 13,482,764 shares of common stock, 466,602 shares of our class C stock and outstanding options and warrants to purchase 5,713,750 additional shares of common stock. The existence of the outstanding options and warrants may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the fair market value and trading price of our common stock.

We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on your investment in our common stock must come from increases in the fair market value and trading price of our common stock.

We likely will issue additional equity securities which will dilute your share ownership.

We likely will issue additional equity securities to raise capital and through the exercise of options and warrants that are outstanding or may be outstanding. These additional issuances will dilute your share ownership.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our financial condition, results of operations and business, including, without limitation, statements pertaining to:

- our substantial and continuing losses;
- our spending capital on research and development programs, pre-clinical studies and clinical trials, regulatory processes, establishment of marketing capabilities and licensure or acquisition of new products;
- our existing cash and whether and how long these funds will be sufficient to fund our operations; and
- our raising of additional capital through future equity financings.

These and other forward-looking statements are primarily in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Conditions and Results of Operations" and "Business." Generally, you can identify these statements because they use phrases like "anticipates," "believes," "expects," "future," "intends," "plans," and similar terms. These statements are only predictions. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy, and actual results may differ materially from those we anticipated due to a number of uncertainties, many of which are unforeseen. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this prospectus. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, among others, the risks we face as described in the

section entitled "Risk Factors" and elsewhere in this prospectus.

We believe it is important to communicate our expectations to our investors. There may be events in the future, however, that we are unable to predict accurately or over which we have no control. The risk factors listed in the section entitled "Risk Factors," as well as any cautionary language in this prospectus, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the section entitled "Risk Factors" and elsewhere in this prospectus could negatively impact our business, operating results, financial condition and stock price.

We are not obligated to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as otherwise required by law. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this prospectus and other statements made from time to time from us or our representatives, might not occur. For these statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares offered under this prospectus by the selling stockholders. This offering is intended to satisfy our obligations to register, under the Securities Act of 1933, the resale of the shares of our common stock, including shares of our common stock that will be issued to the selling stockholders upon the exercise of warrants held by them, that we issued to the selling stockholders in a private placement. The net proceeds from our sale of these shares to the selling stockholders will be used for general corporate purposes, including working capital.

DIVIDEND POLICY

We never have declared or paid cash dividends on our common stock or our class C special stock. We currently intend to retain all future earnings for the operation and expansion of our business. We do not anticipate declaring or paying cash dividends on our common stock or class C special stock in the foreseeable future. Any payment of cash dividends on our common stock or class C special stock will be at the discretion of our Board of Directors and will depend upon our results of operations, earnings, capital requirements, contractual restrictions and other factors deemed relevant by our Board of Directors.

SELLING STOCKHOLDERS

All of the selling stockholders named below acquired or have the right to acquire upon the exercise of warrants the shares of our common stock being offered under this prospectus directly from us in a private transaction. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of August 7, 2003 as provided by the selling stockholders. In accordance with the rules of the SEC, beneficial ownership includes the shares issuable pursuant to warrants and options that are exercisable within 60 days of August 7, 2003. Shares issuable pursuant to warrants and options are considered outstanding for computing the percentage of the person holding the warrants and options but are not considered outstanding for computing the percentage of any other person.

The percentage of beneficial ownership for the following table is based on 13,482,764 shares of common stock outstanding as of August 7, 2003. To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person.

Except as set forth below, none of the selling stockholders has had any position, office or other material relationship with us within the past three years. The table assumes that the selling stockholders will sell all of the shares offered by them in this offering. However, we are unable to determine the exact number of shares that will actually be sold or when or if these sales will occur. We will not receive any of the proceeds from the sale of the shares offered under this prospectus.

Selling Stockholder	Shares Beneficially Owned Prior to the Offering: Shares Subject to Options, Warrants, and Class C Special Stock	Shares Beneficially Owned Prior to the Offering: Total Shares Beneficially Owned	Shares Beneficially Owned Prior to the Offering: Percentage	Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering: Number	Shares Beneficially Owned After Completion of the Offering: Percentage
SCO Capital Partners LLC(1)	335,473	585,473	4.2%	585,473	0	
Jeffrey B. Davis(1)	66,600	66,600	*	66,600	0	
Preston Tsao(1)	20,000	20,000	*	20,000	0	
Daniel DiPietro(1)	20,000	20,000	*	20,000	0	
Joshua Golomb(1)	8,700	8,700	*	8,700	0	
Kristin Woolley(1)	4,000	4,000	*	4,000	0	
SDS Merchant Fund, LP(2)	232,558	697,674	4.9%	697,674	0	
North Sound Legacy Fund LLC	10,465	31,395	*	31,395	0	
North Sound Legacy Institutional Fund LLC	105,814	317,442	2.3%	317,442	0	
North Sound Legacy International Ltd.	116,279	348,837	2.6%	348,837	0	
Perceptive Life Sciences Master Fund, Ltd.(3)	550,000	1,650,000	11.8%	1,650,000	0	
Joseph Edelman(4)	112,500	337,500	2.5%	337,500	0	
Multi-National Consulting Services IV, LLC	11,500	34,500	*	34,500	0	
Daniel B. Heller	5,750	17,250	*	17,250	0	
Paul Scharfer(1)	149,850	316,350	1.8%	316,350	0	
Quogue Capital LLC	145,000	435,000	3.2%	435,000	0	
Orion Biomedical Offshore Fund, LP	41,502	124,505	*	124,505	0	
Orion Biomedical Fund, LP	190,999	572,996	4.2%	572,996	0	
Richard Stone	10,000	30,000	*	30,000	0	
Steven M. Oliveira 1998 Charitable Remainder Trust	116,250	348,750	2.6%	348,750	0	
Victor Morgenstern(5)	309,000	1,105,308	8.0%	229,500	875,808	5.3%
Morningstar Trust(6)	102,500	372,500	2.7%	210,000	162,500	1.0%
Panacea Fund, LLC(7)	75,000	285,000	2.1%	225,000	60,000	*
Irving B. Harris Revocable Trust	87,333	285,499	2.1%	87,000	198,499	1.2%
Virginia H. Polsky Trust	43,667	143,000	1.1%	43,500	99,500	*
Roxanne H. Frank Trust	58,139	190,416	1.4%	57,750	132,666	*
Couderay Partners	58,139	190,416	1.4%	57,750	132,666	*
JO & Co.(8)	521,512	1,835,539	13.1%	439,535	1,396,004	8.3%
Crestview Capital Fund II, LP	46,512	419,535	2.8%	139,535	280,000	1.7%
James S. Levy Living Trust	23,625	82,725	*	24,000	58,725	*

Mitchell I. Dolins Revocable Trust	27,151	81,453	*	13,953	67,500	*
Bradley S. Glaser & Amy E. Glaser as Tenants by the Entirety	7,776	23,328	*	13,953	9,375	*
Dr. Hermann S. Graf Zu Munster	35,250	168,585	1.3%	12,000	156,585	1.0%
Richard Sheiner	4,000	22,000	*	12,000	10,000	*
Roscoe F. Nicholson II Profit Sharing Plan	16,550	64,350	*	8,400	55,950	*
Shirley M. Nicholson IRA	1,000	15,062	*	3,000	12,062	*
Dr. Terry L. Lazarus	4,000	12,000	*	12,000	0	
Charles Burns	4,000	24,000	*	12,000	12,000	*
John E. Urheim	7,125	28,125	*	12,000	16,125	*
Stephen M. Simes Revocable Trust(9)	400,550	537,796	3.9%	1,500	536,296	3.2%
Leah M. Lehman(10)	86,637	246,414	1.8%	1,500	244,914	1.5%
Phillip B. Donenberg(11)	117,790	131,764	1.0%	1,500	130,264	*

*
Less than one percent (1%)

(1)

SCO Securities LLC acted as agent in connection with our August 2003 private placement. In connection with the August 2003 private placement, SCO Securities received a commission of approximately $560,000 and a warrant to purchase an aggregate of 371,373 shares of common stock. SCO Securities assigned its rights under the warrant to employees of SCO Securities.

(2)

The terms of the warrant held by SDS Merchant Fund LP provide that the warrant is exercisable on any given date only to the extent that the number of shares of common stock issued upon the exercise of the warrant, together with any other shares of common stock beneficially owned by SDS Merchant or any of its affiliates (excluding for this purpose shares of common stock which may be deemed beneficially owned through the ownership of the unexercised warrant) would not exceed 4.95% of the common stock then issued and outstanding. Accordingly, SDS Merchant's ability to fully convert or exercise the warrant is limited by the terms of the warrant.

(3)

Perceptive Life Science Master Fund LP's business address is 5437 Connecticut Avenue, NW, Suite 100, Washington, DC 20015.

(4)

Joseph Edelman's address is 300 Central Park West, Apt. 25-G, New York, NY 10024.

(5)

Mr. Morgenstern is a director of BioSante. Mr. Morgenstern's beneficial ownership includes: (1) 10,000 shares of common stock issuable upon exercise of a stock option, (2) 171,500 shares of common stock issuable upon exercise of warrants, (3) 102,500 shares of common stock issuable upon exercise of warrants and 270,000 shares of common stock held by Mr. Morgenstern's wife as trustee of the Morningstar Trust, as to which Mr. Morgenstern disclaims control, direction or beneficial ownership, (4) 10,000 shares of common stock issuable upon exercise of a warrant and 70,000 shares of common stock held by Mr. Morgenstern's wife, as to which Mr. Morgenstern disclaims control, direction or beneficial ownership, and (5) 25,000 shares of common stock issuable upon exercise of a warrant and 50,000 shares of common stock held by Resolute Partners L.P. Victor Morgenstern is managing director of Resolute Partners L.P. Mr. Morgenstern's address is 106 Vine Avenue, Highland Park, IL 60035.

(6)

Shares held by Mr. Morgenstern's wife as trustee of the Morningstar Trust, as to which Mr. Morgenstern disclaims control, direction or beneficial ownership.

(7)

Mr. Holubow, a director of BioSante, is a co-general partner of Panacea Fund, LLC.

(8)

Ross Mangano, a director of BioSante, is President of JO & Co. JO & Co's business address is P.O. Box 1655, South Bend, IN 46634.

(9)

Mr. Simes is the Vice Chairman, President and Chief Executive Officer of BioSante.

(10)

Dr. Lehman is the Vice President, Clinical Development of BioSante.

(11)

Mr. Donenberg is the Chief Financial Officer, Treasurer and Secretary of BioSante.

PLAN OF DISTRIBUTION

We are registering the shares of common stock on behalf of the selling security holders. Sales of shares may be made by selling security holders, including their respective donees, transferees, pledgees or other successors-in-interest, directly to purchasers or to or through underwriters, broker-dealers or through agents. Sales may be made from time to time on the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);

purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchases;

through options, swaps or derivatives;

in privately negotiated transactions;

in making short sales or in transactions to cover short sales; and

put or call option transactions relating to the shares.

The selling security holders may effect these transactions by selling shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling security holders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

The selling security holders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling security holders. The selling security holders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions or loan or pledge shares of common stock to a broker-dealer, who may sell the loaned shares or, in the event of default, sell the pledged shares. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

The selling security holders and any broker-dealers that act in connection with the sale of shares may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling security holders and each selling security holder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

The selling security holders will be subject to the prospectus delivery requirements of the Securities Act. We have informed the selling security holders that the anti-manipulative provisions of Regulation M promulgated under the Securities Exchange Act of 1934 may apply to their sales in the market.

Selling security holders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of Rule 144.

Upon being notified by a selling security holder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of each such selling security holder and of the participating broker-dealer(s);

the number of shares involved;

the initial price at which the shares were sold;

the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the SEC, we will file a supplement to this prospectus when a selling security holder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

We are paying all expenses and fees customarily paid by an issuer in connection with the registration of the shares. The selling security holders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

PRICE RANGE OF COMMON STOCK

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

The following table sets forth, in U.S. dollars and in dollars and cents (in lieu of fractions), the high and low sales prices for each of the calendar quarters indicated, as reported by the OTC Bulletin Board. The prices in the table may not represent actual transactions. These quotations reflect inter-dealer prices, without retail mark up, mark down or commissions and may not represent actual transactions. On May 31, 2002, we effected a one-for-ten reverse split of our issued and outstanding shares of common stock and class C special stock. All per share numbers in the following tables have been adjusted to reflect the reverse split.

OTC Bulletin Board

2003	**High**	**Low**
First Quarter	$ 3.60	$ 1.65
Second Quarter	$ 3.10	$ 1.85
Third Quarter (through September 4, 2003)	**$ 3.10**	**$ 2.45**

2002	**High**	**Low**
First Quarter	$ 7.90	$ 5.10
Second Quarter	$ 7.00	$ 3.60
Third Quarter	$ 5.25	$ 3.35
Fourth Quarter	$ 3.75	$ 1.91

2001	**High**	**Low**
First Quarter	$ 7.50	$ 3.80
Second Quarter	$ 10.70	$ 3.90

2001	High	Low
Third Quarter	$ 10.00	$ 4.60
Fourth Quarter	$ 10.50	$ 4.80

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

Canadian Venture Exchange

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

As of August 7, 2003, there were 723 record holders of our common stock and 10 record holders of our class C stock.

SELECTED FINANCIAL DATA

The selected statement of operations data shown below for the years ended December 31, 2000, 2001 and 2002 and the balance sheet data as of December 31, 2001 and 2002 are derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data shown below for the period from August 29, 1996 (date of incorporation) to December 31, 1997 and for the years ended December 31, 1998 and 1999 and the balance sheet data as of December 31, 1998, 1999 and 2000 are derived from our audited financial statements not included elsewhere in this prospectus. The selected statement of operations data for the six months ended June 30, 2002 and 2003 and the balance sheet data as of June 30, 2003 has been derived from our unaudited financial statements included elsewhere in this prospectus, which, in the opinion of management, include all adjustments, consisting solely of normal recurring adjustments, necessary for a fair presentation of the financial information shown in these statements. The results for the six months ended June 30, 2002 and 2003 are not necessarily indicative of the results to be expected for the full year or for any future period. When you read this selected consolidated financial data, it is important that you also read the historical financial statements and related notes included in this prospectus, as well as "Management's Discussion and Analysis of Financial Condition and Results of Operations." Historical results are not necessarily indicative of future results.

	Period from August 29, 1996 (date of incorporation) to December 31, 1997	Year Ended December 31,					Six Months Ended June 30,	
		1998	1999	2000	2001	2002	2002	2003
	(in thousands, except per share data)							
Statement of Operations Data:								
Licensing income	$	$	$	$	$ 1,747	$ 2,770	$	$ 65
Interest income	197	123	199	228	174	64	30	30
Total income	197	123	199	228	1,921	2,834	30	95
Expenses:								
Research and development	336	1,400	661	1,888	2,142	4,787	1,632	1,742
General and administration	2,165	1,112	853	1,679	2,299	1,766	951	1,167
Depreciation and amortization	53	140	91	98	93	93	45	47
Loss on disposal of capital assets	28	130						
Total expenses	2,582	2,782	1,605	3,665	4,533	6,645	2,628	2,956

	Period from August 29, 1996 (date of incorporation) to December 31, 1997						Six Months Ended June 30,	
Loss before other expenses	(2,385)	(2,659)	(1,406)	(3,437)	(2,611)	(3,811)	(2,598)	(2,861)
Cost of acquisition of Structured Biologicals, Inc.	375							
Purchased in-process research and development	5,377							
Total other expenses	5,752							
Net loss	$ (8,137)	$ (2,659)	$ (1,406)	$ (3,437)	$ (2,611)	$ (3,811)	$ (2,598)	$ (2,861)
Basic and diluted net loss per share	$ (2.45)	$ (0.76)	$ (0.28)	$ (0.60)	$ (0.40)	$ (0.51)	$ (0.38)	$ (0.32)
Weighted average number of shares outstanding	3,316	3,487	4,942	5,754	6,485	7,503	6,788	9,057

	As of December 31,					As of June 30,
	1998	1999	2000	2001	2002	2003
	(in thousands)					
Balance Sheet Data:						
Cash and cash equivalents	$ 2,841	$ 5,275	$ 2,612	$ 4,502	$ 4,884	$ 2,335
Working capital	2,099	5,004	1,735	3,666	4,292	1,734
Total assets	3,449	5,780	3,067	4,979	5,880	2,740
Convertible debenture current			500			
Stockholders' equity	2,631	5,451	2,126	4,051	4,624	2,019

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the results of the operations and financial condition of BioSante should be read in conjunction with our financial statements and the related notes thereto.

Overview

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

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

The products we in-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), a combination of estradiol and testosterone and a combination of estradiol and progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Indonesia, Malaysia, Australia, New Zealand, China and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of the hormone therapy products, we paid Antares an upfront license fee of $1.0 million in June 2000. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, after all necessary regulatory approvals are received, pay royalties to Antares on sales of the products.

In a series of amendments executed during 2001 between us and Antares, we returned to Antares the license rights to one of four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, it was agreed that we are the owner of Bio-T-Gel, our testosterone gel for men with no milestone or royalty obligations to Antares. We also returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted us a credit for approximately $600,000 of manufacturing and formulation services, which have been fully utilized, and a license for the combination estradiol plus testosterone gel product for all countries described above.

In August 2001, we entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed our estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, we received a $950,000 milestone payment pursuant to the Solvay sub-license agreement. Solvay is responsible for all costs of development and marketing of the product. We have retained co-promotion

rights to the product and will be compensated for sales generated by us over and above those attributable to Solvay's marketing efforts. As described further below, the Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by us prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of our common stock with a market value of $125,000 at the date of the transaction.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone therapy products in Canada to Paladin Labs Inc. In exchange for the sub-license, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. Upon execution of the sub-license agreement, Paladin made an initial investment of $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $10.50 per share. In August 2001, we exercised our right and declared the debenture converted in full. Accordingly, 47,619 shares of our common stock were issued to Paladin in August 2001. During the third quarter 2001, Paladin made a series of equity investments in us as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in issuing an additional 18,940 shares of our common stock to Paladin.

In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. Patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if the product gets approved and subsequently marketed.

In December 2002, we entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., under which we will collaborate with Teva USA on the development of a hormone therapy product for the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA, future development and sales related milestone payments and royalties on sales of the commercialized product in exchange for rights to develop and market a hormone therapy product. Teva USA will also be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

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

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

a women's sexual desire and activity. We hope to initiate the one required pivotal Phase III clinical trial in 2003.

