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Filed Pursuant to
Rule 424b1
File No. 333-87542

PROSPECTUS

5,000,000 Shares
Common Stock

BioSante Pharmaceuticals, Inc. is offering 5,000,000 shares of common stock on a "best efforts" basis directly through its officers and directors, who will not receive any commissions or other remuneration for selling shares. BioSante may also offer the shares through brokers or sales agents, who may receive compensation in the form of commissions, which total commissions will not exceed 10% of the selling price of the shares.

We have not established a minimum amount of proceeds that must be received in the offering before any proceeds may be accepted. Once accepted, funds will be deposited into an account maintained by us and considered our general assets. Funds will not be placed into escrow, trust or any other similar arrangement.

The offering will commence promptly after the effectiveness of the registration statement of which this prospectus is a part, and will be made on a continuous basis for a period of 90 days, unless extended by us in our discretion, for up to an additional 90 days. The offering may be terminated by us earlier if we sell all of the shares being offered or we decide to cease selling efforts.

Our common stock is quoted on the Over-the-Counter Bulletin Board under the symbol "BISP." On August 13, 2002, the last reported sale price of our common stock on the OTC Bulletin Board was $3.80 per share.

The common stock offered involves a high degree of risk. We refer you to "Risk Factors," beginning on page 8.

	Per Share	Total
Public Offering Price	$ 2.00	$ 10,000,000
Commissions (1)	$ 0.20	$ 1,000,000
Proceeds to BioSante (before expenses)	$ 1.80	$ 9,000,000

(1) Assumes total commissions to be paid equal to 10% of the selling price of the shares.

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 September 5, 2002

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In this prospectus, references to "BioSante," "the company," "we," and "our," 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™, Bio-Vant™, NanoVant™, CAP-Oral™, Bio-Air™, Bio-T-Gel™, Bio-E-Gel™, Bio-E/P-Gel™, LibiGel™ and LibiGel-E/T™

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 replacement products to treat hormone deficiencies in both men and women. We also are engaged in the development of our proprietary calcium phosphate, nanoparticulate-based platform technology, or CAP, for vaccine adjuvants, drug delivery systems and to purify the milk of transgenic animals.

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

- accelerate the development of our hormone replacement products;
- continue to develop our nanoparticle-based platform technology, or CAP, and seek assistance in such development through corporate partner sub-licenses;
- license or otherwise acquire other drugs that will add value to our current product portfolio; and
- implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

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

Our proposed hormone replacement products, which we license on an exclusive basis from Antares Pharma Inc., are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and progestogen. The gels are designed to be absorbed quickly through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. Human clinical trials have begun on four of our hormone replacement products, a necessary step in the process of obtaining United States Food and Drug Administration, or FDA, approval to market the products.

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

- LibiGel—a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.
- Bio-T-Gel—a transdermal testosterone gel in development for testosterone deficiency in men.
- Bio-E-Gel—a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.
- Bio-E/P-Gel—a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.
- LibiGel-E/T—a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

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

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

- the creation of improved versions of current vaccines 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 by selectively isolating biologically active therapeutic proteins from the transgenic milk.

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

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

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

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

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

Our company, which was initially formed as a corporation organized under the laws of the Province of Ontario on August 29, 1996, was continued as a corporation under the laws of the State of Wyoming on December 19, 1996 and 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.

Recent Developments

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 share and per share numbers in this prospectus have been adjusted to reflect the reverse stock split.

The Offering

Common stock offered by us	5,000,000 shares
Common stock to be outstanding immediately after the offering	11,321,458 shares (based upon shares outstanding as of August 13, 2002 and excludes 2,415,017 shares issuable upon the exercise of outstanding options and warrants)
Use of proceeds	Expenses related to the human clinical development of our proposed hormone replacement products and general corporate purposes, including working capital and funding operating losses.
Type of offering	Best efforts basis by our directors and officers, who will not receive any commissions or other remuneration for selling shares. We may also offer the shares through brokers or sales agents, who may receive compensation in the form of commissions, which total commissions will not exceed 10% of the selling price of the shares. The offering will commence promptly after the effectiveness of the registration statement of which this prospectus is a part, and will be made on a continuous basis for a period of 90 days, unless extended by us in our discretion, for up to an additional 90 days. The offering may be terminated by us earlier if we sell all of the shares being offered or we decide to cease selling efforts.
Minimum amount of proceeds; no escrow	We have not established a minimum amount of proceeds that must be received in the offering before any proceeds may be accepted. Once accepted, funds will be deposited into an account maintained by us and considered our general assets. Funds will not be placed into escrow, trust or any other similar arrangement.
OTC Bulletin Board symbol	"BISP"