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

Our CAP technology, which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles," as immune

system boosters, for drug delivery and to purify the milk of transgenic animals, among other uses. We have identified three potential initial applications for our CAP technology:

- the creation of improved versions of current vaccines and of new vaccines by the "adjuvant" activity of our proprietary nanoparticles that enhance the ability of a vaccine to stimulate an immune response;
- the creation of inhaled and oral forms of drugs that currently must be given by injection (*e.g.*, insulin); and
- the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

Our strategy with respect to CAP over the next 12 months is to continue development of our nanoparticle technology and actively to seek collaborators and licensees to accelerate the development and commercialization of products incorporating this technology. We received clearance in August 2000 from the FDA to initiate a Phase I clinical trial of our CAP as a vaccine adjuvant and delivery system based on an Investigational New Drug Application that we filed in July 2000. The Phase I trial was a double-blind, placebo-controlled trial in 18 subjects to determine the safety of CAP as a vaccine adjuvant. The trial was completed in October 2000. The results showed that there was no apparent difference in side effect profile between CAP and placebo.

In October 2001, we licensed our BioVant calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay us milestone payments upon the achievement by Corixa of certain milestones plus royalty payments on sales by Corixa if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sub-licenses vaccines that include BioVant, we will share in milestone payments and royalties received by Corixa. The license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

In January 2003, we announced the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Navy's Naval Medical Research Center's (NMRC) Malaria Program for the development of a malaria vaccine. The development agreement leverages our expertise with NMRC's expertise to develop an enhanced vaccine for malaria. Under the agreement, we will provide the NMRC with BioVant our proprietary vaccine adjuvant and delivery system, and the NMRC will provide DNA plasmids or proteins encoding antigens for *Plasmodium spp.*, the parasite that causes malaria. It is hoped that the resulting DNA vaccine will improve the effectiveness of the ensuing humoral and cell-mediated immunity against malaria and therefore be more effective as it activates both arms of the immune system.

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

- Continue the development of our hormone therapy products;
- Continue the development of our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses;
- Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies; and

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

We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $3,810,690 for the year ended December 31, 2002, resulting in an accumulated deficit of $22,061,723. We incurred a net loss of $2,860,781 for the six

month period ended June 30, 2003 resulting in an accumulated deficit of $24,922,504. In order to generate revenues, we must successfully develop and commercialize our proposed products or enter into collaborative agreements with others who can successfully develop and commercialize them. Even if our proposed products and the products we may license or otherwise acquire are commercially introduced, they may never achieve market acceptance and we may never generate revenues or achieve profitability.

Critical Accounting Policies

Revenue Recognition

We recognize revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees. Revenue is recognized when amounts are earned, cash is received and we have completed all of our obligations under our licensing arrangement which are required for the payment to be non-refundable. Revenue also includes reimbursement for certain research and development expenses which we recognize as both revenue and expense at the time the expense is incurred. Any ancillary payment related to the products being licensed, such as royalties to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized. Interest income on invested cash balances is recognized on the accrual basis as earned.

Research and Development

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

Results of Operations

Three Months Ended June 30, 2003 Compared to Three Months Ended June 30, 2002

We earned no licensing income during the three month period ended June 30, 2003 or the three month period ended June 30, 2002. Interest income increased from $6,712 during the three month period ended June 30, 2002 to $11,490 during the three month period ended June 30, 2003 as a result of higher invested cash balances during the three months ended June 30, 2003.

Research and development expenses decreased from $987,528 during the three month period ended June 30, 2002 to $939,124 during the three month period ended June 30, 2003. This overall decrease is the result of decreased expenses associated with the clinical development of certain of our hormone therapy products. We expect that our research and development expenses will continue to be significant in future periods as a result of human clinical trials of certain of our hormone therapy products. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds dedicated to research and development activities. The amount of our research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) available resources; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

General and administrative expenses increased 35% from $491,851 during the three month period ended June 30, 2002 to $664,918 during the three month period ended June 30, 2003. This increase is the result of an increase in expenses related to BioSante common stock paid to our directors as compensation for serving on board and committees throughout the year compared to the same period last year.

We incurred a net loss of $1,616,100 for the three month period ended June 30, 2003, compared to a net loss of $1,495,364 for the three month period ended June 30, 2002. The increase in net loss is

largely the result of increased expenses associated with the aforementioned director stock compensation recorded during the three month period ended June 30, 2003 compared to the same period last year. We anticipate that our operating losses will continue for the foreseeable future.

Six Months Ended June 30, 2003 Compared to Six Months Ended June 30, 2002

We earned licensing income of $65,494 during the six month period ended June 30, 2003 due to the reimbursement by a licensee of certain research and development expenses. There was no licensing income during the six month period ended June 30, 2002. Interest income increased slightly from $29,971 during the six month period ended June 30, 2002 to $30,309 during the six month period ended June 30, 2003 as a result of higher invested cash balances during the six months ended June 30, 2003.

Research and development expenses increased from $1,631,922 during the six month period ended June 30, 2002 to $1,742,277 during the six month period ended June 30, 2003. This overall increase is the result of increased expenses associated with the clinical development of certain of our hormone therapy products.

General and administrative expenses increased 23% from $950,980 during the six month period ended June 30, 2002 to $1,167,211 during the six month period ended June 30, 2003. This increase is the result of an increase in expenses associated with BioSante common stock paid to our directors as compensation recorded during the six month period ended June 30, 2003 compared to the same period last year.

We incurred a net loss of $2,860,781 for the six month period ended June 30, 2003, compared to a net loss of $2,598,290 for the six month period ended June 30, 2002. The increase in net loss is largely the result of increased general and administrative expenses as mentioned above during the six month period ended June 30, 2003 compared to the same period last year.

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

Revenues increased from $1,921,802 during the year ended December 31, 2001 to $2,833,851 during the year ended December 31, 2002, primarily due to a $1.5 million upfront payment by Teva USA and a $950,000 ($750,000 net of a related payment due to Antares) milestone payment by Solvay. All of our revenue to date has been derived from interest earned on invested funds and upfront and milestone payments earned on licensing and sub-licensing transactions.

Research and development expenses increased from $2,141,944 during the year ended December 31, 2001 to $4,786,818 during the year ended December 31, 2002. This overall increase is the result of increased expenses during 2002 associated with the clinical development of certain of our hormone therapy products. We expect that our research and development expenses will continue to be significant in future periods as a result of human clinical trials of our hormone therapy products. Management estimates that its 2002 spending of approximately $300,000 to $400,000 per month on research and development activities and approximately $500,000 to $600,000 per month in total expenses, including research and development activities will decline slightly in 2003 based on our planned clinical development schedule. These expenses are planned to increase as our clinical development progresses.

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

Interest income decreased from $174,416 during the year ended December 31, 2001 to $63,788 during the year ended December 31, 2002 as a result of lower average cash balances in 2002 and as a

result of lower interest rates on invested cash balances in 2002. We expect interest income to increase in future periods as a result of increased cash balances due to our August 2003 financing.

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

commence and continue. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

the timing and cost of product development;

the progress and cost of preclinical and clinical development programs;

the costs of licensure or acquisition of new products;

the timing and cost of obtaining necessary regulatory filings and approvals; and

the timing and cost of obtaining third party reimbursement.

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

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

On August 7, 2001, we entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay paid us an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin) and has agreed to make future milestone payments and pay escalating sales-based royalties. Solvay is responsible for all costs of development and marketing of the estrogen/progestogen combination transdermal hormone therapy gel product. We have retained co-promotion rights to the product and will be compensated for sales we generate over and above those attributable to Solvay's marketing efforts. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by us prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of our common stock with a market value of $125,000 at the date of the transaction.

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

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

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

Liquidity and Capital Resources

To date, including the August 2003 private placement financing, we have raised equity financing and received licensing income to fund our operations, and we expect to continue this practice to fund our ongoing operations. Since inception, we have raised net proceeds of

approximately $31.0 million from equity financings, class A and class C stock conversions, warrant exercises and the issuance of a $500,000 convertible debenture, which was subsequently converted into 47,619 shares of common stock. Since inception, we have received $4.6 million, net of sublicensing costs, as a result of licensing upfront payments and milestones.

On August 4, 2003, we closed a private placement, raising approximately $10.3 million, ($9.7 million net of estimated transaction costs) upon the issuance of units, which consisted of an aggregate of approximately 4.8 million shares of common stock and five-year warrants to purchase an aggregate of approximately 2.8 million shares of common stock (includes placement agent warrants issued in conjunction with the financing). The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $2.15. The exercise price of the warrants is $2.15 per share.

Six Months Ended June 30, 2003 Compared to Six Months Ended June 30, 2002

Our cash and cash equivalents were $2,334,937 and $4,883,697 at June 30, 2003 and December 31, 2002, respectively. We used cash in operating activities of $2,545,999 for the six month period ended June 30, 2003 versus cash used in operating activities of $2,725,352 for the six month period ended June 30, 2002. The decrease in cash used in operating activities largely reflects payments from a licensee during the six month period ended June 30, 2003 related to the clinical development of a product within our hormone therapy product portfolio. The $218,378 reduction of the Due to Licensor account during the six month period ended June 30, 2003, which represents expenses related to manufacturing and formulation services provided by Antares, partially offset the increase in cash used in operating activities. There was no net cash used in investing activities for the six month period ended June 30, 2003 versus $25,836 used in investing activities for the six month period ended June 30, 2002. The uses of cash in investing activities during the six month period ended June 30, 2002 were capital expenditures for the purchase of computer equipment and filing cabinets. There was $2,761 net cash used in financing activities as a result of transaction costs incurred associated with our private placement financing during the six months ended June 30, 2003 compared to net cash used in financing activities of $46,704 for the six months ended June 30, 2002. The net cash used in financing activities during the six month period ended June 30, 2002 reflects the transaction costs associated with a previous financing.

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

We used cash in operating activities of $3,962,493 for the year ended December 31, 2002 versus cash used in operating activities of $1,823,820 for the year ended December 31, 2001. The increase in cash used in operating activities reflects an increase in cash expenditures in: (1) research and development and associated personnel-related expenses, and (2) expenses related to the clinical

development of our hormone therapy products. Net cash used in investing activities for capital expenditures for computer equipment was $38,992 for the year ended December 31, 2002 versus $86,735 for the year ended December 31, 2001. Net cash provided by financing activities was $4,382,795 for the year ended December 31, 2002 compared to $3,801,187 for the year ended December 31, 2001. Net cash provided by financing activities during 2002 was primarily the result of $4.4 million net cash proceeds pursuant to our equity offering that closed in September 2002.

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

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

Commitments

We did not have any material commitments for capital expenditures as of June 30, 2003. We have, however, several financial commitments, including product development milestone payments to the licensors of our hormone therapy products, payments under our license agreements with the University of California and Wake Forest University, as well as minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments as of June 30, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 61,122	$ 61,122	$	$	$
Commitments Under License Agreement with UCLA	6,800,000		150,000	350,000	6,300,000
Commitments Under License Agreement with Wake Forest	1,740,000	10,000	125,000	155,000	1,450,000
Total Contractual Cash Obligations	$ 8,601,122	$ 71,122	$ 275,000	$ 505,000	$ 7,750,000

We expect to continue to spend capital on:

research and development programs;

pre-clinical studies and clinical trials;

regulatory processes;

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

the licensure or acquisition of new products.

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

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

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

time and cost necessary to obtain regulatory approvals;

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

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

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

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

In addition, our license agreement with the licensor of our hormone therapy products requires us to make certain payments as development milestones are achieved, and our license agreement with the University of California requires us to have available minimum amounts of funds each year for research and development activities relating to our licensed technology and to achieve research and development milestones. Moreover, our fixed expenses, such as rent, license payments and other contractual commitments, may increase in the future, as we may:

enter into additional leases for new facilities and capital equipment;

enter into additional licenses and collaborative agreements; and

incur additional expenses associated with being a public company.

Outlook

Our cash on hand as of June 30, 2003 was $2,334,937 and approximately $11.5 million as of August 4, 2003 after closing our private placement financing which raised approximately $9.7 million in net proceeds. We believe our cash on hand will be sufficient to fund our operations through December 2004. 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 currently do not have sufficient resources to complete the commercialization of any of our proposed products. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business. We are also in the process of exploring strategic alternatives, which could include selling some or all of our assets or entering into a business combination, but we have not entered into any definitive agreements for such a strategic alternative.

BUSINESS

General

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

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis.

The products we in-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), combinations of estradiol and testosterone and estradiol and progestogen (another female hormone). The gels are designed to be quickly absorbed through the skin after application on the arms, shoulders, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

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

Bio-T-Gel once daily transdermal bioidentical testosterone gel in clinical development for treatment of hypogonadism, or testosterone deficiency, in men.

Bio-E-Gel once daily transdermal bioidentical estrogen gel in clinical development for treatment of menopausal symptoms in women.

LibiGel once daily transdermal bioidentical testosterone gel in clinical development for treatment of female sexual dysfunction (FSD).

Bio-E/P-Gel once daily transdermal combination gel of bioidentical estrogen and a progestogen in clinical development for treatment of menopausal symptoms in women.

LibiGel-E/T once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone in development for treatment of FSD in menopausal women.

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

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

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

the purification of the milk of transgenic animals, in which protein pharmaceuticals are grown.

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

BioVant proprietary CAP adjuvant technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others.

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

BioAir proprietary technology using CAP as a delivery system for inhalable versions of proteins and other therapies that currently must be injected.

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

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

pursuing the development of our hormone therapy products;

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

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

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

We are also in the process of exploring strategic alternatives, which could include selling some or all of our assets or entering into a business combination, but we have not entered into any definitive agreements for such a strategic alternative.

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

Business Strategy

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

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

Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses. We are seeking opportunities to enter into business collaborations, joint ventures or sub-licenses with companies that have businesses or technologies complementary to our CAP technology business, such as vaccine and drug delivery pharmaceutical companies and transgenic milk companies. We believe that this partnering strategy will enable us to capitalize on our partners' strengths in product development, manufacturing and commercialization and thereby enable us to introduce into the market

products incorporating our CAP technology sooner than which we otherwise would be able. In addition, these collaborations have and will significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology.

Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies. We intend to seek opportunities to enter into business collaborations or joint ventures with entities that have businesses or technologies complementary to our business. We are particularly interested in entering into product licenses, co-development or co-marketing arrangements. We are also in the process of exploring strategic alternatives, which could include selling some of our assets or entering into a business combination.

License or otherwise acquire other drugs that will add value to our current product portfolio. We will consider opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. In reviewing these opportunities, we consider products that cover therapeutic areas treated by a limited number of physicians and drugs that are in or require human clinical trials that involve a limited number of patients and not a significant amount of time and cost needed to complete them. We believe that products that are currently in or ready for human clinical trials would decrease the risks associated with product development and would likely shorten the time before we can introduce the products into the market. In addition to late-stage development products, we would also consider opportunities to in-license or otherwise acquire products that (1) have the U.S. Food and Drug Administration, or FDA, approval, (2) have been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience, and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have a full portfolio in development.

Description of Our Hormone Therapy Products

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

The following is a list our hormone therapy products in development:

Bio-T-Gel once daily transdermal bioidentical testosterone gel in clinical development for treatment of hypogonadism, or testosterone deficiency, in men.

Bio-E-Gel once daily transdermal bioidentical estrogen gel in clinical development for treatment of menopausal symptoms in women.

LibiGel once daily transdermal bioidentical testosterone gel in clinical development for treatment of female sexual dysfunction (FSD).

Bio-E/P-Gel once daily transdermal combination gel of bioidentical estrogen and a progestogen in clinical development for treatment of menopausal symptoms in women.

LibiGel-E/T once daily transdermal combination gel of bioidentical estrogen and bioidentical testosterone in development for treatment of FSD in menopausal women.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men

with severe and prolonged reduction of testosterone may also experience loss of body hair, reduced muscle mass, osteoporosis and bone fractures due to osteoporosis. Approximately five million men in the United States, primarily in the over age 40 male population group, have lower than normal levels of testosterone. Testosterone therapy has been shown to restore levels of testosterone with minimal side effects.

Prior to 2000, testosterone often was delivered through injections or dermal, or skin, patches. Delivery of testosterone through dermal patches was developed primarily to promote the therapeutic effects of testosterone therapy without the often painful side effects associated with testosterone injections. Dermal patches, however, have a physical presence and have been associated with skin irritation. Our testosterone formulated gel product for men, Bio-T-Gel, is designed to deliver testosterone without the pain of injections, the physical presence and skin

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

Estrogen deficiency in women can result in hot flashes and flushes, vaginal atrophy, decreased libido and osteoporosis. Hormone therapy in women decreases the chance that women will experience the symptoms of estrogen deficiency. According to industry estimates, approximately 15 million women in the U.S. currently are receiving some form of estrogen or combined estrogen hormone therapy.

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

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product, Bio-E/P-Gel. Women whose uteri are intact often use a combined hormone therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial cancer and endometrial hyperplasia associated with estrogen therapy in women. In July 2002, the National Institutes of Health (NIH) released data from its Women's Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of the estrogen-progestin tablet combination from the WHI study because Prempro, the combination oral hormone therapy product used in the study, was shown to cause an increase in the risk of invasive breast cancer after an average follow-up period of 5.2 years. Both the estrogen and progestin components of Prempro are different chemical entities than those used in our proposed gel formulated Bio-E/P-Gel, and the means of delivery into the system are significantly different. Prempro is an oral tablet formulation consisting of conjugated equine estrogen and medroxyprogesterone acetate as active ingredients. Our proposed Bio-E/P-Gel is a gel formulated delivery system containing estradiol, which is identical to the estrogen produced naturally by a woman's ovaries, and progestin, different than the type of progestin in Prempro. The WHI study results do not necessarily apply to estrogen and progestin administered through the transdermal route and to different hormones which may provide a different risk-benefit profile. In addition, the intended use for our proposed gel-formulated Bio-E/P-Gel is no more than two years.

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

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

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

- our transdermal gels can be spread over areas of skin where they dry rapidly and decrease the chance for skin irritation versus hormone dermal patches;
- our transdermal gels may have fewer side effects than many pills which have been known to cause gallstones, blood clots and complications related to metabolism;
- adding progestogen to estrogen may reduce the potential risks of endometrial cancer and endometrial hyperplasia of estrogen therapy alone when the uterus is intact;
- our transdermal gels have been shown to be absorbed evenly, thus allowing clinical hormone levels to reach the systemic circulation;

hormone therapy using gels may allow for better dose adjustment than either dermal patches or oral tablets or capsules; and

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

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

Under the terms of our license agreement with Antares, we acquired exclusive marketing rights, with the right to grant sub-licenses, to the single active ingredient testosterone and estradiol products for all therapeutic indications in the U.S., Canada, Mexico, Israel, Indonesia, Malaysia, Australia, New Zealand, China and South Africa. We acquired exclusive marketing rights, with the right to grant sub-licenses, for the combination estradiol and progestogen product in the U.S. and Canada. In partial consideration for the license of the hormone therapy products, we paid Antares an upfront license fee of $1.0 million in June 2000. In addition, under the terms of the license agreement, we agreed to fund the development of the proposed products, make milestone payments and, after all necessary regulatory approvals are received, pay royalties to Antares on sales of the products.

In a series of amendments executed during 2001 and 2002 between us and Antares, we returned to Antares the license rights to one of four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, it was agreed that we are the owner of Bio-T-Gel, our testosterone gel for men with no milestone or royalty obligations to Antares. We also returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted us a credit for approximately $600,000 of manufacturing and formulation services, which have been fully utilized, and a license for the combination estradiol plus testosterone gel product for all countries described above.

In August 2001, we entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed our estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, we received a $950,000 milestone payment pursuant to the Solvay sub-license agreement. Solvay will be responsible for all costs of development and marketing of the product. We have retained co-promotion

rights to the product and are compensated for sales generated by us over and above those attributable to Solvay's marketing efforts. As described further below, the Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by us prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of our common stock with a market value of $125,000 at the date of the transaction.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone therapy products in Canada to Paladin Labs Inc. In exchange for the sub-license, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in our common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. Upon execution of the sub-license agreement, Paladin made an initial investment of $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $10.50 per share. In August 2001, we exercised our right and declared the debenture converted in full. Accordingly, 47,619 shares of our common stock were issued to Paladin in August 2001. During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in issuing an additional 18,940 shares of our common stock to Paladin.

In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by us, regulatory milestones, maintenance payments and royalty payments by us if the product gets approved and subsequently marketed.

In December 2002, we entered into a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd., under which we will collaborate with Teva USA on the development of a hormone therapy product for

the U.S. market. The financial terms of the development and license agreement included a $1.5 million upfront payment by Teva USA, future development and sales related milestone payments and royalties on sales of the commercialized product upon approval in exchange for rights to develop and market a hormone therapy product. Teva USA will also be responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

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

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

Description of Our CAP Technology and CAP Technology Products

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

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

BioVant proprietary CAP adjuvant technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others.

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

BioAir proprietary technology using CAP as a delivery system for inhalable versions of proteins and other therapies that currently must be injected.

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

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

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

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

and confirmed by others that when these combinations are injected into animals, the attachment can enhance the biological activity as compared to injection of the molecule alone.

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

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

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

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

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

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

Research in these areas has resulted in the issuance of a number of patents, which we either license from the University of California or own.

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

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

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

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

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

In addition to continuing our own research and development in this area, we intend to seek opportunities to enter into business collaborations or joint ventures with vaccine companies and others interested in co-development and co-marketing arrangements with respect to our CAP nanoparticles for

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

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

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

In January 2003, we announced the signing of a Cooperative Research and Development Agreement (CRADA) with the U.S. Navy's Naval Medical Research Center's (NMRC) Malaria Program for the development of a malaria vaccine. The development agreement leverages our expertise with NMRC's expertise to develop an enhanced vaccine for malaria. Under the agreement, we will provide the NMRC with BioVant our proprietary vaccine adjuvant and delivery system, and the NMRC will provide DNA plasmids or proteins encoding antigens for *Plasmodium spp*., the parasite that causes malaria. It is hoped that the resulting DNA vaccine will improve the effectiveness of the ensuing humoral and cell-mediated immunity against malaria and therefore be more effective as it activates both arms of the immune system.

Drug delivery systems. The second field of use in which we are exploring applying our CAP technology involves creating novel and improved forms of delivery of drugs, including proteins (*e.g.*, insulin). The attachment of drugs to CAP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We have shown pre-clinical efficacy in the oral delivery of insulin in normal and diabetic mouse models. In the oral insulin mouse models in fasted mice, our product, which we call CAP-Oral, has shown an 80% reduction of glucose levels within the first hour of treatment. These reduced glucose levels were maintained for 12 hours versus 20-25% glucose reduction for three hours for free insulin. In fed mouse models, our oral formulation reduced glucose levels by 50% for six hours versus no significant reduction with free insulin. Furthermore, we believe we may have successfully created a formulation for the inhaled delivery of insulin, which we call BioAir. We are working with potential licensees for the further development of our CAP-Oral and BioAir. Our research and development efforts in these areas are ongoing.

Transgenic Milk Purification. The third field of use in which we are exploring applying our CAP technology is in the purification of the milk of transgenic animals in which protein drugs are grown. This is achieved by selectively isolating biologically active therapeutic proteins from the milk of transgenic animals. This method uses our CAP technology to recover greater than 90% of drug protein from the milk in a way that may require less downstream processing and may produce higher overall

yields at lower cost than currently used methods. Our method dissolves casein clusters, thereby freeing the drug proteins, and then reforms the casein clusters using CAP as the core. Caseins are then removed from the milk, leaving high concentrations of the drug protein in the remaining crystal clear whey fraction.

Sales and Marketing

We currently have no sales and marketing personnel to sell on a commercial basis any of our proposed products. Under our agreements with Solvay and Teva, Solvay and Teva have agreed to market the products covered by the agreements in certain countries. If and when we are ready to commercially launch a product not covered by our agreements with Solvay and Teva, we will either contract with or hire qualified sales and marketing personnel or seek a joint marketing partner to assist us with this function.

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately $1,742,000 for the six month period ended June 30, 2003, $4,787,000 in the year ended December 31, 2002 and $2,142,000 in the year ended December 31, 2001 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues from the sale of our products, these research and development costs must be financed by us or a strategic partner. We estimate that we are currently spending approximately $300,000 to $400,000 per month on research and development activities. These expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending upon the resources available and our development schedule. Results of preclinical studies, clinical trials, regulatory decisions and competitive developments may significantly influence the amount of our research and development expenditures. In addition, we expect that our spending on product development will increase if we are successful at in-licensing or otherwise acquiring other late-stage development products, although these activities are considered a low priority in our overall business strategy.

Manufacturing

We currently do not have any facilities suitable for manufacturing on a commercial scale basis any of our proposed products nor do we have any experience in volume manufacturing. Our plan is to use third-party Good Manufacturing Practices, or GMP, manufacturers to manufacture our proposed products in accordance with FDA and other appropriate regulations.

Currently, our gel hormone products used in the clinical trial process are manufactured through a U.S.-based GMP approved manufacturer.

Patents, Licenses and Proprietary Rights

Our success depends and will continue to depend in part upon our ability to maintain our exclusive licenses, to maintain patent protection for our products and processes, to preserve our proprietary information and trade secrets and to operate without infringing the proprietary rights of third parties. Our policy is to attempt to protect our technology by, among other things, filing patent applications or obtaining license rights for technology that we consider important to the development of our business.

Antares Pharma, Inc. In June 2000, we entered into a license agreement with Antares Pharma, Inc. pursuant to which Antares has granted us an exclusive license to four proposed hormone therapy products for the treatment of testosterone deficiency in men and women and estrogen deficiency in women, including rights to sublicense the hormone therapy products, in order to develop and market the hormone therapy products in certain territories. Antares has an issued patent for these

products in the United States and has filed patent applications for this licensed technology in several foreign jurisdictions, including Argentina, Australia, Canada, Europe, Italy, Japan, Korea, New Zealand, South Africa, and Taiwan.

In a series of amendments executed during 2001 between us and Antares, we returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, it was agreed that we are the owner of Bio-T-Gel, our testosterone gel for men with no milestone or royalty obligations to Antares. We also returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the single entity estradiol and testosterone gel products in Malaysia and Australia, Antares granted us a credit for approximately $600,000 of manufacturing and formulation services and a license for a transdermal hormone therapy gel combination of testosterone and estradiol. In August 2002 and December 2002, BioSante and Antares further amended the license agreement to clarify interpretations of the license agreement, including products covered by the license agreement, and to terminate the Supply Agreement with

Antares.

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

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

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

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

- payment of royalties to the University based on a percentage of the net sales of any products we sell incorporating the licensed technology;
- payment of minimum annual royalties on February 28 of each year beginning in the year 2004 to be credited against earned royalties, for the life of the agreement;
- maintaining an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market;

- payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which amounted to $12,241 in fiscal 2002;
- meeting performance milestones relating to:
  - hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;

testing proposed products;

conducting clinical trials;

obtaining government approvals;

introducing products incorporating the licensed technology into the market; and

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

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

Wake Forest University. In April 2002, we exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by us in exchange for exclusive rights to the license, and regulatory milestones, maintenance payments and royalty payments by us if a product incorporating the licensed technology gets approved and subsequently marketed.

Patents and patent applications. We own two United States patents and no foreign patents. In June 1999, we filed a patent for our advanced method of selectively isolating biologically active therapeutic proteins from transgenic milk. This patent issued in February 2001. In February 2000, we filed a patent application with the U.S. Patent and Trademark Office relating to our development work with CAP, including its applications as a vaccine adjuvant, as a carrier for biologically active material and as part of a controlled release matrices for biologically active material. A patent directed to methods of formulating the CAP particles issued in March 2002. In addition, we have other patent applications pending in the U.S. and internationally for products in development.

Trademarks and trademark applications. We have filed trademark applications in the U. S. for the mark BIOSANTE for vaccines and vaccine adjuvants and for our proposed hormone therapy products. The BIOSANTE mark is registered for the hormone preparations. The application for vaccines and vaccine adjuvants has been allowed for registration and will register upon submission of proof of use. We have also filed U.S. trademark applications and received Notices of Allowance for the marks BIOVANT, BIOAIR, NANOVANT and LIBIGEL. Two other U. S. trademark applications are pending

for BIO-E-GEL and BIO-T-GEL for products in development. The BIOSANTE mark is also registered in the European Union and Israel, BIOAIR is registered in the European Union and Israel, BIOVANT is registered in Israel and Mexico, NANOVANT is registered in the European Union, Israel and Mexico, and BIO-E-GEL and BIO-T-GEL are registered in Mexico. There are 10 other applications pending in the European Union, Canada and Mexico for these marks. We do not have any other registered trademarks.

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

that all inventions conceived by these individuals will be our property.

Competition

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

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

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

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

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

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

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

Governmental Regulation

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

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

preclinical laboratory and animal tests;

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

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

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

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

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

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

The initial phase of clinical testing, which is known as Phase I, is conducted to evaluate the metabolism, uses and physiological effects of the experimental product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence of possible effectiveness. Phase I studies can also evaluate various routes, dosages and schedules of product administration. These studies generally involve a small number of healthy volunteer subjects, but may be conducted in people with the disease the product is intended to treat. The total number of subjects is generally in

the range of 20 to 80. A demonstration of therapeutic benefit is not required in order to complete Phase I trials successfully. If acceptable product safety is demonstrated, Phase II trials may be initiated.

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

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

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

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

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

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

Products marketed outside of the United States are subject to regulatory approval requirements similar to those in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain European

countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. We intend to seek and utilize foreign partners to apply for foreign approvals of our products.

Employees

We had twelve full-time employees and one part-time employee as of June 30, 2003, including nine in research and development and four in management or administrative positions. None of our employees is covered by a collective bargaining agreement. We believe we have an excellent relationship with our employees.

Properties

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

Legal Proceedings

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

MANAGEMENT

Executive Officers, Directors and Key Employees

Set forth below is information concerning our executive officers, directors and key employees, including their age, as of August 15, 2003:

Name	Age	Title
Stephen M. Simes	51	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	42	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D	40	Vice President, Clinical Development

Name	Age	Title
Steven J. Bell, Ph.D	43	Vice President, Research and Pre-Clinical Development
Louis W. Sullivan, M.D.(1)(2)(3)(4)	69	Chairman of the Board
Victor Morgenstern(3)	60	Director
Fred Holubow(1)(3)	64	Director
Ross Mangano(2)(3)	57	Director
Edward C. Rosenow III, M.D.(3)(4)	68	Director
Angela Ho(2)(3)	50	Director
Peter Kjaer(1)(3)	42	Director

(1) Member of the Audit and Finance Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Governance Committee

(4) Member of the Scientific Review Committee

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

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

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

Steven J. Bell, Ph.D. has served as our Vice President, Research and Pre-Clinical Development since October 2000 and served as a Director of Research and Development of BioSante from July 1997

to October 2000. Prior to joining our company, Dr. Bell held various positions with Boehringer Mannheim, Hoffman-LaRoche, The Upjohn Company and Boehringer Ingelheim.

The Honorable Louis W. Sullivan, M.D. has been our Chairman of the Board of Directors since March 1998 and has been a director of our company since its formation. Dr. Sullivan served as Secretary of Health and Human Services in the cabinet of President George H.W. Bush from 1989 to 1993. Since retiring from the Bush Administration, Dr. Sullivan has been associated with the Morehouse School of Medicine in Atlanta, Georgia. Currently, he serves as President Emeritus and he previously served as President and Dean of the School from 1981 to 1985 and as President from 1985 to 1989 and from 1993 to 2002. Since 1993, Dr. Sullivan has served and continues to serve on the Boards of several large U.S. corporations, including 3M Corp., Bristol-Myers Squibb Company, Cigna Corporation, Georgia Pacific Corp., Equifax Inc. and United Therapeutics Corporation.

Victor Morgenstern was elected a director of our company in July 1999. Mr. Morgenstern has more than 32 years of investment experience and is the Chairman of the Board of Trustees of The Oakmark Funds, an open-end registered investment company and serves as managing director of Resolute Partners L.P. and Chairman and principal of Valor Equity Partners, LLC, a private equity fund. He is a trustee of the Illinois Institute of Technology.

Fred Holubow was elected a director of our company in July 1999. Mr. Holubow has been a Vice President of Pegasus Associates since he founded Pegasus in 1982. Pegasus Associates is currently an operating division of William Harris Investors, a registered investment advisory firm. He specializes in analyzing and investing in pharmaceutical and biotechnology companies. Mr. Holubow has served on the Board of Directors for ThermoRetec Corporation, Bio-Technology General Corp., Gynex Pharmaceuticals, Inc. and Unimed Pharmaceuticals, Inc.

Ross Mangano was elected a director of our company in July 1999. Mr. Mangano has been the President and a director of Oliver Estate, Inc., a management company specializing in investments in public and private companies, since 1971. He serves as a director for Blue Chip Casino, Inc., Orchard Software Corporation, Mego Financial Corp. and U.S. RealTel Inc.

Edward C. Rosenow, III, M.D. has been a director of our company since November 1997. Dr. Rosenow is a Master Fellow of the American College of Physicians as well as Master Fellow the American College of Chest Physicians. Dr. Rosenow was the Arthur M. and Gladys D. Gray Professor of Medicine at the Mayo Clinic from 1988 until his recent retirement. Beginning with his residency in 1960, Dr. Rosenow has worked at the Mayo Clinic in many professional capacities including as a Consultant in Internal Medicine (Thoracic Diseases) from 1966 to 1996, an Assistant Professor, Associate Professor and Professor of Medicine at the Mayo Clinic Medical School, President of the Mayo Clinic Staff in 1986, and Chair of the Division of Pulmonary and Critical Care Medicine from 1987 to 1994. Dr. Rosenow has also served as a consultant to NASA, space station FREEDOM at the Johnson Space Center in Houston, Texas from 1989 to 1990 and as the President of the American College of Chest Physicians from 1989 to 1990. In 1998, he received the Mayo Distinguished Alumnus Award.

Angela Ho has been a director of our company since June 1998. Ms. Ho has been the Vice Chairman and Chief Managing Officer of Jet-Asia Ltd., a Hong Kong-based aircraft and management company, since April 1996. From June 1996 to June 1998, Ms. Ho was the President of Ho Galleries Ltd., a New York art gallery.

Peter Kjaer has been a director of our company since July 1999. Mr. Kjaer has been President and Chief Executive Officer of Jet-Asia Ltd., a Hong Kong-based aircraft and management company, since April 1996. From April 1989 to July 1996, Mr. Kjaer was the General Manager and a director of the Gallery of Contemporary Living Ltd., a Hong Kong-based art gallery.

Information About the Board of Directors and its Committees

The Board of Directors has an Audit and Finance Committee, Compensation Committee, Nominating and Governance Committee and Scientific Review Committee. The Board of Directors and each board committee is in the process of reviewing its respective membership and committee charters as the requirements of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Securities and Exchange Commission are finalized and become effective.

Audit and Finance Committee. The Audit and Finance Committee provides assistance to the Board of Directors in satisfying its fiduciary responsibilities relating to our accounting, auditing, operating and reporting practices, and reviews our annual financial statements, the selection and work of our independent auditors and the adequacy of internal controls for compliance with corporate policies and directives. The Audit and Finance Committee operates under a written charter adopted by the Board of Directors. The Audit and Finance Committee consists of Mr. Kjaer, Dr. Sullivan and Mr. Holubow. Each of these individuals is "independent" as defined under the National Association of Securities Dealers listing standards. In addition, each of these individuals is able to read and understand fundamental financial statements, including a company's balance sheet, income statement, and cash flow statement. At least one of these individuals has past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities.

Compensation Committee. The Compensation Committee:

reviews general programs of compensation and benefits for all of our employees;

makes recommendations to the Board of Directors concerning matters such as compensation to be paid to our officers and directors; and

administers our stock plan, pursuant to which stock options may be granted to our eligible employees, officers, directors and consultants.

The Compensation Committee consists of Dr. Sullivan, Mr. Mangano and Ms. Ho.

Nominating and Governance Committee. The primary functions of the Nominating and Governance Committee are to develop and recommend corporate governance principles, to identify and recommend individuals qualified to become members of our Board and to develop and oversee the annual Board and Board Committee evaluation process. As a part of this review of our committee structure, our Board will review, revise and create each of our committee charters, establishing new independence standards and refining the authority and responsibilities of each committee. The Nominating and Governance Committee consists of Dr. Sullivan, Mr. Mangano, Mr. Morgenstern, Mr. Holubow, Dr. Rosenow, Mr. Kjaer and Ms. Ho.

Scientific Review Committee. The Scientific Review Committee assists in evaluating potential new licenses or new products. The Scientific Review Committee consists of Dr. Sullivan and Dr. Rosenow.

Director Compensation

Each of our non-employee directors is paid a $10,000 annual retainer paid in shares of our common stock and $1,000 for each board or committee meeting attended in person and $500 for each board or committee meeting attended via telephone paid in shares of our common stock. All of our directors are reimbursed for travel expenses for attending meetings.

Summary of Cash and Other Compensation

The following table provides summary information concerning cash and non-cash compensation paid to or earned by our Chief Executive Officer and our executive officers, who received or earned cash and non-cash salary and bonus of more than $100,000, for the fiscal year ended December 31, 2002.