Abandoned Private Offering

From January 15 to February 20, 2002, we offered to sell up to approximately $10,000,000 of shares of our common stock to qualified institution buyers and accredited investors in a private placement in reliance upon Rule 506 under Regulation D under the Securities Act of 1933. The per share offer price was equal to approximately $5.00, a slight discount to the then market price of our common stock. We abandoned this private offering and terminated all offering activity in connection with the offering on February 28, 2002. Any offers to buy or indications of interest given in the private offering were rejected or otherwise not accepted by BioSante. This prospectus supersedes any offering materials used in the abandoned private offering.

Summary Consolidated Financial Data

The selected statement of operations data shown below for the years ended December 31, 1999, 2000 and 2001 and the balance sheet data as of December 31, 2000 and 2001 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, 1996 and for the years ended December 31, 1997 and 1998 and the balance sheet data as of December 31, 1997, 1998 and 1999 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, 2001 and 2002 and the balance sheet data as of June 30, 2002 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, 2001 and 2002 are not necessarily indicative of the results to be expected for the full year or for any future period. All share and per share numbers have been adjusted to reflect the one-for-ten reverse stock split effected on May 31, 2002. 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)	Year Ended December 31,			Six Months Ended June 30,	

	to December 31, 1996	1997	1998	1999	2000	2001	2001	2002
				(in thousands, except per share and share data)				
Statement of Operations Data:								
Licensing income	$ —	$ —	$ —	$ —	$ —	$ 1,747	$ —	$ —
Interest income	53	144	123	199	228	175	83	30
Total income	53	144	123	199	228	1,922	83	30
Expenses:								
Research and development	—	336	1,400	661	1,888	2,142	620	1,632
General and administration	547	1,618	1,112	853	1,679	2,299	963	951
Depreciation and amortization	1	52	140	91	98	92	49	45
Loss on disposal of capital assets	—	28	130	—	—	—	—	—
Total expenses	548	2,034	2,782	1,605	3,665	4,533	1,632	2,628
Loss before other expenses	(495)	(1,890)	(2,659)	(1,406)	(3,437)	(2,611)	(1,549)	(2,598)
Cost of acquisition of Structured Biologicals, Inc.	375	—	—	—	—	—	—	—
Purchased in-process research and development	5,377	—	—	—	—	—	—	—
Total other expenses	5,752	—	—	—	—	—	—	
Net loss	$ (6,247)	$ (1,890)	$ (2,659)	$ (1,406)	$ (3,437)	$ (2,611)	$ (1,549)	$ (2,598)
Basic and diluted net loss per share	$ (2.56)	$ (0.53)	$ (0.76)	$ (0.28)	$ (0.60)	$ (0.40)	$ (0.25)	$ (0.38)
Weighted average number of shares outstanding	2,437	3,596	3,486	4,942	5,754	6,485	6,209	6,788

The as adjusted column (without broker commissions) in the balance sheet data below gives effect to the sale of 5,000,000 shares of common stock in this offering at a public offering price of $2.00 per share, after deducting estimated offering expenses and assuming no broker, dealer or sales agent commissions are paid. The as adjusted column (with broker commissions) in the balance sheet data below gives effect to the sale of 5,000,000 shares of common stock in this offering at a public offering price of $2.00 per share, after deducting estimated offering expenses and assuming the payment of broker, dealer or sales agent commissions equal to 10% of the aggregate selling price of the shares. Because the shares being offered in this offering are being offered and sold by us on a best efforts basis, we may not sell all or any of the shares and therefore may not receive all or any of the net proceeds in this offering.

	As of June 30, 2002		
	Actual	As Adjusted (without broker commissions)	As Adjusted (with broker commissions)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 1,704	$ 11,631	$ 10,631
Working capital	1,041	10,968	9,968
Total assets	2,142	12,069	11,069
Stockholders' equity	1,406	11,333	10,333

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 $2,611,361 for the year ended December 31, 2001, and as of December 31, 2001, our accumulated deficit was $18,251,033. We incurred a net loss of $2,598,290 for the six months ended June 30, 2002, and as of June 30, 2002, our accumulated deficit was $20,849,323.

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

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

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

We 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 own product development programs or pass on opportunities to in-license or otherwise acquire new products that we believe may be beneficial to our business.

Our cash on hand as of June 30, 2002 was $1,704,495. If we do not sell any of the shares offered in this offering, we believe our existing cash will be sufficient to fund our operations through

December 2002. If we are able to sell all of the shares offered in this offering, we believe that with the net proceeds of this offering and our existing cash, we will have sufficient working capital to meet our needs through December 2003. We have based these estimates, 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. If we are unable to sell any shares offered in this offering, we will be required to seek alternative forms of equity or debt financing. Any 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.

In July 2002, the National Institutes of Health announced that it was discontinuing the oral tablet estrogen-progestin combination arm of the Women's Health Initiative study because Prempro, the combination oral HRT product used in the study, caused an increase in the risk of invasive breast cancer. Although the estrogen and progestin components of Prempro are different chemical entities than those used in our proposed gel-formulated HRT products and the means of delivery into the system are significantly different. We do not anticipate that any of our proposed products will receive the requisite regulatory approvals for commercialization in the United States or abroad for several years, if at all, and we cannot assure you that any of our proposed products, if approved and marketed, will generate significant product revenue and provide an acceptable return on your investment.

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

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

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

- problems assimilating the purchased products;
- unanticipated costs associated with the purchase;
- incorrect estimates made in the accounting for acquisitions; and
- risks associated with entering markets in which we have no or limited prior experience.

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

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

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

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

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

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

- slow patient enrollment;
- longer treatment time required to demonstrate efficacy;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

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

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

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

We license the technology underlying our proposed hormone replacement products from Antares Pharma, Inc. and our CAP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these

agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owing at the time of termination. Our failure to retain the right to license the technology underlying our proposed hormone replacement products or CAP technology could harm our business and future operating results. For example, if we were to enter into an outlicense agreement with a third party under which we agree to outlicense our hormone replacement 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 ensure the protection of our intellectual property for a number of other reasons:

- We do not know whether our patent applications will result in actual patents. For example, we may not have developed a method for treating a disease or manufacturing a product before others develop 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, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our competitors will not succeed in developing similar technologies and products more rapidly than we do or that these competing technologies and products will not be more effective than any of those that we currently are developing or will develop.

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

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

Risks Relating to this Offering and 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 a national securities exchange, like The New York Stock Exchange or American Stock Exchange.

Because our shares may be deemed "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 may be deemed 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 trades at less than $5.00 per share, trading in our common stock may be 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 and under other registration statements, 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.

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

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 37.3% 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.

Purchasers in this offering will experience immediate and substantial dilution of their investment.

We expect that the public offering price per share will significantly exceed the net tangible book value per share of the outstanding common stock. Accordingly, purchasers of common stock in this offering will suffer immediate and substantial dilution of their investment. In the past, we have granted options and warrants to purchase shares of our common stock at prices below the public offering price. To the extent these outstanding options and warrants are ultimately exercised, there will be further dilution to investors in this offering.

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

As of August 13, 2002, we had issued and outstanding 6,321,458 shares of common stock, 466,602 shares of our class C stock and outstanding options and warrants to purchase 2,415,017 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.

Because this is a best efforts offering with no firm underwriting commitment, we may not receive sufficient proceeds from the offering to justify payment of the offering expenses and finance our operations.