Summary Compensation Table

		Annual Compensation		Long-Term Compensation	
Name and Principal Position	**Year**	**Salary ($)**	**Bonus ($)**	**Securities Underlying Options (#)**	**All Other Compensation ($)**
Stephen M. Simes	2002	$ 308,000	$ 92,400(1)	108,507	$ 44,585(2)
Vice Chairman, President and	2001	291,500	131,175	71,407	18,388(2)
Chief Executive Officer	2000	275,000	150,000(1)	0	29,317(2)
Phillip B. Donenberg	2002	158,300	28,494(3)	37,564	13,759(4)
Chief Financial Officer, Treasurer	2001	150,000	45,000	21,547	13,592(4)
and Secretary	2000	127,000	42,000(3)	0	13,286(4)
Leah M. Lehman, Ph.D.	2002	190,000	34,200(5)	79,071	12,700(6)
Vice President, Clinical	2001	180,000	54,000	50,000	12,450(6)
Development	2000				
Steven J. Bell, Ph.D.	2002	120,000	21,600	33,025	11,500(8)
Vice President, Research and	2001	102,000	30,000	5,000	11,250(8)

Pre-Clinical Development	2000	91,521	26,000(7)	Long-Term Compensation 0		11,250(8)

(1) Represents a cash bonus of ($46,200 in 2002 and $75,000 in 2000) and a stock award of 19,660 shares of common stock valued at $46,200 in 2002 and 12,500 shares of common stock valued at $75,000 in 2000.

(2) Represents an auto allowance ($12,000 in 2002, $12,000 in 2001 and $12,000 in 2000), a 401(k) matching contribution ($6,000 in 2002, $5,250 in 2001 and $5,250 in 2000) and insurance premiums and taxes associated with the premiums ($26,585 in 2002, $1,138 in 2001 and $12,067 in 2000).

(3) Represents a cash bonus of ($14,247 in 2002 and $30,000 in 2000) and a stock award of 6,603 shares of common stock valued at $14,247 in 2002 and 2,000 shares of common stock valued at $12,000 in 2000.

(4) Represents an auto allowance ($7,200 in 2002, $7,200 in 2001 and $7,200 in 2000), a 401(k) matching contribution ($5,500 in 2002, $5,250 in 2001 and $5,250 in 2000) and insurance premiums paid and taxes associated with the premiums ($1,059 in 2002, $1,142 in 2001 and $836 in 2000).

(5) Represents a cash bonus of $17,100 in 2002 and a stock award of 7,277 shares of common stock valued at $17,100 in 2002.

(6) Represents an auto allowance of ($7,200 in 2002 and $7,200 in 2001) and a 401(k) matching contribution of ($5,500 in 2002 and $5,250 in 2001).

(7) Represents a cash bonus of $20,000 and a stock award of 1,000 shares of common stock valued at $6,000.

(8) Represents an auto allowance ($6,000 in 2002, $6,000 in 2001 and $6,000 in 2000) and a 401(k) matching contribution ($5,500 in 2002, $5,250 in 2001 and $5,250 in 2000).

Option Grants in Last Fiscal Year

The following table summarizes option grants during the fiscal year ended December 31, 2002 to or by each of the executive officers named in the Summary Compensation Table on page 51.

	Individual Grants(1)			
Name	**Number of Securities Underlying Options Granted (#)**	**Percent of Total Options Granted to Employees in Fiscal Year**	**Exercise Price ($ Per Share)**	**Expiration Date**
Stephen M. Simes	108,507(2)	33.17%	$ 3.40	9/26/12
Phillip B. Donenberg	37,564(2)	11.48%	$ 3.40	9/26/12
Leah M. Lehman, Ph.D.	40,000(3)	12.23%	$ 5.30	3/7/12
	39,071(2)	11.94%	$ 3.40	9/26/12
Steven J. Bell, Ph.D.	20,000(3)	6.11%	$ 5.30	3/7/12
	13,025(2)	3.98%	$ 3.40	9/26/12

(1) All of the options granted to the individuals in this table were granted under our Amended and Restated 1998 Stock Option Plan.

(2) This option vests in equal quarterly installments over three years so long as the executive officer remains employed by us at that date. To the extent not already exercisable, this option becomes immediately exercisable in full upon certain changes in control of our company and remains exercisable for the remainder of its term.

(3) This option vests annually over three years so long as the executive officer remains employed by us at that date. To the extent not already exercisable, this option becomes immediately exercisable in full upon certain changes in control of our company and remains exercisable for the remainder of its term.

Aggregated Option Exercises In Last Fiscal Year and Fiscal Year-End Option Values

The following table summarizes the number and value of options held by each of the executive officers named in the Summary Compensation Table on page 51 at December 31, 2002. None of these executive officers exercised any stock options during 2002.

	Number of Securities Underlying Unexercised Options at December 31, 2002		Value of Unexercised In-the-Money Options at December 31, 2002(1)	
Name	**Exercisable**	**Unexercisable**	**Exercisable**	**Unexercisable**
Stephen M. Simes	324,420	141,119	$ 224,115	$ 0
Phillip B. Donenberg	98,296	47,003	67,504	0
Leah M. Lehman, Ph.D	33,096	95,975	0	0
Steven J. Bell, Ph.D.	27,752	35,273	6,235	0

(1) Value based on the difference between the fair market value of one share of our common stock at December 31, 2002 ($3.35), and the exercise price of the options ranging from $2.30 to $6.70 per share. Options are in-the-money if the market price of the shares exceeds the option exercise price.

Employment Agreements

Simes Employment Agreement

In January 1998, we entered into a letter agreement with Stephen M. Simes pursuant to which Mr. Simes serves as our Vice Chairman, President and Chief Executive Officer. The term of this agreement continues until December 31, 2005, after which time the term will be automatically extended for three additional years unless on or before October 1 immediately preceding the extension, either party gives written notice to the other of the termination of the agreement. Under the letter agreement, Mr. Simes is entitled to receive an annual performance bonus of up to 50% of his then base salary if certain performance criteria are met. If Mr. Simes is terminated without cause or upon a change in control or if he terminates his employment for good reason, all of his options will become immediately exercisable and will remain exercisable for a period of one year (for the remainder of their term in the event of a change in control), and he will be entitled to a minimum severance payment of 12 months base salary. In addition, Mr. Simes will receive health and dental benefits from BioSante during any severance period. Mr. Simes is also subject to customary assignment of inventions, confidentiality and non-competition provisions.

Donenberg Employment Agreement

In June 1998, we entered into a letter agreement with Phillip B. Donenberg pursuant to which Mr. Donenberg serves as our Chief Financial Officer. The term of this agreement continues until either party gives 30 days written notice to the other of the termination of the agreement. Under the letter agreement, Mr. Donenberg is entitled to receive an annual performance bonus of up to 30% of his then base salary if certain

performance criteria are met. If Mr. Donenberg is terminated without cause or upon a change in control or if he terminates his employment for good reason, all of his options will become immediately exercisable and will remain exercisable for a period of one year (for the remainder of their term in the event of a change in control), and he will be entitled to a minimum severance payment of 12 months base salary. In addition, Mr. Donenberg will receive health and dental benefits from BioSante during any severance period. Mr. Donenberg is also subject to customary assignment of inventions, confidentiality and non-competition provisions.

Employment Agreements with Other Executive Officers

We have entered into employment agreements with each of our other executive officers, Leah M. Lehman, Ph.D. and Steven J. Bell, Ph.D. These agreements provide for a fixed salary which may be adjusted from time to time by the Chief Executive Officer and the Compensation Committee of the Board. In addition, BioSante may pay Dr. Lehman and Dr. Bell an annual performance bonus of up to a maximum of 30% of their then base salary. The term of each of these employment agreements is for one year and will renew automatically every year unless either party gives the other party written notice of termination at least 30 days prior to the end of the then term of the agreement. If the executive officer's employment is terminated as a result of death or disability, by BioSante without cause or by the executive officer for good reason, the officer will be entitled to a severance payment in an amount equal to his or her base salary for the shorter of (a) 12 months or the date upon which Dr. Lehman obtains full-time employment or a consulting position with another company and (b) 6 months or the date upon which Dr. Bell obtains full-time employment or a consulting position with another company. In addition, the executive officer will receive health and dental benefits from BioSante during any severance period. Dr. Lehman and Dr. Bell are also subject to customary assignment of inventions, confidentiality and non-competition provisions.

Change in Control Arrangements

Under our Amended and Restated 1998 Stock Plan, incentive awards granted under that plan will become fully exercisable following certain changes in control of our company, such as:

- the sale, lease, exchange or other transfer of all or substantially all of the assets of our company to a corporation that is not controlled by us;
- the approval by our stockholders of any plan or proposal for the liquidation or dissolution of our company;
- certain merger or business combination transactions;
- more than 50% of our outstanding voting shares are acquired by any person or group of persons who did not own any shares of common stock on the effective date of the plan; and
- certain changes in the composition of our Board of Directors.

Stock Plan

From time to time we grant incentive awards under our Amended and Restated 1998 Stock Plan. The plan was approved by our Board of Directors on December 8, 1998 and approved by our stockholders on July 13, 1999. The plan has been amended several times to increase the number of shares reserved for issuance and was most recently amended on May 30, 2003, to:

- change the name of the plan to the "Amended and Restated 1998 Stock Plan";
- increase the number of shares of common stock reserved for issuance under the plan by 1,000,000 shares, from 1,000,000 shares to 2,000,000 shares;

add additional equity compensation features that permit the granting of stock awards and stock units in addition to stock options;

delete the requirement that the exercise price of non-statutory options must be at least 85% of the fair market value of one share of BioSante common stock on the date of grant of such option;

permit the transfer of options and other incentive awards to certain family members as permitted under the federal securities laws; and

effect certain other changes.

The plan provides for the grant to employees, including officers and directors who are also employees, of BioSante and any non-employee director, individual consultant and independent contractor of BioSante, other than consultants and independent contractors providing services in connection with the offer or sale of securities in a capital raising transaction or who directly or indirectly promote or maintain BioSante's securities, who, in the judgment of the Compensation Committee, have contributed, are contributing or are expected to contribute to the achievement of our economic objectives are eligible to participate in the plan. This plan is administered by the Compensation Committee of our Board of Directors, which determines the persons who are to receive awards, as well as the type, terms and number of shares subject to each award.

We have reserved an aggregate of 2,000,000 shares of common stock for incentive awards under the plan. As of August 7, 2003, options to purchase an aggregate of 1,302,634 shares of common stock were outstanding under the plan and a total of 697,366 shares of common stock remained available for grant. As of August 7, 2003, the outstanding options under the plan were held by an aggregate of 21 individuals and were exercisable at prices ranging from $2.30 to $9.10 per share of common stock.

Incentive stock options and non-statutory stock options granted under the plan may not have an exercise price less than the fair market value of the common stock on the date of the grant (or, if incentive stock options granted to a person holding more than 10% of our voting stock, at less than 110% of fair market value). Aside from the maximum number of shares of common stock reserved under the plan, there is no minimum or maximum number of shares that may be subject to incentive awards under the plan. However, the aggregate fair market value of the stock subject to incentive stock options granted to any optionee that are exercisable for the first time by an optionee during any calendar year may not exceed $100,000. Incentive awards generally expire when the optionee's employment or other service is terminated with us. Incentive awards generally may not be transferred, other than by will or the laws of descent and distribution, and during the lifetime of an optionee, may be exercised only by the optionee. The term of each option is 10 years, which is fixed by our Board of Directors at the time of grant, except that the term of an incentive stock option granted to a person holding more than 10% of our voting stock may be exercisable only for five years.

Stock awards are awards of shares of common stock under the plan that will be subject to such terms and conditions consistent with the other provisions of the plan as may be determined by the Compensation Committee. Generally, the participant will have all voting, dividend, liquidation and other rights with respect to the shares of common stock issued to a participant as a stock award under the plan.

Stock units are a bookkeeping entry representing the equivalent of one share of common stock that is payable in the form of common stock, cash or any combination of an incentive award. The stock unit feature of the plan combined with a new deferred compensation plan permits BioSante's non-employee directors and executive officers to defer the receipt of their stock compensation for tax purposes.

The plan contains provisions under which incentive awards would become fully exercisable following certain changes in control of our company, such as (1) the sale, lease, exchange or other transfer of all or substantially all of the assets of our company to a corporation that is not controlled by us, (2) the approval by our stockholders of any plan or proposal for the liquidation or dissolution of our company, (3) certain merger or business combination transactions, (4) more than 50% of our outstanding voting shares are acquired by any person or group of persons who did not own any shares of common stock on the effective date of the plan, or (5) certain changes in the composition of our Board of Directors.

Payment of an incentive award exercise price may be made in cash, or at the Compensation Committee's discretion, in whole or in part by tender of a broker exercise notice, a promissory note or previously acquired shares of our common stock having an aggregate fair market value on the date of exercise equal to the payment required.

Deferred Compensation Plan

The deferred compensation plan permits BioSante's executive officers to defer the receipt of the stock portion of their annual bonus and BioSante's non-employee directors to defer the receipt of their annual stock retainer and stock compensation for attending board and committee meetings. The deferred plan was approved by our Board of Directors on May 30, 2003.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Director Relationships

Messrs. Morgenstern, Holubow and Mangano were elected to our Board of Directors in July 1999 as representatives of the lead investors in our May 1999 private placement. Neither Mr. Morgenstern, Mr. Holubow nor Mr. Mangano has entered into any voting agreements with the lead investors nor does Mr. Morgenstern, Mr. Holubow or Mr. Mangano otherwise have any control over the voting of shares held by the lead investors.

Ms. Ho and Mr. Kjaer were elected to our Board of Directors as representatives of several investors located in Hong Kong. Neither Ms. Ho nor Mr. Kjaer has entered into any voting agreements with these Hong Kong investors nor does Ms. Ho or Mr. Kjaer otherwise have any control over the voting of shares held by these investors.

August 2003 Private Placement

In connection with our August 2003 private placement, we sold an aggregate of 4,791,982 shares of our common stock and warrants to purchase an aggregate of 2,395,993 shares of our common stock for $2.15 per unit, each unit consisting of one share of common stock and a warrant to purchase 0.50 shares of our common stock, for an aggregate purchase price of $10,302,764, to accredited investors, including certain existing stockholders, directors and officers. Stephen M. Simes, through his trust, purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock, Phillip B. Donenberg purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock, Leah M. Lehman, Ph.D. purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock, Victor Morgenstern, including an affiliated Trust and his wife, purchased an aggregate of 293,000 shares of common stock and warrants to purchase 146,500 shares of common stock, Ross Mangano, through an affiliated entity, purchased 293,023 shares of common stock and a warrant to purchase 146,512 shares of common stock and Fred Holubow, through an affiliated entity, purchased 150,000 shares of common stock and a warrant to purchase 75,000 shares of common stock.

September 2002 Offering

In connection with our September 2002 best-efforts, self-underwritten public offering of our common stock, we sold an aggregate of 2,250,000 shares of our common stock for $2.00 per share for an aggregate purchase price of $4.5 million, to accredited investors, including certain existing stockholders, directors and officers. Stephen M. Simes, including his trust and his sons, purchased an aggregate of 50,201 shares of common stock, Phillip B. Donenberg purchased 500 shares of common stock, Leah M. Lehman, Ph.D. purchased 114,000 shares of common stock, Victor Morgenstern, through his son, an affiliated trust and his wife, purchased an aggregate of 115,000 shares of common stock, Fred Holubow and an affiliated LLC, purchased an aggregate of 67,500 shares of common stock and Ross Mangano, through an affiliated entity, purchased 241,004 shares of common stock.

April 2001 Private Placement

In connection with our April 2001 private placement, we sold an aggregate of 925,000 shares of our common stock and warrants to purchase an aggregate of 462,500 shares of our common stock for $4.00 per unit, each unit consisting of one share of common stock and a warrant to purchase 0.50 shares of our common stock, for an aggregate purchase price of $3,700,000, to accredited investors, including certain existing stockholders, directors and officers. Stephen M. Simes purchased 12,500 shares of common stock and a warrant to purchase 6,250 shares of common stock, Phillip B. Donenberg purchased 1,250 shares of common stock and a warrant to purchase 625 shares of common stock, Leah M. Lehman, Ph.D. purchased 37,500 shares of common stock and a warrant to purchase

18,750 shares of common stock, Steven J. Bell, Ph.D. purchased 375 shares of common stock and a warrant to purchase 187 shares of common stock, Victor Morgenstern, including an affiliated Trust and his wife, purchased an aggregate of 75,000 shares of common stock and warrants to purchase an aggregate of 37,500 shares of common stock and Fred Holubow purchased 12,500 shares of common stock and a warrant to purchase 6,250 shares of common stock.

Other Agreements with Affiliates

In January 2001, we entered into a consulting agreement with Scientific Research Development Corporation, a company owned and operated by Ronald B. McCright, the husband of Leah M. Lehman, Ph.D., an executive officer of BioSante. Under the agreement, Scientific Research Development Corporation provides us with database and statistical programming, database management, medical writing and project management services. In consideration for such services, we paid Scientific Research Development Corporation an aggregate of approximately $60,000 during the fiscal year ended December 31, 2001. This agreement expired on December 31, 2002.

In July 2001, Avi Ben-Abraham, M.D., a director of BioSante, and BioSante entered into a settlement agreement with a stockholder of BioSante in connection with certain claims and disputes among the stockholder, Dr. Ben-Abraham and BioSante arising out of actions of Dr. Ben-Abraham during 1996. In exchange for a release of all claims, suits, damages and judgments among the stockholder, BioSante and Dr. Ben-Abraham, Dr. Ben-Abraham transferred 50,000 shares of his BioSante common stock to the stockholder.

SECURITY OWNERSHIP OF PRINCIPAL STOCKHOLDERS AND MANAGEMENT

The following table sets forth information known to us with respect to the beneficial ownership of each class of our capital stock as of August 7, 2003 for (1) each person known by us to beneficially own more than 5% of any class of our voting securities, (2) each of the executive officers named in the Summary Compensation Table under the heading "Management," (3) each of our directors and (4) all of our executive officers and directors as a group. Except as otherwise indicated, we believe that each of the beneficial owners of our capital stock listed below, based on information provided by these owners, has sole investment and voting power with respect to its shares, subject to community property laws where applicable.

Unless otherwise noted, each of the stockholders listed in the table possesses sole voting and investment power with respect to the shares indicated. Shares not outstanding but deemed beneficially owned by virtue of the right of a person or member of a group to acquire them within 60 days are treated as outstanding only when determining the amount and percent owned by such person or group.