The shares are initially being offered by us on a best efforts basis, although we may engage brokers and sales agents to offer the shares on a best efforts basis from time to time in the future. We currently do not have any agreements with any brokers or sales agents to assist us in offering and selling the shares in this offering. We may not sell all or any of the shares offered under this prospectus. No one has committed to purchase any of the shares offered. As a result, we may not receive sufficient proceeds from the offering to justify payment of the offering expenses. We also may be required to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products.

None of the proceeds from the sale of shares in this offering will be placed in escrow and therefore there are no investor protections for the return of subscription funds once accepted.

We have not established a minimum amount of proceeds that we must receive in the offering before any proceeds may be accepted. Once accepted, the funds will be deposited into an account maintained by us and considered general assets of BioSante. None of the proceeds will be placed in any escrow, trust or other arrangement, therefore, there are no investor protections for the return of subscription funds once accepted.

Management has broad discretion as to the use of proceeds of this offering and could spend or invest the net proceeds in ways in which the stockholders may not agree.

We expect to use most of the net proceeds from this offering for expenses related to the human clinical development of our hormone replacement products, working capital or other general corporate purposes, including funding operating losses. Our management has broad discretion as to the use of proceeds of this offering and could spend or invest the net proceeds from this offering in ways in which the stockholders may not agree. The investment of these proceeds may not yield a favorable return to BioSante or its stockholders.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our financial condition, results of operations and business, the anticipated financial and other benefits of this offering and the plans and objectives of our management following this offering, including, without limitation, statements pertaining to:

- our substantial and continuing losses;
- our raising of additional capital through future equity financings;
- 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; and

- our existing cash and any net proceeds from this offering and whether and how long these funds will be sufficient to fund our operations.

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.

ABANDONED PRIVATE OFFERING

From January 15 to February 20, 2002, we offered to sell up to approximately $10,000,000 of shares of our common stock to qualified institution buyers and accredited investors in a private placement in reliance upon Rule 506 under Regulation D under the Securities Act of 1933. The per share offer price was equal to approximately $5.00, a slight discount to the then market price of our common stock. We abandoned this private offering and terminated all offering activity in connection with the offering on February 28, 2002. Any offers to buy or indications of interest given in the private offering were rejected or otherwise not accepted by BioSante. This prospectus supersedes any offering materials used in the abandoned private offering.

PLAN OF DISTRIBUTION

We are offering the shares on a "best efforts" basis directly through our officers and directors, who will not receive any commissions or other remuneration of any kind for selling shares in this offering, other than reimbursement of offering expenses incurred by them. This offering will commence promptly after the effectiveness of the registration statement of which this prospectus is a part. This offering will be made on a continuous basis for a period of 90 days, unless extended by us in our sole discretion, for up to an additional 90 days. This offering may be terminated by us earlier if we sell all of the shares being offered or we decide to cease selling efforts.

This offering is a self underwritten offering, which means that it does not involve the participation of an underwriter to market, distribute or sell the shares offered under this prospectus. We may sell shares from time to time in one or more transactions directly by us or, alternatively, we may offer the shares through brokers or sales agents, who may receive compensation in the form of commissions or fees. We have entered into several agreements with several sales agents to assist us in identifying and contacting potential investors. Under these agreements, we have generally agreed to pay these sales agents fees based on a percentage (not exceeding 10%) of the aggregate purchase price of shares sold by us to the investors identified and contacted by these sales agents. We have also agreed in some cases to reimburse these sales agents for out-of-pocket expenses incurred in connection with their engagement. Any broker, dealer or sales agent that participates in the distribution of shares may be deemed to be an underwriter, and any profits on the sale of the shares by any such broker, dealer or sales agent and any commissions and fees received by any such broker, dealer or sales agents may be deemed to be underwriting compensation under the Securities Act.

The shares may not be offered or sold in certain jurisdictions unless they are registered or otherwise comply with the applicable securities laws of such jurisdictions by exemption, qualification or otherwise. We intend to sell the shares only in the states in which this offering has been qualified or an exemption from the registration requirements is available, and purchases of shares may be made only in those states. To comply with the securities laws of certain jurisdictions, as applicable, the shares may be required to be offered and sold only through registered or licensed brokers or dealers. If such registered or licensed brokers or dealers are engaged, the total commission and fees paid to such brokers and dealers in connection with the sale of shares will not exceed 10% of the selling price of the shares.