	Common Stock		Class C Special Stock			
Name	Number	Percent	Number	Percent	Common Stock and Common Stock Equivalents	Percent of Total Voting Power(1)
Stephen M. Simes(2)	537,796(3)	3.9%			537,796	3.7%
Louis W. Sullivan, M.D.(2)	29,227(4)	*	100,000	21.4%	129,227	*
Edward C. Rosenow III, M.D.(2)	24,356(5)	*			24,356	*
Victor Morgenstern(2)	1,105,308(6)	8.0%			1,105,308	7.7%
Fred Holubow(2)	370,128(7)	2.7%			370,128	2.6%
Ross Mangano(2)	2,174,073(8)	15.4%			2,174,073	14.9%
Angela Ho(2)	86,860(9)	*	100,000	21.4%	186,860	1.3%
Peter Kjaer(2)	20,907(10)	*			20,907	*
Phillip B. Donenberg(2)	131,764(11)	1.0%			131,764	*
Leah M. Lehman, Ph.D.(2)	246,414(12)	1.8%			246,414	1.8%
Steven J. Bell, Ph.D.(2)	41,904(13)	*			41,904	*
JO & Co.	1,835,539(14)	13.1%			1,835,539	12.7%
Joseph Edelman	2,279,900(15)	16.1%			2,279,900	15.6%
Hans Michael Jebsen	425,000(16)	3.1%	100,000	21.4%	525,000	3.7%
King Cho Fung	297,500(17)	2.2%	62,500	13.4%	360,000	2.6%
Marcus Jebsen	125,000(18)	*	50,000	10.7%	175,000	1.3%
Avi Ben-Abraham, M.D.	1,042,980(19)	7.7%			1,042,980	7.5%

			Class C Special Stock			
All executive officers and directors as a group (11 persons)	4,768,737(20)	31.3 %	200,000	42.9%	4,968,737	31.6%

*
less than 1%.

(1)
In calculating the percent of total voting power, the voting power of shares of our common stock and shares of our class C special stock is combined.

(2)
Address: 111 Barclay Boulevard, Lincolnshire, Illinois 60069.

(3)
Mr. Simes' beneficial ownership includes 381,300 shares of common stock issuable upon exercise of stock options and 19,250 shares of common stock issuable upon exercise of warrants.

(4)
Dr. Sullivan's beneficial ownership includes 15,000 shares of common stock issuable upon exercise of a stock option.

(5)
Dr. Rosenow's beneficial ownership includes 12,500 shares of common stock issuable upon exercise of stock options.

(6)
Mr. Morgenstern's beneficial ownership includes: (1) 10,000 shares of common stock issuable upon exercise of a stock option, (2) 171,500 shares of common stock issuable upon exercise of warrants, (3) 102,500 shares of common stock issuable upon exercise of warrants and 270,000 shares of common stock held by

Mr. Morgenstern's wife as trustee of the Morningstar Trust, as to which Mr. Morgenstern disclaims control, direction or beneficial ownership, (4) 10,000 shares of common stock issuable upon exercise of a warrant and 70,000 shares of common stock held by Mr. Morgenstern's wife, as to which Mr. Morgenstern disclaims control, direction or beneficial ownership, and (5) 25,000 shares of common stock issuable upon exercise of a warrant and 50,000 shares of common stock held by Resolute Partners L.P. Victor Morgenstern is managing director of Resolute Partners L.P.

(7)
Mr. Holubow's beneficial ownership includes: (1) 18,750 shares of common stock issuable upon exercise of warrants and 10,000 shares of common stock issuable upon exercise of a stock option and (2) 75,000 shares of common stock issuable upon exercise of a warrant and 210,000 shares of common stock held by Panacea Fund, which Mr. Holubow is a Co-General Partner.

(8)
Mr. Mangano's beneficial ownership includes: (1) 10,000 shares of common stock issuable upon exercise of a stock option and 28,537 shares of common stock, (2) 521,512 shares of common stock issuable upon exercise of a warrant and 1,314,027 shares of common stock held by JO & Co., of which Mr. Mangano is President, and (3) an aggregate of 199,999 shares of common stock and an aggregate of 99,998 shares of common stock issuable upon exercise of warrants held in various accounts, of which Mr. Mangano is an advisor and/or a trustee. Mr. Mangano has sole voting and dispositive power over these shares. See note (14) below.

(9)
Ms. Ho's beneficial ownership includes 15,000 shares of common stock issuable upon exercise of stock options.

(10)
Mr. Kjaer's beneficial ownership includes 10,000 shares of common stock issuable upon exercise of a stock option.

(11)
Mr. Donenberg's beneficial ownership includes 116,665 shares of common stock issuable upon exercise of stock options and 1,125 shares of common stock issuable upon exercise of a warrant.

(12) Dr. Lehman's beneficial ownership includes 67,387 shares of common stock issuable upon exercise of a stock option and 19,250 shares of common stock issuable upon exercise of a warrant.

(13) Dr. Bell's beneficial ownership includes 39,342 shares of common stock issuable upon exercise of stock options and 187 shares of common stock issuable upon exercise of a warrant.

(14) Includes 521,512 shares of common stock issuable upon exercise of a warrant. Ross Mangano, a director of BioSante, has sole voting and dispositive power over these shares. See note (8) above. The address for JO & Co. is 112 West Jefferson Boulevard, Suite 613, South Bend, Indiana 46634.

(15) Pursuant to a Schedule 13G filed on August 13, 2003, Mr. Edelman's ownership includes: (1) 225,000 shares and a warrant to purchase 112,500 shares and (2) 1,392,400 shares and warrants to purchase 550,000 shares held by Perceptive Life Sciences Master Fund Ltd., a Cayman Islands company of which the investment manager is Perceptive Advisors LLC, a Delaware limited liability company of which Mr. Edelman is the managing member. Mr. Edelman's address is 300 Central Park West, Apt. 25-G, New York, NY 10024.

(16) Mr. Jebsen's beneficial ownership includes 75,000 shares of common stock issuable upon exercise of a warrant. Mr. Jebsen's address is c/o Jebsen & Co. Ltd., 28/F Caroline Center, 28 Yun Ping Road, Causeway Bay, Hong Kong.

(17) Mr. Fung's beneficial ownership includes 75,000 shares of common stock issuable upon exercise of a warrant. Mr. Fung's address is c/o SP 2, 15/F, 46 Lyndhurst Terrace, Central Hong Kong.

(18) Mr. Jebsen's beneficial ownership includes 25,000 shares of common stock issuable upon exercise of a warrant. Mr. Jebsen's address is c/o Jebsen & Co. Ltd., 28/F Caroline Center, 28 Yun Ping Road, Causeway Bay, Hong Kong.

(19) Dr. Ben-Abraham's address is 22 Maskit Street, Suite MB-12550, Lumir Bldg., Herzelya Pituach, 46733, Israel.

(20) The amount beneficially owned by all current directors and executive officers as a group includes 917,256 shares issuable upon exercise of warrants and stock options held by these individuals and 2,114,026 shares and 834,010 shares issuable upon exercise of warrants held by entities and individuals affiliated with these individuals. See notes (6), (8) and (14) above.

DESCRIPTION OF CAPITAL STOCK

Authorized Shares

We are authorized to issue 100,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.0001 par value per share. The following is a summary of the material terms and provisions of our capital stock. Because it is a summary, it does not include all of the information that is included in our certificate of incorporation. The text of our certificate of incorporation, which is attached as an exhibit to this registration statement, is incorporated into this section by reference.

Common Stock

We are authorized to issue 100,000,000 shares of common stock, of which 13,482,764 shares were issued and outstanding as of August 7, 2003. Each share of our common stock entitles its holder to one vote per share. Holders of our common stock are entitled to receive dividends as and when declared by our Board of Directors from time to time out of funds properly available to the payment of dividends. Subject to the liquidation rights of any outstanding preferred stock, the holders of our common stock are entitled to share pro rata in the distribution of the

remaining assets of our company upon a liquidation, dissolution or winding up of our company. The holders of our common stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

Class C Special Stock

We are authorized to issue 4,687,684 shares of class C special stock, of which 466,602 shares were issued and outstanding as of August 7, 2003. Each share of class C special stock entitles its holder to one vote per share. Each share of our class C special stock is exchangeable, at the option of the holder, for one share of common stock, at an exchange price of $2.50 per share, subject to adjustment upon certain capitalization events. Holders of our class C special stock are not entitled to receive dividends. Holders of our class C special stock are not entitled to participate in the distribution of our assets upon any liquidation, dissolution or winding-up of our company. The holders of our class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

Undesignated Preferred Stock

We are authorized to issue 10,000,000 shares of preferred stock, none of which are issued and outstanding. Our Board of Directors is authorized to issue one or more series of preferred stock with such rights, privileges, restrictions and conditions as our Board may determine. The preferred stock, if issued, may be entitled to rank senior to our common stock with respect to the payment of dividends and the distributions of assets in the event of a liquidation, dissolution or winding-up of our company.

Options and Warrants

As of August 7, 2003, we had outstanding options to purchase an aggregate of 1,302,634 shares of common stock at a weighted average exercise price of $3.35 per share. All outstanding options provide for antidilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other similar changes in our corporate structure and shares of our capital stock. We typically grant options with a ten-year term. We have outstanding warrants to purchase an aggregate of 4,411,116 shares of common stock at a weighted average exercise price of $2.71 per share with a majority of those warrants having a five-year term. The warrants purchased in our May 1999 private placement provide for antidilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other changes in our corporate structure of our company and, subject to certain exceptions, the issuance by our company of any securities for a purchase price of less than $2.00 per share.

Registration Rights

The holders of the common stock and warrants purchased in our August 2003 private placement are entitled to registration rights under the Securities Act. No later than 35 days after August 4, 2003, we were required to file a registration statement to register under the Securities Act the resale of the outstanding shares of BioSante common stock and the shares of common stock issuable upon exercise of the warrants purchased in our August 2003 private placement. We are required to use our reasonable best efforts to cause the registration statement to become effective under the Securities Act within 90 days or as promptly as practicable and to use our reasonable best efforts to cause the registration statement to remain effective until the earlier of (1) the sale of all the shares of BioSante common stock covered by this registration statement; or (2) such time as the selling stockholders named in this registration statement become eligible to resell the shares of BioSante common stock and the shares of BioSante common stock issuable upon exercise of the warrants pursuant to Rule 144(k) under the Securities Act.

The holders of the common stock and warrants purchased in our April 2001 private placement are entitled to registration rights under the Securities Act. No later than 90 days after April 4, 2001, we were required to file a registration statement to register under the Securities Act the resale of the outstanding shares of BioSante common stock and the shares of common stock issuable upon exercise of the warrants purchased in our April 2001 private placement. We are required to use our reasonable best efforts to cause the registration statement to become effective under the Securities Act as promptly as practicable and to use our reasonable best efforts to cause the registration statement to remain effective until the earlier of (1) the sale of all the shares of BioSante common stock covered by the registration statement; or (2) such time as the selling stockholders named in the registration statement become eligible to resell the shares of BioSante common stock and the shares of BioSante common stock issuable upon exercise of the warrants pursuant to Rule 144(k) under the Securities Act.

The holders of the common stock and warrants purchased in our May 1999 private placement are entitled to certain registration rights under the Securities Act. If at any time after we become listed on Nasdaq, the holders of a specified amount of these registrable shares request that we file a registration statement covering the shares, we will use commercially reasonable efforts to cause these shares to be registered. We are not required to file more than two registration statements under these demand rights, or more than one registration statement in any twelve-month period. In addition, the holders of these registrable shares are entitled to have their shares included in a registration statement under the

Securities Act in connection with the public offering of our securities. In any underwritten public offering, the registration rights are limited to the extent that the managing underwriter has the right to (1) limit the number of registrable shares to be included in the registration statement; (2) prohibit the sale of any of our securities other than those registered and included in the underwritten offering for a period of 180 days; and (3) require holders of registrable shares not to sell or otherwise dispose of any securities of our company (other than securities included in the registration) without the prior written consent of the underwriters for a period of up to 180 days from the effective date of such registration. These registration rights will terminate as to any registrable shares when such registrable shares are effectively registered and sold by the holder thereof or when such registrable shares are sold pursuant to Rule 144(k) or are sold pursuant to Rule 144 under the Securities Act.

In September 2001, we filed a registration statement on Form SB-2 to register, under the Securities Act, the resale of the outstanding shares of BioSante common stock and the shares of common stock issuable upon exercise of the warrants purchased in our April 2001 private placement and the outstanding shares of common stock purchased in our May 1999 private placement. This registration statement became effective on September 19, 2001. In May 2002, we filed a post-effective amendment to our registration statement on Form SB-2. We intend to file another post-effective amendment to the registration statement in the near future.

This registration statement will fulfill our obligation in connection with our August 2003 private placement.

Anti-Takeover Provisions of Delaware Law and Our Certificate of Incorporation

We are subject to Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns or, in the case of affiliates or associates of the corporation, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's voting stock. The existence of this provision could have anti-takeover effects with respect to transactions not approved in advance by the Board of Directors, such as discouraging takeover attempts that might result in a premium over the market price of the common stock.

There are several provisions of our amended and restated certificate of incorporation and bylaws that may have the effect of deterring or discouraging hostile takeovers or delaying changes in control of our company. In addition, stockholders are not entitled to cumulative voting in the election of directors. Our certificate of incorporation has authorized undesignated preferred stock which could make it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change of control of our company. Our bylaws contain an advance notice provision in connection with stockholder proposals that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors.

Limitation on Liability of Directors and Indemnification

Our certificate of incorporation limits our directors' liability to the fullest extent permitted under Delaware's corporate law. Specifically, our directors are not liable to us or our stockholders for monetary damages for any breach of fiduciary duty by a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- dividends or other distributions of our corporate assets that are in contravention of restrictions in Delaware law, our amended and restated certificate of incorporation, bylaws or any agreement to which we are a party; and
- any transaction from which a director derives an improper personal benefit.

This provision generally does not limit liability under federal or state securities laws.

Delaware law, and our certificate of incorporation, provide that we will, in some situations, indemnify any person made or threatened to be made a party to a proceeding by reason of that person's former or present official capacity with our company against judgments, penalties, fines, settlements and reasonable expenses including reasonable attorney's fees. Any person is also entitled, subject to some limitations, to payment or reimbursement of reasonable expenses in advance of the final disposition of the proceeding.

We have also agreed to indemnify the selling stockholders, including some of our officers, directors and related entities, under this registration statement and SCO Securities LLC, against certain losses,

claims, damages, liabilities, costs and expenses under the securities laws, or to contribute to any losses associated with these liabilities. Each of these selling stockholders has also agreed to indemnify us against certain civil liabilities under the securities laws deriving from information provided by it, or to contribute to any losses associated with these liabilities.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of BioSante pursuant to the provisions described above, or otherwise, BioSante has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Transfer Agents and Registrars

The transfer agent and registrar for our common stock is Computershare Investor Services, LLC.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for BioSante by Oppenheimer Wolff & Donnelly LLP, Minneapolis, Minnesota.

EXPERTS

The financial statements as of December 31, 2002 and 2001 and for each of the three years in the period ended December 31, 2002, included in this prospectus, have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report appearing herein (which report expresses an unqualified opinion and includes an explanatory paragraph indicating that BioSante Pharmaceuticals, Inc. is in the development stage), and has been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the Securities and Exchange Commission. Copies of our reports, proxy statements and other information may be inspected and copied at the following public reference facility maintained by the SEC:

Judiciary Plaza
450 Fifth Street, N.W.
Washington, D.C. 20549

Copies of these materials also can be obtained by mail at prescribed rates from the Public Reference Section of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site that contains reports, proxy statements and other information regarding us. The address of the SEC web site is *http://www.sec.gov*. The Securities Act file number for our SEC filings is 0-28637.

In addition, we maintain a web site that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our web site is *www.biosantepharma.com*. Our web site, and the information contained on that site, or connected to that site, are not intended to be part of this prospectus.

We have filed a registration statement on Form SB-2 with the SEC for the common stock offered by the selling stockholders under this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information that is not contained in this prospectus. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, you should refer

to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We also file annual audited and interim unaudited financial statements, proxy statements and other information with the Ontario, Alberta and British Columbia Securities Commissions. Copies of these documents that are filed through the System for Electronic Document Analysis and Retrieval "SEDAR" of the Canadian Securities Administrators are available at its web site *http://www.sedar.com*.

This prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make an offer, solicitation of an offer or proxy solicitation in that jurisdiction.

BIOSANTE PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Balance Sheets

June 30, 2003 and December 31, 2002 (Unaudited)

	June 30, 2003	December 31, 2002
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 2,334,937	$ 4,883,697
Due from Teva Pharmaceuticals USA, Inc.		520,063
Prepaid expenses and other sundry assets	119,991	144,155
	2,454,928	5,547,915
PROPERTY AND EQUIPMENT, NET	284,793	331,889
	$ 2,739,721	$ 5,879,804
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 478,752	$ 470,871
Accrued compensation	144,837	313,287
Other accrued expenses	80,117	236,758
Due to Antares	16,925	235,303
	720,631	1,256,219
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding 466,602 (2002 466,602) Class C special stock	467	467
8,690,782 (2002 8,571,169) Common stock	26,941,127	26,684,841
	26,941,594	26,685,308
Deficit accumulated during the development stage	(24,922,504)	(22,061,723)
	2,019,090	4,623,585
	$ 2,739,721	$ 5,879,804

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Statements of Operations

Three and six months ended June 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003
	2003	2002	2003	2002	
REVENUE					
Licensing income	$	$	$ 65,494	$	$ 4,582,943
Interest income	11,490	6,712	30,309	29,971	1,015,049
	11,490	6,712	95,803	29,971	5,597,992
EXPENSES					
Research and development	939,124	987,528	1,742,277	1,631,922	12,955,411
General and administration	664,918	491,851	1,167,211	950,980	11,041,732
Depreciation and amortization	23,548	22,697	47,096	45,359	613,589
Loss on disposal of capital assets					157,545
Costs of acquisition of Structured Biologicals Inc.					375,219
Purchased in-process research and development					5,377,000
	1,627,590	1,502,076	2,956,584	2,628,261	30,520,496
NET LOSS	$ (1,616,100)	$ (1,495,364)	$ (2,860,781)	$ (2,598,290)	$ (24,922,504)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.18)	$ (0.22)	$ (0.32)	$ (0.38)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	9,076,880	6,788,343	9,057,434	6,788,412	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Statements of Cash Flows

Six months ended June 30, 2003 and 2002 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003

(Unaudited)

	Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003
	2003	2002	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	$ (2,860,781)	$ (2,598,290)	$ (24,922,504)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	47,096	45,359	613,589
Amortization of deferred unearned compensation			42,290
Repurchase of licensing rights			125,000
Employee compensation paid in shares of common stock			151,000
Director compensation paid in shares of common stock	181,500		181,500
Purchased in-process research and development			5,377,000
Loss on disposal of equipment			157,545
Changes in other assets and liabilities affecting cash flows from operations			
Prepaid expenses and other sundry assets	24,164	19,646	(117,023)
Due from licensee (Teva Pharmaceuticals USA, Inc.)	520,063		
Accounts payable and accrued expenses	(239,663)	(46,948)	41,066
Due to licensor (Antares/Regents)	(218,378)	(145,119)	16,925
Due from SBI			(128,328)
Net cash used in operating activities	(2,545,999)	(2,725,352)	(18,461,940)
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets		(25,836)	(1,021,817)
CASH FLOWS (USED IN) FINANCING ACTIVITIES			
Issuance of convertible debenture			500,000
Proceeds from sales or conversion of shares	(2,761)	(46,704)	21,318,694
Net cash (used in) financing activities	(2,761)	(46,704)	21,818,694
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(2,548,760)	(2,797,892)	2,334,937
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,883,697	4,502,387	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 2,334,937	$ 1,704,495	$ 2,334,937
SUPPLEMENTAL SCHEDULE OFCASH FLOW INFORMATION			
Acquisition of SBI			
Purchased in-process research and development	$	$	$ 5,377,000
Other net liabilities assumed			(831,437)
			4,545,563
Less: common stock issued therefor			4,545,563

	$	$	$ **Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003**
Income tax paid	$	$	$
Interest paid	$	$	$

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

FORM 10-QSB

JUNE 30, 2003

Notes to the Financial Statements (Unaudited)

1. INTERIM FINANCIAL INFORMATION

In the opinion of management, the accompanying unaudited financial statements contain all necessary adjustments, which are of a normal recurring nature, to present fairly the financial position of BioSante Pharmaceuticals, Inc. (the "Company") as of June 30, 2003, the results of operations for the three and six months ended June 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003, and the cash flows for the six months ended June 30, 2003 and 2002 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2003, in conformity with accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

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

These unaudited interim financial statements should be read in conjunction with the financial statements and related notes contained in the Company's Annual Report on Form 10-KSB for the year ended December 31, 2002.

2. BASIC AND DILUTED NET LOSS PER SHARE

The basic and diluted net loss per share is computed based on the weighted average number of shares of common stock and class C stock outstanding, all being considered as equivalent of one another. Basic net loss per share is computed by dividing the net loss by the weighted average number of shares outstanding for the reporting period. Diluted net 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. Because the Company has incurred net losses from operations in each of the periods presented, there is generally no difference between basic and diluted net loss per share amounts. The computation of diluted net loss per share does not include options and warrants with dilutive potential that would have an antidilutive effect on net loss per share.

3. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted the Company an exclusive license to seven United States patents owned by the University, including rights to sublicense such patents. The license agreement with the University of California requires the Company to undertake various obligations, including but not limited to, the payment of royalties based on net sales, when and if they occur, and the payment of minimum annual royalties.

In June 2000, the Company entered into a license agreement with Antares Pharma Inc. covering four hormone therapy products for the treatment of men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty.

Under the terms of the license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain events.

In August 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal

hormone therapy gel product licensed from Antares. Under the terms of the agreement, Solvay sub-licensed the Company's estrogen/progestogen combination transdermal hormone therapy gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin Labs Inc.), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, the Company received a $950,000 milestone payment pursuant to the Solvay sub-license agreement.

In October 2001, the Company sub-licensed its BioVant calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by Corixa. Under the agreement, Corixa has agreed to pay the Company milestone payments upon the achievement of certain milestones plus royalty payments on sales if and when vaccines are approved using BioVant and sold on a commercial basis. If Corixa sub-licenses vaccines that include BioVant , the Company will share in milestone payments and royalties received by Corixa. The sub-license agreement covers access to BioVant for a variety of cancer, infectious and autoimmune disease vaccines.

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company, regulatory milestones, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology is approved and subsequently marketed.

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., under which Teva USA and the Company will collaborate on the development of a hormone therapy product for the U.S. market. Upon signing the U.S. development and license agreement, the Company received an upfront payment of $1.5 million. In addition, Teva will pay the Company development and sales-related milestone payments plus royalties on sales of the product commercialized in this collaboration. In exchange, the Company granted Teva exclusive rights to develop and market a certain hormone therapy product. Teva also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

4. COMMITMENTS

University of California License

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

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

Payment of minimum annual royalties beginning for the year 2004 to be paid by February 28 of the following year 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

Year	Minimum Annual Royalty Due
2005	100,000
2006	150,000
2007	200,000
2008	400,000
2009	600,000
2010	800,000
2011	1,500,000
2012	1,500,000
2013	1,500,000
	$ 6,800,000

Development of products incorporating the licensed technology until a product is introduced to the market;

Payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which for the year ended December 31, 2002 amounted to $12,240;

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 and obtaining government approvals;

Conducting clinical trials; and

Introducing products incorporating the licensed technology into the market;

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

Indemnifying, holding harmless and defending 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 the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability related to this obligation as no events occurred that would require indemnification.

Antares Pharma, Inc. License

The Company's license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares. The Company expects to fund the development of the products, has made and will continue to make milestone payments and once regulatory approval to market is received, pay royalties on the sales of products.

Wake Forest License

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone

contraception. The financial terms of the license include an upfront payment by the Company in exchange for exclusive rights to the license, and regulatory milestones, maintenance payments and royalty payments by the Company if a product incorporating the licensed technology gets approved and subsequently marketed.

Future minimum payments due under this agreement are as follows:

Year	Minimum Amount Due
2004	$ 10,000
2005	45,000
2006	80,000
2007	65,000
2008	90,000
2009	140,000
2010	90,000
2011	40,000
2012	140,000
2013	240,000
Thereafter	800,000

The Company has agreed to indemnify, hold harmless and defend Wake Forest University against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation as no events occurred that would require indemnification.

5. STOCK BASED COMPENSATION

The Company follows the provisions of APB Opinion No. 25, "Accounting For Stock-Based Compensation" (APB No. 25) which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the measurement date (generally the date of grant) and the amount the employee must pay to acquire the stock. As a result of the Company's application of APB No. 25, SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure" (SFAS 148), requires certain additional disclosures of the pro forma compensation expense arising from the Company's fixed and performance stock compensation plans. The expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected term of the option, the current price of the underlying stock, its expected volatility, expected dividends on the stock and the expected risk-free rate of return during the term of the option. The compensation cost is recognized over the service period, usually the period from the grant date to the

vesting date. The following table illustrates the effect on net loss and net loss per share if the Company had applied fair value based method.

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Net loss		
As reported	**$ (2,860,781)**	$ (2,598,290)
Total stock-based employee compensation determined under fair value based method for all awards	**(294,937)**	(263,851)

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Net loss, pro forma	**$ (3,155,718)**	$ (2,862,141)
Basic and diluted net loss per share		
As reported	**$ (0.32)**	$ (0.38)
Pro forma	**$ (0.35)**	$ (0.42)
Cumulative net loss		
As reported	**$ (24,922,504)**	
Total stock-based employee compensation determined under fair value based method for all awards	**(3,112,992)**	
Pro forma	**$ (28,035,496)**	

	Three Months Ended June 30, 2003	Three Months Ended June 30, 2002
Net loss		
As reported	**$ (1,616,100)**	$ (1,495,364)
Total stock-based employee compensation determined under fair value based method for all awards	**(155,971)**	(222,357)
Net loss, pro forma	**$ (1,772,071)**	$ (1,717,721)
Basic and diluted net loss per share		
As reported	**$ (0.18)**	$ (0.22)
Pro forma	**$ (0.20)**	$ (0.25)

There were 22,000 options granted during the three and six month periods ended June 30, 2003, with a weighted average fair value at the date of grant of $1.57. The weighted average fair value of the options at the date of grant for options granted during 2002 was $2.44. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2003
Expected option life (years)	10
Risk free interest rate	3.98%
Expected stock price volatility	64.17%
Dividend yield	

In addition, during the second quarter of 2003, BioSante issued 285,000 options to certain officers of BioSante which vest only upon the achievement of certain milestones in connection with BioSante's evaluation of strategic alternatives.

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue. No warrants were issued in 2002 or during the six month period ended June 30, 2003.

6. STOCKHOLDERS' EQUITY

In June 2003, BioSante issued 119,613 shares of common stock to its officers and directors as partial payment of the officers' 2002 annual bonus (approximately $78,000) and payment of fees to BioSante's directors for their significant involvement during 2002 and 2003 for various director-related services rendered, including attendance at board and committee meetings (approximately $180,000). The 2002 officer bonuses of approximately $78,000 had been previously accrued at December 31, 2002.

BioSante paid directors with shares of common stock, which related to their efforts for 2002 and 2003. However, as BioSante had historically not paid fees to directors, the $180,000 of fees paid to directors was expensed in the three month period ended June 30, 2003.

The number of shares issued was determined by dividing the dollar amount of bonus or director fees owed to the officer or director, respectively, by the closing market price of BioSante's common stock on the date of issuance. The share price used in computing the number of shares to issue was approximately $2.16. Shares were issued in lieu of cash in order to conserve the cash funds of BioSante.

Each of our non-employee directors are paid a $10,000 annual retainer to be paid in shares of our common stock and $1,000 for each board or committee meeting attended in person and $500 for each board or committee meeting attended via telephone to be paid in shares of our common stock.

7. SUBSEQUENT EVENT

On August 4, 2003, BioSante closed a private placement, raising approximately $10.3 million, ($9.7 million net of estimated transaction costs) upon the issuance of units, which consisted of an aggregate of approximately 4.8 million shares of common stock and five-year warrants to purchase an aggregate of approximately 2.8 million shares of common stock (includes placement agent warrants issued in conjunction with the financing). The price of each unit, which consisted of one share of common stock plus a warrant to purchase one half-share of common stock, was $2.15. The exercise price of the warrants is $2.15 per share.

Independent Auditors' Report

Board of Directors and Stockholders
BioSante Pharmaceuticals, Inc.
Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (a development stage company) as of December 31, 2002 and 2001 and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2002, and for the period from August 29, 1996 (date of incorporation) through December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatements. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, such financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2002 and 2001 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, and for the period from August 29, 1996 (date of incorporation) through December 31, 2002 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the financial statements, the Company is in the development stage.

/s/ Deloitte & Touche LLP

February 14, 2003
Chicago, Illinois

Balance Sheets

December 31, 2002, 2001

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

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Statements of Operations

Years ended December 31, 2002, 2001 and 2000
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	Cumulative period form August 29, 1996 (date of incorporation) to December 31, 2002
REVENUE				
Licensing income, net (Note 5)	$ 2,770,063	$ 1,747,386	$	$ 4,517,449
Interest income	63,788	174,416	227,718	984,740
	2,833,851	1,921,802	227,718	5,502,189
EXPENSES				
Research and development	4,786,818	2,141,944	1,887,832	11,213,134
General and administration	1,765,624	2,298,659	1,678,581	9,874,521
Depreciation and amortization	92,099	92,560	98,500	566,493
Loss on disposal of capital assets				157,545
Costs of acquisition of Structured Biologicals Inc.				375,219
Purchased in-process research and development				5,377,000
	6,644,541	4,533,163	3,664,913	27,563,912
NET LOSS	$ (3,810,690)	$ (2,611,361)	$ (3,437,195)	$ (22,061,723)
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	$ (0.51)	$ (0.40)	$ (0.60)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	7,503,134	6,485,349	5,753,676	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Stockholders' Equity

Years ended December 31, 2002, 2001 and 2000

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

	Class A Special Shares		Class C Special Shares		Common Stock		Deferred Unearned	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount	Shares	Amount	Compensation		
Balance, August 29, 1996,		$		$		$	$	$	$
Date of incorporation									
Issuance of Class "C" shares August 29, 1996 ($0.0001 per share)			415,000	415					415
Issuance of Class "A" shares September 23, 1996 ($0.0001 per share)	2,000,000	2,000							2,000
Issuance of common shares September 23, 1996					410,000	4,100,000			4,100,000
Financing fees accrued						(410,000)			(410,000)
November 27, 1996 issued as consideration upon acquisition of SBI (Note 3)					743,432	4,545,563			4,545,563
Exercise of Series "X" warrants					21,571	275,387			275,387
Exercise of Series "Z" warrants					143	2,553			2,553
Net loss								(6,246,710)	(6,246,710)
Balance, December 31, 1996	2,000,000	2,000	415,000	415	1,175,146	8,513,503		(6,246,710)	2,269,208
Conversion of shares									
January 13, 1997			(28,285)	(28)	28,285	70,741			70,713
January 13, 1997			(9,428)	(9)	9,429	23,580			23,571
December 2, 1997			(10,639)	(11)	10,639	26,607			26,596
December 2, 1997			(10,000)	(10)	10,000	25,010			25,000
Exercise of Series "V" warrants					2,400	36,767			36,767
Exercise of Series "X" warrants					2,857	36,200			36,200
Exercise of Series "W" warrants					2,000	25,555			25,555
Adjustment for partial shares issued upon amalgamation					13				
Financing fees reversed						410,000			410,000
Net loss								(1,890,093)	(1,890,093)
Balance, December 31, 1997	2,000,000	2,000	356,648	357	1,240,769	9,167,963		(8,136,803)	1,033,517
Conversion of shares									
March 4, 1998			(2,000)	(2)	2,000	5,002			5,000
March 16, 1998			(1,000)	(1)	1,000	2,501			2,500
May 8, 1998	(1,500,000)	(1,500)			1,500,000	3,751,500			3,750,000

	Class A Special Shares		Class C Special Shares				Deferred Unearned	Deficit Accumulated During the Development Stage	
June 1, 1998	)	(100			100,000	250,100			250,000
June 1, 1998	(100,000)	(100)			100,000	250,100			250,000
Return of shares to treasury									
May 8, 1998	(146,861)	(147)							(147)
May 8, 1998			(25,000)	(25)					(25)
Net loss								(2,659,415)	(2,659,415)
Balance, December 31, 1998	153,139	153	328,648	329	2,943,769	13,427,166		(10,796,218)	2,631,430
Conversion of shares									
February 2, 1999			(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net May 6, 1999					2,312,500	4,197,843			4,197,843
Share redesignation July 13, 1999	(153,139)	(153)	153,139	153					
Issuance of common shares August 15, 1999					7,000	25,000			25,000
Net loss								(1,406,259)	(1,406,259)
Balance, December 31, 1999			480,787	481	5,264,269	17,652,510		(12,202,477)	5,450,514

Conversion of shares									
March 17, 2000			(1,000)	(1)	1,000	2,501			2,500
March 24, 2000			(3,184)	(3)	3,184	7,963			7,960
June 12, 2000			(5,000)	(5)	5,000	12,505			12,500
July 13, 2000			(2,835)	(3)	2,834	7,088			7,085
Issuance of common shares July 18, 2000					19,007	58,000			58,000
Issuance of warrants for services received						42,290	(42,290)		
Amortization of deferred unearned compensation							24,290		24,290
Net loss								(3,437,195)	(3,437,195)
Balance, December 31, 2000			468,768	469	5,295,294	17,782,857	(18,000)	(15,639,672)	2,125,654
Conversion of shares									
September 15, 2001			(1,166)	(1)	1,166	2,916			2,915
December 15, 2001			(1,000)	(1)	1,000	2,501			2,500
Private placement of common shares, net April 4, 2001					925,000	3,659,408			3,659,408
Issuance of common shares									
August 15, 2001					15,500	93,000			93,000
August 15, 2001					47,619	500,000			500,000
September 15, 2001					17,361	125,000			125,000

September 15, 2001				18,940	136,364			136,364
Amortization of deferred unearned compensation						18,000		18,000
Net loss							(2,611,361)	(2,611,361)
Balance, December 31, 2001		466,602	467	6,321,880	22,302,046		(18,251,033)	4,051,480
Reverse stock stock split May 31, 2002 Fractional share adjustment				(711)	(3,050)			(3,050)
Issuance of registered common shares, net September 6, 2002				2,250,000	4,385,845			4,385,845
Net loss							(3,810,690)	(3,810,690)
Balance, December 31, 2002		466,602	467	8,571,169	26,684,841		(22,061,723)	4,623,585

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

(a development stage company)

Statements of Cash Flows

Years ended December 31, 2002, 2001 and 2000

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	$ (3,810,690)	$ (2,611,361)	$ (3,437,195)	$ (22,061,723)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	92,099	92,560	98,500	566,493
Amortization of deferred unearned compensation		18,000	24,290	42,290
Repurchase of licensing rights		125,000		125,000
Employee compensation paid in shares of common stock			93,000	151,000
Purchased in-process research and development				5,377,000
Loss on disposal of equipment				157,545
Changes in other assets and liabilities affecting cash flows from operations				
Prepaid expenses and other sundry assets	(52,296)	(27,518)	(5,347)	(141,187)
	(520,063)			(520,063)

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002
Due from licensee (Teva Pharmaceuticals USA, Inc.)				
Accounts payable and accrued expenses	526,473	146,180	102,148	280,729
Due to licensor (Antares/Regents)	(198,016)	433,319	(25,000)	235,303
Due from SBI				(128,328)
Net cash used in operating activities	(3,962,493)	(1,823,820)	(3,149,604)	(15,915,941)
CASH FLOWS USED IN INVESTING ACTIVITIES				
Purchase of capital assets	(38,992)	(86,735)	(43,238)	(1,021,817)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture			500,000	500,000
Proceeds from sale or conversion of shares	4,385,845	3,801,187	30,045	21,324,505
Fractional Share Payout	(3,050)			(3,050)
Net cash provided by financing activities	4,382,795	3,801,187	530,045	21,821,455
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	381,310	1,890,632	(2,662,797)	4,883,697
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	4,502,387	2,611,755	5,274,552	
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 4,883,697	$ 4,502,387	$ 2,611,755	$ 4,883,697
SUPPLEMENTAL SCHEDULE OFCASH FLOW INFORMATION				
Acquisition of SBI				
Purchased in-process research and development	$	$	$	$ 5,377,000
Other net liabilities assumed				(831,437)
				4,545,563
Less: subordinate voting shares issued therefor				4,545,563
	$	$	$	$
Income tax paid	$	$	$	$
Interest paid	$	$	$	$

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)

Notes to the Financial Statements

For the years ended December 31, 2002, 2001 and 2000, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2002

1. ORGANIZATION

On December 19, 1996, Ben-Abraham Technologies, Inc. ("BAT") was continued under the laws of the State of Wyoming, U.S.A. Previously, BAT had been incorporated under the laws of the Province of Ontario effective August 29, 1996. Pursuant to the shareholders meeting to approve the arrangement on November 27, 1996 and subsequent filing of the articles of arrangement on December 6, 1996, BAT acquired Structured Biologicals Inc. and its wholly-owned subsidiary 923934 Ontario Inc. ("SBI"), a Canadian public company listed on the Alberta Stock Exchange. The "acquisition" was effected by a statutory amalgamation wherein the stockholders of BAT were allotted a significant majority of the shares of the amalgamated entity. Upon amalgamation, the then existing stockholders of SBI received 743,432 subordinate voting shares of BAT (1 such share for every 35 shares held in SBI). On November 10, 1999, BAT changed its name to BioSante Pharmaceuticals, Inc. ("the Company").