In connection with their selling efforts in the offering, our officers and directors will not register as broker-dealers pursuant to Section 15 of the Securities Exchange Act of 1934, but rather will rely upon the "safe harbor" provisions of Rule 3a4-1 under the Exchange Act. Generally speaking, Rule 3a4-1 provides an exemption from the broker-dealer registration requirements of the Exchange Act for persons associated with an issuer that participate in an offering of the issuer's securities. The conditions to obtaining this exemption include the following:

- None of the selling persons are subject to a statutory disqualification, as that term is defined in Section 3(a)(39) of the Exchange Act, at the time of participation;
- None of the selling persons are compensated in connection with his or her participation by the payment of commissions or other remuneration based either directly or indirectly on transactions in securities;
- None of the selling persons are, at the time of participation, an associated person of a broker or dealer, and
- All of the selling persons meet the conditions of paragraph (a)(4)(ii) of Rule 3a4-1 of the Exchange Act, in that they (A) primarily perform or are intending primarily to perform at the end of the offering, substantial duties for or on behalf of the issuer otherwise than in connection with transactions in securities, and (B) are not a broker or dealer, or an associated person of a

broker or dealer, within the preceding 12 months, and (C) do not participate in selling an offering of securities for any issuer more than once every 12 months other than in reliance on this rule.

We have not established a minimum amount of proceeds that we must receive in the offering before any proceeds may be accepted. We cannot assure you that all or any of the shares offered under this prospectus will be sold. No one has committed to purchase any of the shares offered. We reserve the right to withdraw, cancel or modify this offer and to accept or reject any subscription in whole or in part, for any reason or for no reason. Subscriptions will be accepted or rejected promptly. All monies from rejected subscriptions will be returned immediately by us to the subscriber, without interest or deductions. Any accepted subscriptions will be made on a rolling basis. Once accepted, the funds will be deposited into an account maintained by us and considered general assets of BioSante. Subscription funds will not be placed into escrow, trust or any other similar arrangement. There are no investor protections for the return of subscription funds once accepted. Certificates for shares purchased will be issued and distributed by our transfer agent within 10 business days after a subscription is accepted and "good funds" are received in our account. Certificates will be sent to the address supplied in the investor subscription agreement by certified mail.

Our officers, directors, existing stockholders and affiliates may purchase shares in this offering and there is no limit to the number of shares they may purchase.

USE OF PROCEEDS

If all of the shares offered hereby are sold, we will receive net proceeds of approximately $9,927,080, after payment of offering expenses. This amount of the proceeds will be up to 10% or $1,000,000 less if we use a broker, dealer or sales agent to assist us in offering and selling the shares. We cannot assure you that we will sell any shares or receive any proceeds. We estimate that we will use approximately $8.0 million of the net proceeds received in this offering for expenses related to the human clinical development of our hormone replacement products and the remaining amount for general corporate purposes, including working capital and funding operating losses. Pending these uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities.

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.

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. From September 10, 1999 to May 4, 2000, our common stock was traded in the United States on the National Quotation Bureau, commonly referred to as the "Pink Sheets," under the symbol "BTPH."

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

OTC Bulletin Board

2002	High	Low
First Quarter	$ 7.90	$ 5.10
Second Quarter	$ 7.00	$ 3.60
Third Quarter (through August 13, 2002)	$ 5.25	$ 3.80

2001	High	Low
First Quarter	$ 7.50	$ 3.80
Second Quarter	$ 10.70	$ 3.90
Third Quarter	$ 10.00	$ 4.60
Fourth Quarter	$ 10.50	$ 4.80

2000	High	Low
Second Quarter	$ 12.50	$ 4.70
Third Quarter	$ 10.30	$ 8.00
Fourth Quarter	$ 9.20	$ 5.20

National Quotation Bureau ("Pink Sheets")