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

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

The Company was established to develop prescription pharmaceutical products, vaccines, vaccine adjuvants and drug delivery systems using its nanoparticle technology ("CAP") licensed from the University of California. The research and development on the CAP technology is conducted in the Company's Smyrna, Georgia laboratory facility. In addition to its nanoparticle technology, the Company also is developing its pipeline of hormone therapy products to treat hormone deficiencies in men and women, the technology for which has been licensed from Antares Pharma, Inc. The business office is located in Lincolnshire, Illinois.

The Company has been in the development stage since its inception. The Company's successful completion of its development program and its transition to profitable operations is dependent upon obtaining regulatory approval from the United States (the "U.S.") Food and Drug Administration ("FDA") prior to selling its products within the U.S., and foreign regulatory approval must be obtained to sell its products internationally. There can be no assurance that the Company's products will receive regulatory approvals, and a substantial amount of time may pass before the achievement of a level of sales adequate to support the Company's cost structure. The Company will also incur substantial expenditures to achieve regulatory approvals and will need to raise additional capital during its developmental period. Obtaining marketing approval will be directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. It is not possible at this time to predict with assurance the outcome of these activities.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These financial statements are expressed in U.S. dollars.

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("generally accepted accounting principles") and Statement of Financial Accounting Standards ("SFAS") No. 7 "Accounting and Reporting by Development Stage Enterprises." The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

Property and Equipment

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

Long-Lived Assets

Long-lived assets are reviewed for possible impairment whenever events indicate that the carrying amount of such assets may not be recoverable. If such a review indicates an impairment, the carrying amount of such assets is reduced to estimated recoverable value.

Research and Development

Research and development ("R&D") costs are charged to expense as incurred. R&D is capitalized only when FDA approval has occurred. To date, no R&D expenses have been capitalized.

Basic and Diluted Net Loss Per Share

The basic and diluted net loss per share is computed based on the weighted average number of the aggregate of common stock and Class C shares outstanding, all being considered as equivalent of one another. Basic earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted average number of shares outstanding for the reporting period. Diluted earnings (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. The computation of diluted earnings (loss) per share does not include the Company's stock options, warrants or convertible debt with dilutive potential because of their antidilutive effect on earnings (loss) per share.

Stock-based Compensation

The Company follows the provisions of APB Opinion No. 25, "Accounting For Stock-Based Compensation" (APB No. 25) which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the measurement date (generally the date of grant) and the amount the employee must

pay to acquire the stock. As a result of the Company's application of APB No. 25, SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure" (SFAS 148), requires certain additional disclosures of the pro forma compensation expense arising from the Company's fixed and performance stock compensation plans. The expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected term of the option, the current price of the underlying stock, its expected volatility, expected dividends on the stock and the expected risk-free rate of return during the term of the option. The compensation cost is recognized over the service period, usually the period from the grant date to the vesting date. The following table illustrates the effect on net loss and loss per share if the Company had applied the fair value based method.

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

	2002	2001	2000
Pro forma	**$ (0.56)**	$ (0.54)	$ (0.69)

Cumulative net loss

As reported	**$ (22,061,723)**		
Total stock-based employee compensation determined under fair value based method for all awards	**(2,818,055)**		
Pro forma	**$ (24,879,778)**		

The weighted average fair value of the options at the date of grant for options granted during 2002, 2001 and 2000 was $2.44, $5.00 and $9.00, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2002	2001	2000
Expected option life (years)	**10**	10	10
Risk free interest rate	**4.61%**	5.39%	6.03%
Expected stock price volatility	**45.47%**	118.79%	157.06%
Dividend yield			

Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue.

Revenue Recognition

The Company recognizes revenue from licensing arrangements in the form of upfront license fees, milestone payments, royalties and other fees. Revenue is recognized when amounts are earned, cash is received and the Company has completed all of its obligations under the licensing arrangement which are required for the payment to be non-refundable. Revenue also includes reimbursement for certain research and development expenses, which the Company recognizes as both revenue and expense at the time the expense is incurred. Any ancillary payments related to the products being licensed, such as royalties to the head licensor, are netted against revenues at the time of revenue recognition. To date, there has been no royalty revenue recognized. Interest income on invested cash balances is recognized on the accrual basis as earned.

New Statements of Financial Accounting Standards

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

3. ACQUISITION

Pursuant to the shareholders meeting to approve the arrangement held on November 27, 1996 and the subsequent filing of the articles of arrangement December 6, 1996, the Company completed the acquisition of 100% of the outstanding shares of SBI. The acquisition was effected by a statutory amalgamation wherein the stockholders of the Company were allotted a significant majority of the shares of the amalgamated entity. Upon amalgamation, the then existing shareholders of SBI received 743,432 shares of common stock of the Company (1 such share for every 35 shares they held in SBI). SBI's results of operations have been included in these financial statements from the date of acquisition. The acquisition was accounted for by using the purchase method of accounting, as follows:

Assets	
In-process research and development	**$ 5,377,000**
Other	**37,078**

	5,414,078
Liabilities	
Current liabilities	**679,498**
Due to directors	**60,689**
Due to the Company	**128,328**
	868,515
Net assets acquired	**$ 4,545,563**
Consideration	
Common stock	**$ 4,545,563**

In connection with the acquisition of SBI, accounted for under the purchase method, the Company acquired the rights to negotiate with the Regents of the University of California for licenses of specific CAP-related technologies and products. The specific technologies and products relate to investigative research funded by SBI. At the time of acquisition, the technologies and products had not yet been approved for human clinical research. The value ascribed to the rights, based on an independent evaluation, was $5,377,000. This amount was immediately expensed as the technologies and products did not have their technological feasibility established and had no identified future alternative use.

As of the date of acquisition, the technology related to the development of products for six indications (i.e. applications of the technology). The Company determined the value of the in process

research and development related to the acquired rights based on an independent valuation using discounted cash flows. Principle assumptions used in the valuation were as follows:

FDA approval for the CAP-related six indications was expected to be received at various dates between 2002 and 2004, however, there are many competitive products in development. There are also many requirements that must be met before FDA approval is secured. There is no assurance that the products will be successfully developed, proved to be safe in clinical trials, meet applicable regulatory standards, or demonstrate substantial benefits in the treatment or prevention of any disease.

The estimated additional research and development expenditures required before FDA approval was $26.5 million, to be incurred over 8 to 10 years.

Future cash flows were estimated based on estimated market size, with costs determined based on industry norms, an estimated annual growth rate of 3%.

The cash flows were discounted at 25%. The rate was preferred due to the high-risk nature of the biopharmaceutical business.

The Company is continuing to develop the technology related to five of the six indications.

In June 1997, the Company exercised its option and entered into a license agreement with UCLA for the technology that it had previously supported.

4. FINANCING

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

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

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

5. LICENSE AGREEMENTS

In June 1997, the Company entered into a licensing agreement with the Regents of the University of California, which has subsequently been amended, pursuant to which the University has granted the Company an exclusive license to nine United States patents owned by the University, including rights to sublicense such patents, in fields of use initially pertaining to: (1) vaccine adjuvants; (2) vaccine constructs or combinations for use in immunization against herpes virus; (3) drug delivery systems; and (4) red blood cell surrogates. The University of California has filed patent applications for this licensed technology in several foreign jurisdictions, including Canada, Europe and Japan. The license agreement requires the Company to undertake various obligations as described in Note 14.

On June 13, 2000, the Company entered into a license agreement with Antares Pharma, Inc. (Antares), covering four hormone products for the treatment of men and women. The license agreement requires the Company to pay Antares a percentage of future net sales, if any, as a royalty. Under the terms of the license agreement, the Company is also obligated to make milestone payments upon the occurrence of certain future events.

As allowed by the licensing agreement with Antares, on September 1, 2000, the Company entered into a sub-license agreement with Paladin Labs Inc. (Paladin) to market the female hormone therapy products in Canada. In exchange for the sub-license, Paladin agreed to make an initial investment in the Company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments have been made in the form of a series of equity investments by Paladin in the Company's common stock at a 10% premium to the market price of the Company's common stock at the date of the equity investment.

These equity investments resulted in the Company issuing an additional 18,940 shares of its common stock to Paladin at a 10 percent premium to the Company's market price. The dollar value of the premium, $39,394, is recorded as licensing income in the statements of operations.

In a series of amendments executed during 2001 and 2002 between the Company and Antares, the Company returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. It was agreed, that the Company is the owner of Bio-T-Gel, its testosterone gel for men with no milestone or royalty obligations to Antares. Additionally, the Company returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted the Company a credit for approximately $600,000 of manufacturing and formulation services and a license for LibiGel E/T, a transdermal combination gel of bioidentical estrogen and bioidentical testosterone. During the third quarter of 2001, Antares informed the Company that the total costs for manufacturing and formulation services had exceeded the $600,000 credit. Accordingly, beginning in third quarter of 2001 and going forward, the Company will be required to reimburse Antares for such services. At December 31, 2002, the amount owed to Antares for such services was $35,303.

On August 7, 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. Under the terms of the agreement, Solvay sub-licensed the Company's estrogen/progestogen combination transdermal hormone gel product for an initial payment of $2.5 million ($1.7 million net of the related payments due to Antares and Paladin), future milestone payments and escalating sales-based royalties. During the third quarter ended September 30, 2002, the Company received a $950,000 ($750,000 net of the related payment due to Antares as a result of a series of amendments executed during 2002 between the Company and Antares) milestone payment pursuant to the Solvay sub-license agreement. Solvay is responsible for all costs of development and marketing of the product. The Company has retained co-promotion rights to the product and will be compensated for sales generated by the Company over and above those attributable to Solvay's marketing efforts. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of the Company's common stock with a market value of $125,000 at the date of the transaction.

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

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. Patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company, regulatory milestones, maintenance payments and royalty payments by the Company if the product gets approved and subsequently marketed.

In December 2002, the Company signed a development and license agreement with Teva Pharmaceuticals USA, Inc., a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., under which Teva USA and the Company will collaborate on the development of a hormone therapy product for the U.S. market. Upon signing the U.S. development and license agreement, the Company received an upfront payment of $1.5 million. In addition, Teva will pay the Company development and sales-related milestone payments plus royalties on sales of the product commercialized in this collaboration. In exchange, the Company granted Teva exclusive rights to develop and market a certain hormone therapy product. Teva also is responsible for continued development, regulatory filings and all manufacturing and marketing associated with the product.

6. PROPERTY AND EQUIPMENT

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

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

7. INCOME TAXES

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

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

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2002, the Company had approximately $16,931,149 of net operating loss carryforwards that are available to reduce future taxable income for a

period of up to 20 years. The net operating loss carryforwards expire in the years 2011-2022. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, generate deferred tax benefits, which have been recorded as deferred tax assets and are

entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, the amount management believes is more likely than not to be realized. Additionally, the Company has approximately $1,006,817 of research and development credits available to reduce future income taxes through the year 2022.

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate of 35% to pre-tax income as follows:

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

8. CONVERTIBLE DEBENTURE

In September 2000, in connection with entering into a sub-license agreement, the Company issued a convertible debenture to Paladin Labs Inc. (Paladin) in the face amount of $500,000. The debenture did not bear interest and was due September 1, 2001, unless converted into shares of the Company's common stock. On August 13, 2001, the Company exercised its right and declared the debenture converted in full at a price of $10.50 per share. Accordingly, 47,619 shares of the Company's common stock were issued to Paladin. This was a non-cash financing transaction.

9. STOCKHOLDERS' EQUITY

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

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

a) Authorized

Preference shares

Ten million preference shares, $0.0001 par value per share, issuable in series subject to limitation, rights, and privileges as determined by the directors. No preference shares have been issued as of December 31, 2002.

Special Shares

4,687,684 Class C special shares, $0.0001 par value per share, convertible to common stock on the basis of one Class C special share and U.S. $2.50. These shares are not entitled to a dividend and carry one vote per share.

Common Stock

One hundred million common shares of stock, $0.0001 par value per share, which carry one vote per share.

Significant Equity Transactions

Significant equity transactions since the date of the Company's incorporation are as follows:

Prior to the Amalgamation on December 6, 1996, the Company issued 2,000,000 shares of the Company's Class A stock for $0.001 per share, 415,000 shares of Class C stock for $0.001 per share and 410,000 shares of the Company's common stock for $10.00 per share.

Pursuant to the shareholders meeting to approve the arrangement held on November 27, 1996 and the subsequent filing of articles of arrangement on December 6, 1996, the Company completed the acquisition of 100% of the outstanding shares of SBI. Upon the effectiveness of this Amalgamation, the then existing stockholders of SBI received 743,432 shares of common stock of the Company (1 common share of the Company for every 35 shares of SBI). The deemed fair market value of this stock was $4,545,563.

In May 1998, the Company and Avi Ben-Abraham, M.D., a then director and a founder of the Company and the Company's then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. Effective May 21, 2002, Dr. Ben-Abraham chose not to stand for re-election as a director of the Company. Pursuant to the agreement, Dr. Ben-Abraham converted shares of the Company's Class A stock held by him into 1,500,000 shares of common stock at $2.50 per share for proceeds to the Company of $3,750,000. In addition, Dr. Ben-Abraham agreed to return to the Company 146,861 shares of Class A stock and 25,000 shares of Class C stock to the Company, and also agreed not to sell any of his shares of common stock or any other securities of the Company for a period of 15 months. The Company and Dr. Ben-Abraham agreed to cross-indemnify each other upon the occurrence of certain events.

In June 1998, the Company issued an aggregate of 200,000 shares of common stock pursuant to the conversion of Class A stock at a conversion price of $2.50 per share.

On May 6, 1999, the Company sold an aggregate of 2,312,500 common shares and warrants to purchase 1,156,250 shares of common stock at an exercise price of $3.00 per share to 31 accredited investors in a private placement, including several current members of the board of directors and one executive officer. Net proceeds to the Company from this private placement were approximately $4.2 million.

In August 1999, an outstanding liability of $25,000 was converted into 7,000 shares of common stock.

In July 2000, 19,007 shares of common stock were issued to certain corporate officers in lieu of a cash bonus.

On April 4, 2001, the Company sold an aggregate of 925,000 common shares and warrants to purchase 462,500 shares of common stock at an exercise price of $5.00 per share to 48 accredited investors in a private placement, including several current members of the board of directors and five executive officers. Net proceeds to the Company from this private placement were approximately $3.7 million.

During the third quarter 2001, Paladin made a series of equity investments in the Company as result of certain sub-licensing transactions and the Company reaching certain milestones. These equity investments resulted in the Company issuing an additional 18,940 shares of its common stock to Paladin at a 10 percent premium to the Company's market price on the date of the transactions. The dollar value of the premium is recorded as licensing income in the statements of operations.

On August 7, 2001, the Company entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone therapy gel product licensed from Antares in June 2000. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of the Company's common stock with a market value of $125,000 at the date of the transaction.

In August 2001, 15,500 shares of common stock were issued to certain corporate officers in lieu of a cash bonus.

On August 13, 2001, the Company exercised its right and declared a convertible debenture in the face amount of $500,000 issued to Paladin Labs Inc. ("Paladin") converted in full at a price of $10.50 per share. See Note 7. Accordingly, 47,619 shares of the Company's common stock were issued to Paladin.

On September 6, 2002, the Company sold an aggregate of 2,250,000 common shares in a "best efforts" self-underwritten offering to 39 accredited investors, including several current members of the board of directors and three executive officers. Net proceeds from this offering were approximately $4.4 million.

b) Warrants

The Company, upon the acquisition of SBI, assumed 257,713 exercisable warrants to purchase common stock, all of which expired prior to or as of December 31, 1998. Of this amount, 7,257 were exercised in 1997 prior to their expiration.

Pursuant to the Company's private placement financing in May 1999, warrants to purchase an aggregate of 1,156,250 shares of common stock were issued at an exercise price of $3.00 per share with a term of five years. These warrants remain outstanding and are all exercisable as of December 31, 2002.

In June 2000, a five-year warrant to purchase 25,000 shares of common stock at an exercise price of $8.80 was issued to a communications firm for various consulting services. As of December 31, 2002, all 25,000 of these shares were exercisable. The Company recognized expense of approximately $18,000 for this warrant grant during 2000 and 2001.

Pursuant to the Company's private placement financing in April 2001, warrants to purchase an aggregate of 462,500 shares of common stock were issued at an exercise price of $5.00 per share with a term of five years. These warrants remain outstanding and are all exercisable as of December 31, 2002.

10. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 1,000,000 shares of common stock have been reserved for issuance. Options for 997,300 shares of common stock have been granted as of December 31, 2002 under this plan at prices equal to either the ten-day weighted average closing price, or the closing bid price of the stock at the date of the grant, and are exercisable and vest in a range substantially over a three-year period. The options expire either in substantially five or ten years from the date of the grants.

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

	2002	Weighted Average Exercise Price	2001	Weighted Average Exercise Price	2000	Weighted Average Exercise Price
Options outstanding, Beginning of period	699,467	$ 3.80	526,312	$ 3.30	497,312	$ 3.00
Options granted	327,167	$ 3.71	174,155	$ 5.20	51,000	$ 9.10
Options cancelled/expired	(29,334)	$ 3.44	(1,000)	$ 7.50	(22,000)	$ 10.00

	2002	Weighted Average Exercise Price	2001	Weighted Average Exercise Price	2000	Weighted Average Exercise Price
Options exercised		$		$		$
Options outstanding, End of period	997,300	$ 3.74	699,467	$ 3.80	526,312	$ 3.30
Options exercisable, End of year	631,611	$ 3.55	542,483	$ 3.40	386,502	$ 2.80

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

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

11. RETIREMENT PLAN

The Company offers a discretionary 401(k) Plan (the Plan) to all of its employees. Under the Plan, employees may defer income on a tax-exempt basis, subject to IRS limitation. Under the Plan the Company can make discretionary matching contributions. Company contributions expensed in 2002, 2001 and 2000 totaled $44,605, $30,743 and $26,296, respectively.

12. LEASE ARRANGEMENTS

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

Rent expense amounted to $148,184, $119,765 and $82,069 for the years ended December 31, 2002, 2001 and 2000, respectively. Effective September 16, 1999, the Company entered into a sublease agreement for its Atlanta office space under which the Company received approximately $3,400 per month from the sub-tenant through May 14, 2002.

13. RELATED PARTY TRANSACTIONS

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

Prior to the Amalgamation on December 6, 1996, the Company issued 2,000,000 shares of class A stock and 415,000 shares of class C stock for $0.001 per shares. 1,700,000 of the class A shares were sold to a director of the Company. 105,000 of the class C shares were sold to the same director of the Company to be held by him in trust for the benefit of others; 50,000 of the class C shares were sold to a separate company controlled by a then officer of the Company; and 200,000 of the class C shares were sold to other directors of the Company.

The 2,000,000 class A shares and 415,000 class C shares were founder's shares and the terms under the authorization of these shares, provided for their conversion to common stock at $2.50 per share.

In May 1998, the Company and Avi Ben-Abraham, M.D., a then director and a founder of the Company and the Company's then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. See Note 9.

In connection with the May 1999 private placement of 2,312,500 shares of common stock and warrants to purchase 1,156,250 shares of common stock, the Company's Chief Executive Officer purchased 25,000 shares of the common stock sold and warrants to purchase 12,500 shares of common stock. Three other individuals, who purchased either individually or through affiliated entities, an aggregate 1,025,000 shares of common stock and warrants to purchase 512,500 shares of common stock, became directors of the Company upon their acquisition of the shares or sometime later.

In connection with the April 2001 private placement of 925,000 shares of common stock and warrants to purchase 462,500 shares of common stock, the Company's Chief Executive Officer, Chief Financial Officer and other senior officers purchased an aggregate of 52,875 shares of the common stock sold and warrants to purchase 26,437 shares of common stock. Three directors, either individually or through affiliated entities, purchased an aggregate 312,500 shares of common stock and warrants to purchase 156,250 shares of common stock.

In connection with the September 2002 best-efforts, self-underwritten offering of 2,250,000 shares of common stock, the Company's Vice President of Clinical Development, Chief Executive Officer and Chief Financial Officer purchased an aggregate of 164,701 shares of the common stock sold. Three directors, either individually or through affiliated entities, purchased an aggregate 453,504 shares of common stock.

14. COMMITMENTS

University of California License

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

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

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

Year	Minimum Annual Royalty Due
2004	$ 50,000
2005	100,000
2006	150,000
2007	200,000
2008	400,000
2009	600,000
2010	800,000
2011	1,500,000
2012	1,500,000
2013	1,500,000
	$ 6,800,000

Development of products incorporating the licensed technology until a product is introduced to the market;

Payment of the costs of patent prosecution and maintenance of the patents included in the agreement which for the year ended December 31, 2002 have amounted to $12,240 and which management estimates will equal approximately $15,000 per year;

Meeting performance milestones relating to:

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

Testing proposed products;

Obtaining government approvals;

Conducting clinical trials; and

Introducing products incorporating the licensed technology into the market.

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

The Company has agreed to indemnify, hold harmless and defend the University of California and its affiliates, as designated in the license agreement, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation.

Antares Pharma, Inc. License

The Company's license agreement with Antares Pharma, Inc. required the Company to make a $1.0 million upfront payment to Antares. The Company expects to fund the development of the products, make milestone payments and once regulatory approval to market is received, pay royalties on the sales of products.

Wake Forest License

In April 2002, the Company exclusively in-licensed from Wake Forest University and Cedars-Sinai Medical Center three issued U.S. Patents claiming triple hormone therapy (the combination use of estrogen plus progestogen plus androgen, *e.g.* testosterone) and an option for triple hormone contraception. The financial terms of the license include an upfront payment by the Company, regulatory milestones, maintenance payments and royalty payments by the Company if the product gets approved and subsequently marketed.

Future minimum payments due under this agreement are as follows:

Year	Minimum Annual Royalty Due
2004	$ 10,000
2005	45,000
2006	55,000
2007	90,000
2008	90,000
2009	40,000

Year	Minimum Annual Royalty Due
2010	140,000
2011	265,000
2012	165,000
2013	240,000
	$ 1,140,000

The Company has agreed to indemnify, hold harmless and defend Wake Forest University against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims. The Company has not recorded any liability in connection with this obligation.

7,584,348 Shares

Common Stock

Prospectus

, 2003

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 24. Indemnification of Directors and Officers.

BioSante's Certificate of Incorporation limits the liability of its directors to the fullest extent permitted by the Delaware General Corporation Law. Specifically, Article VII of BioSante's Certificate of Incorporation provides that no director of BioSante shall be personally liable to BioSante or its stockholders for monetary damages for any breach of fiduciary duty by such a director as a director, except to the extent provided by applicable law (i) for any breach of the director's duty of loyalty to BioSante or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which such director derived an improper personal benefit. If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of BioSante shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law as so amended. No amendment to or repeal of Article VII shall apply to or have any effect on the liability or alleged liability of any director of BioSante for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal.

BioSante's Certificate of Incorporation provides for indemnification of BioSante's directors and officers. Specifically, Article VI provides that BioSante shall indemnify, to the fullest extent authorized or permitted by law, as the same exists or may thereafter be amended, any person who was or is made or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of BioSante), by reason of the fact that such person is or was a director or officer of BioSante, or is or was serving at the request of BioSante as a director, officer, employee or agent of any other company, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise; provided, however, that BioSante shall not indemnify any director or officer in connection with any action by such director or officer against BioSante unless BioSante shall have consented to such action. BioSante may, to the extent authorized from time to time by BioSante's Board of Directors, provide rights to indemnification to employees and agents of BioSante similar to those conferred in Article VI to directors and officers of BioSante. No amendment or repeal of Article VI shall apply to or have any effect on any right to indemnification provided thereunder with respect to any acts or omission occurring prior to such amendment or repeal.

BioSante has also agreed to indemnify its selling stockholders, including some of its officers, directors and related entities, and SCO Securities LLC under this registration statement, against certain losses, claims, damages, liabilities, costs and expenses under the securities laws, or to contribute to any losses associated with these liabilities. Each of these selling stockholders has also agreed to indemnify us against certain civil liabilities under the securities laws deriving from information provided by it, or to contribute to any losses associated with these liabilities.

BioSante maintains an insurance policy for its directors and executive officers pursuant to which its directors and executive officers are insured against liability for certain actions in their capacity as directors and executive officers of BioSante.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to BioSante's directors, officers or persons controlling BioSante pursuant to the foregoing provisions, BioSante is aware that in the opinion of the Securities and Exchange Commission that this indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable.

Item 25. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses payable by BioSante in connection with the issuance and distribution of the shares of common stock being registered. All such expenses are estimated except for the SEC registration fee.

SEC registration fee	$	1,687
Printing expenses		1,000
Fees and expenses of legal counsel for BioSante		25,000
Fees and expenses of accountants for BioSante		10,000
Blue sky fees and expenses		10,000
Miscellaneous		10,000
*Total	$	57,687

* None of the expenses listed above will be borne by the selling stockholders.

Item 26. Recent Sales of Unregistered Securities.

Since August 15, 2000, we have issued the following securities without registration under the Securities Act:

1. In September 2000, we issued a $500,000 convertible debenture to Paladin Labs Inc.

2.

In July 2000, we issued an aggregate of 19,007 shares of common stock (16,385 shares to Stephen Simes and 2,621 shares to Phillip Donenberg) pursuant to the granting of common stock bonuses, in lieu of cash valued at $58,000.

3.

In July 2000, we issued 2,834 shares of common stock to an accredited investor pursuant to the conversion of class C stock, at a conversion price of $2.50 per share for a payment of $7,085.25.

4.

In April 2001, we issued an aggregate of 925,000 shares of our common stock and warrants to purchase an aggregate of 462,500 shares of our common stock for $4.00 per unit, each unit consisting of one share of common stock and a warrant to purchase 0.50 shares of our common stock, for an aggregate purchase price of $3,700,000, to 49 accredited investors, including certain existing stockholders, directors and officers. Stephen Simes purchased 12,500 shares of common stock and a warrant to purchase 6,250 shares of common stock, Leah Lehman purchased 37,500 shares of common stock and a warrant to purchase 18,750 shares of common stock, Fred Holubow purchased 12,500 shares of common stock and a warrant to purchase 6,250 shares of common stock, Victor Morgenstern, including an affiliated trust and his wife, purchased an aggregate of 75,000 shares of common stock and warrants to purchase an aggregate of 37,500 shares of common stock, Phillip Donenberg and John Lee, each purchased 1,250 shares of common stock and a warrant to purchase 625 shares of common stock, Steve Bell purchased 375 shares of common stock and a warrant to purchase 187 shares of common stock, and Ross Mangano, as a trustee and investment advisor purchased an aggregate of 225,000 shares of common stock and warrant to purchase an aggregate of 112,499 shares of common stock.

5.

In August 2001, we issued 47,619 shares of our common stock upon conversion of a $500,000 convertible debenture to Paladin Labs Inc. at a conversion price of $10.50 per share.

6.

In August 2001, we issued a stock bonus of 12,500 shares of common stock to Stephen Simes at a price of $6.00 per share, a stock bonus of 2,000 shares of our common stock to Phillip Donenberg at a price of $6.00 per share, and a stock bonus of 1,000 shares of common stock to Steve Bell at a price of $6.00 per share.

7.

In September 2001, we issued 1,166 shares of common stock to an accredited investor pursuant to the conversion of class C stock, at a conversion price of $2.50 per share.

8.

In August 2003, we issued an aggregate of 4,791,982 shares of our common stock and warrants to purchase an aggregate of 2,395,993 shares of our common stock for $2.15 per unit, each unit consisting of one share of common stock and a warrant to purchase 0.50 shares of our common stock, for an aggregate purchase price of approximately $10,302,765 to 37 accredited investors, including certain existing stockholders, directors and officers. Stephen Simes, through his trust, purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock, Leah M. Lehman, Ph.D. purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock, Fred Holubow, through Panacea Fund, LLC, purchased 150,000 shares of common stock and a warrant to purchase 75,000 shares of common stock, Victor Morgenstern, including an affiliated trust, purchased an aggregate of 293,000 shares of common stock and warrants to purchase an aggregate of 146,500 shares of common stock, Phillip Donenberg, purchased 1,000 shares of common stock and a warrant to purchase 500 shares of common stock and Ross Mangano, through JO & Co. purchased 293,023 shares of common stock and warrant to purchase 146,512 shares of common stock. We also issued a warrant to purchase 371,373 shares of common stock to SCO Securities LLC such warrant was subsequently assigned to employees of SCO Securities LLC.

No underwriting commissions or discounts were paid with respect to the sales of the unregistered securities described above. In addition, all of the above sales were made in reliance on either Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering or Regulation D of the Securities Act. In all such transactions, certain inquiries were made by BioSante to establish that such sales qualified for such exemption from the registration requirements. In particular, BioSante confirmed that with respect to the exemption claimed under Section 4(2) of the Securities Act (i) all offers of sales and sales were made by personal contact from officers and directors of BioSante or other persons closely associated with BioSante, (ii) each investor made representations that he or she was sophisticated in relation to this investment (and BioSante has no reason to believe that such representations were incorrect), (iii) each purchaser gave assurance of investment intent and the certificates for the shares bear a legend accordingly, and (iv) offers and sales within any offering were made to a limited number of persons.

Item 27. Exhibits.

See the Exhibit Index attached to this registration statement that is incorporated herein by reference.

Item 28. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described above, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB-2 and authorized this registration statement to be signed on its behalf by the undersigned, in the City of Lincolnshire, State of Illinois on September 5, 2003.

BIOSANTE PHARMACEUTICALS, INC.

By /s/ Stephen M. Simes

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

By /s/ Phillip B. Donenberg

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints jointly and severally, Stephen M. Simes and Phillip B. Donenberg, and each one of them acting singly, as the person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the person and in the person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement and any additional registration statements filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Act of 1933, this registration statement was signed by the following person in the capacities indicated, on September 5, 2003.

Name and Signature	Title
/s/ STEPHEN M. SIMES Stephen M. Simes	Vice Chairman, President and Chief Executive Officer (Principal Executive Officer)
/s/ PHILLIP B. DONENBERG Phillip B. Donenberg	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
/s/ LOUIS W. SULLIVAN, M.D. Louis W. Sullivan, M.D.	Chairman of the Board

/s/ EDWARD C. ROSENOW, III, M.D. Edward C. Rosenow, III, M.D.	Director
 Victor Morgenstern	Director
/s/ ROSS MANGANO Ross Mangano	Director

/s/ PETER KJAER	Director
Peter Kjaer	
/s/ FRED HOLUBOW	Director
Fred Holubow	
/s/ ANGELA HO	Director
Angela Ho	

BIOSANTE PHARMACEUTICALS, INC.
REGISTRATION STATEMENT ON FORM SB-2
EXHIBIT INDEX

Exhibit No.	Exhibit	Method of Filing
2.1	Arrangement Agreement, dated October 23, 1996, between Structured Biologicals Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 2.1 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
3.1	Amended and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 contained in BioSante's Registration Statement on Form SB-2, as amended, (File No. 333-64218)
3.2	Bylaws of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.2 contained in BioSante's Registration Statement on Form SB-2, as amended, (File No. 333-64218)
4.1	Form of Warrant issued in connection with May 1999 Private Placement	Incorporated by reference to Exhibit 4.1 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
4.2	Form of Warrant issued in connection with April 2001 Private Placement	Incorporated by reference to Exhibit 4.2 contained in BioSante's Registration Statement on Form SB-2, as amended (File No. 333-64218)
4.3	Form of Warrant issued in connection with the August 2003 Private Placement	Incorporated by reference to Exhibit 10.2 contained in BioSante's Form 8-K, filed on August 6, 2003 (File No. 0-28637)
5.1	Opinion of Oppenheimer Wolff & Donnelly	Filed herewith electronically
10.1	License Agreement, dated June 18, 1997, between BioSante Pharmaceuticals, Inc. and The Regents of the University of California(1)	Incorporated by reference to Exhibit 10.1 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.2	Amendment to License Agreement, dated October 26, 1999, between BioSante Pharmaceuticals, Inc. and the Regents of the University of California(1)	Incorporated by reference to Exhibit 10.2 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.3	Amended and Restated 1998 Stock Option Plan	Incorporated by reference to Exhibit 10.1 contained in BioSante's 10-QSB filed on

Exhibit No.	Exhibit	Method of Filing
		August 14, 2003 (File 0-28637)
10.4	Stock Option Agreement, dated December 7, 1997, between BioSante Pharmaceuticals, Inc. and Edward C. Rosenow, III, M.D.	Incorporated by reference to Exhibit 10.5 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.5	Form of Stock Option Agreement between BioSante Pharmaceuticals, Inc. and each of BioSante's executive officers	Incorporated by reference to Exhibit 10.5 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.6	Escrow Agreement, dated December 5, 1996, among BioSante Pharmaceuticals, Inc., Montreal Trust Company of Canada, as Escrow Agent, and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.9 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.7	Registration Rights Agreement, dated May 6, 1999, between BioSante Pharmaceuticals, Inc. and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.13 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.8	Securities Purchase Agreement, dated May 6, 1999, between BioSante Pharmaceuticals, Inc. and certain shareholders of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.14 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.9	Lease, dated September 15, 1997, between BioSante Pharmaceuticals, Inc. and Highlands Park Associates	Incorporated by reference to Exhibit 10.15 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.10	Employment Agreement, dated January 21, 1998, between BioSante Pharmaceuticals, Inc. and Stephen M. Simes, as amended	Incorporated by reference to Exhibit 10.16 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.11	Employment Agreement, dated June 11, 1998, between BioSante Pharmaceuticals, Inc. and Phillip B. Donenberg, as amended	Incorporated by reference to Exhibit 10.17 contained in BioSante's Registration Statement on Form 10-SB, as amended (File No. 0-28637)
10.12	License Agreement, dated June 13, 2000, between Permatec Technologie, AG and BioSante Pharmaceuticals, Inc.(1)	Incorporated by reference to Exhibit 10.1 contained in BioSante's Current Report on Form 8-K on July 11, 2000 (File No. 0-28637)
10.14	Employment Agreement, dated December 15, 2000, between BioSante Pharmaceuticals, Inc. and Leah Lehman, Ph.D.	Incorporated by reference to Exhibit 10.19 to BioSante's Annual Report on Form 10-KSB filed on March 30, 2001 (File No. 0-28637)
10.15	Form of Subscription Agreement in connection with the April 2001 Private Placement	Incorporated by reference to Exhibit 10.19 to BioSante's Registration Statement on Form SB-2, as amended, (File No. 333-64218)
10.17	Amendment No. 1 to the License Agreement, dated May 20, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc.(1)	Incorporated by reference to Exhibit 10.18 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.18	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma and BioSante Pharmaceuticals, Inc.(1)	Incorporated by reference to Exhibit 10.19 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.19	Amendment No. 3 to the License Agreement, dated August 30, 2001,	Incorporated by reference to Exhibit 10.20 to

	between Antares Pharma and BioSante Pharmaceuticals, Inc.(1)	BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.20	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma and BioSante Pharmaceuticals, Inc.(1)	Incorporated by reference to Exhibit 10.20 to BioSante's Registration Statement on Form SB-2, as amended (File No. 333-87542)
10.21	Consulting Agreement, dated January 1, 2001, between BioSante Pharmaceuticals, Inc. and Scientific Research Development Corp.	Incorporated by reference to Exhibit 10.21 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.22	Employment Agreement, dated October 1, 2000, between BioSante Pharmaceuticals, Inc. and Steven J. Bell, Ph.D.	Incorporated by reference to Exhibit 10.22 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.23	Amendment No. 2 to the License Agreement, dated May 7, 2001, between BioSante Pharmaceuticals, Inc. and The Regents of the University of California(1)	Incorporated by reference to Exhibit 10.23 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.24	Separation and Release Agreement, dated February 1, 2002, between BioSante Pharmaceuticals, Inc. and John E. Lee	Incorporated by reference to Exhibit 10.24 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.25	Amendment No. 5 to the License Agreement, dated December 30, 2002 between Antares Pharma and BioSante Pharmaceuticals, Inc.(2)	Incorporated by reference to Exhibit 10.25 to BioSante's Annual Report on Form 10-KSB, filed on March 28, 2002 (File No. 0-28637)
10.26	Common Stock and Warrant Purchase Agreement dated August 4, 2003 between BioSante Pharmaceuticals, Inc. and the purchasers listed on schedule 1 thereto	Incorporated by reference to Exhibit 10.1 contained in BioSante's Form 8-K, filed on August 6, 2003 (File No. 0-28637)
10.27	Investor Rights Agreement dated August 4, 2003 between BioSante Pharmaceuticals, Inc. and the purchasers listed on Schedule 1 attached to the Common Stock and Warrant Purchase Agreement	Incorporated by reference to Exhibit 10.3 contained in BioSante's Form 8-K, filed on August 6, 2003 (File No. 0-28637)
10.28	Deferred Compensation Plan	Incorporated by reference to Exhibit 10.2 contained in BioSante's 10-QSB, filed on August 14, 2003 (File No. 0-28637)
23.1	Consent of Deloitte & Touche LLP	Filed herewith electronically
23.2	Consent of Oppenheimer Wolff & Donnelly LLP (included in Exhibit 5.1)	Filed herewith electronically
24.1	Power of Attorney	On signature page to this registration statement

(1) Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.

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

QuickLinks

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