2000	High	Low
First Quarter	$ 15.00	$ 2.80

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

2000	High	Low
First Quarter	$ 13.80	$ 2.20
Second Quarter	$ 10.70	$ 4.60
Third Quarter	$ 10.10	$ 7.10
Fourth Quarter	$ 9.50	$ 4.90

As of August 13, 2002, there were 713 record holders of our common stock and 10 record holders of our class C stock.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2002:

- on an actual basis;
- on an as adjusted basis (without broker commissions) to reflect the sale of 5,000,000 shares of common stock at a public offering price of $2.00 per share and our receipt of estimated net proceeds of $9,927,080 from the offering, after deducting estimated offering expenses and assuming no broker, dealer or sales agent commissions are paid; and
- on an as adjusted basis (with broker commissions) to reflect the sale of 5,000,000 shares of common stock at a public offering price of $2.00 per share and our receipt of estimated net proceeds of $8,927,080 from the offering, after deducting estimated offering expenses and assuming the payment of broker, dealer or sales agent commissions equal to 10% of the aggregate selling price of the shares.

Because the shares being offered in this offering are being offered and sold by us on a best efforts basis, we may not sell all or any of the shares and therefore may not receive all or any of the net proceeds in this offering.

You should read the information presented below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. For a description of our capital stock, you should read the information under the caption "Description of Capital Stock."

	June 30, 2002		
	Actual	As Adjusted (without broker commissions)	As Adjusted (with broker commissions)
Stockholders' equity:			
Undesignated preferred stock, par value $0.0001 per share; 10,000,000 shares authorized; no shares issued and outstanding (actual and as adjusted)	$ —	$ —	$ —
Common stock, par value $0.0001 per share; 100,000,000 shares authorized; 6,321,458 shares issued and outstanding (actual); 11,321,458 shares issued and outstanding (as adjusted)	22,255,342	32,182,422	31,182,422
Class C special stock, par value $0.0001 per share; 4,687,684 shares authorized; 466,602 shares issued and outstanding (actual and as adjusted)	467	467	467
Accumulated deficit	(20,849,323)	(20,849,323)	(20,849,323)
Total stockholders' equity	1,406,486	11,333,566	10,333,566

Total capitalization	$ 1,406,486	$ 11,333,566	$ 10,333,566

The outstanding share information excludes 771,267 shares of common stock issuable upon exercise of outstanding options as of June 30, 2002 with a weighted average exercise price of $3.88 and warrants to purchase 1,643,750 shares of common stock with a weighted average exercise price of $3.70 per share.

DILUTION

Our net tangible book value as of June 30, 2002 was $1,406,486 or $0.22 per common share. Net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of shares of our common stock outstanding. After giving effect to the sale of the 5,000,000 shares of common stock offered by this prospectus at a public offering price of $2.00 and after deducting estimated offering expenses and assuming no broker, dealer or sales agent commissions are paid, and without taking into account any other changes in our net tangible book value after June 30, 2002, our net tangible book value as of June 30, 2002 would have been $11,333,566, or $1.00 per common share. This represents an immediate increase in net tangible book value of $0.78 per common share to our existing stockholders and an immediate and substantial dilution of $1.00 per common share to new investors. Dilution is an accounting concept that refers to the difference between what an investor pays for shares of a company and the book value of the shares immediately after the transaction. Whenever the book value per share is less than the investor paid, the investor suffers dilution. The dilution to investors in the offering is as illustrated in the following table:

		As Adjusted (without broker commissions)
Public offering price per share		$ 2.00
Net tangible book value per common share before the offering	$ 0.22	
Increase per share attributable to new investors	0.78	
As adjusted net tangible book value per common share after the offering, assuming no broker, dealer or sales agent commissions are paid		1.00
Dilution per common share to new investors		$ 1.00

After giving effect to the sale of the 5,000,000 shares of common stock offered by this prospectus at a public offering price of $2.00 and after deducting estimated offering expenses and assuming the payment of broker, dealer or sales agent commissions equal to 10% of the aggregate selling price of the shares, and without taking into account any other changes in our net tangible book value after June 30, 2002, our net tangible book value as of June 30, 2002 would have been $10,333,566, or $0.91 per common share. This represents an immediate increase in net tangible book value of $0.69 per common share to our existing stockholders and an immediate and substantial dilution of $1.09 per common share to new investors. The dilution to investors in the offering is as illustrated in the following table:

		As Adjusted (with broker commissions)
Public offering price per share		$ 2.00
Net tangible book value per common share before the offering	$ 0.22	
Increase per share attributable to new investors	0.69	
As adjusted net tangible book value per common share after the offering, assuming the payment of broker or sales agent commissions		0.91
Dilution per common share to new investors		$ 1.09

SELECTED CONSOLIDATED FINANCIAL DATA

The selected statement of operations data shown below for the years ended December 31, 1999, 2000 and 2001 and the balance sheet data as of December 31, 2000 and 2001 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, 1996 and for the years ended December 31, 1997 and 1998 and the balance sheet data as of December 31, 1997, 1998 and 1999 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, 2001 and 2002 and the balance sheet data as of June 30, 2002 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, 2001 and 2002 are not necessarily indicative of the results to be expected for the full year or for any future period. All share and per share numbers have been adjusted to reflect the one-for-ten reverse stock split effected on May 31, 2002. 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, 1996	Year Ended December 31,					Six Months Ended June 30,	
		1997	1998	1999	2000	2001	2001	2002
	(in thousands, except per share and share data)							
Statement of Operations Data:								
Licensing income	$ —	$ —	$ —	$ —	$ —	$ 1,747	$ —	$ —
Interest income	53	144	123	199	228	175	83	30
Total income	53	144	123	199	228	1,922	83	30
Expenses:								

Research and development	—	336	1,400	661	1,888	2,142	620	1,632
General and administration	547	1,618	1,112	853	1,679	2,299	963	951
Depreciation and amortization	1	52	140	91	98	92	49	45
Loss on disposal of capital assets	—	28	130	—	—	—	—	—
Total expenses	548	2,034	2,782	1,605	3,665	4,533	1,632	2,628
Loss before other expenses	(495)	(1,890)	(2,659)	(1,406)	(3,437)	(2,611)	(1,549)	(2,598)
Cost of acquisition of Structured Biologicals, Inc.	375	—	—	—	—	—	—	—
Purchased in-process research and development	5,377	—	—	—	—	—	—	—
Total other expenses	5,752	—	—	—	—	—	—	—
Net loss	$ (6,247)	$ (1,890)	$ (2,659)	$ (1,406)	$ (3,437)	$ (2,611)	$ (1,549)	$ (2,598)
Basic and diluted net loss per share	$ (2.56)	$ (0.53)	$ (0.76)	$ (0.28)	$ (0.60)	$ (0.40)	$ (0.25)	$ (0.38)
Weighted average number of shares outstanding	2,437	3,596	3,486	4,942	5,754	6,485	6,209	6,788

The as adjusted column (without broker commissions) in the balance sheet data below gives effect to the sale of 5,000,000 shares of common stock in this offering at a public offering price of $2.00 per share, after deducting estimated offering expenses and assuming no broker, dealer or sales agent commissions are paid. The as adjusted column (with broker commissions) in the balance sheet data below gives effect to the sale of shares of common stock in this offering at a public offering price of $2.00 per share, after deducting estimated offering expenses and assuming the payment of broker, dealer or sales agent commissions equal to 10% of the aggregate selling price of the shares. Because

the shares being offered in this offering are being offered and sold by us on a best efforts basis, we may not sell all or any of the shares and therefore may not receive all or any of the net proceeds in this offering.

	As of December 31,					As of June 30,		
	1997	1998	1999	2000	2001	Actual	2002 As Adjusted (without broker commissions)	2002 As Adjusted (with broker commissions)
	(in thousands)							
Balance Sheet Data:								
Cash and cash equivalents	$ 1,750	$ 2,841	$ 5,275	$ 2,612	$ 4,502	$ 1,704	$ 11,631	$ 10,631
Working capital	356	2,099	5,004	1,735	3,666	1,041	10,968	9,968
Total assets	2,450	3,449	5,780	3,067	4,979	2,142	12,069	11,069
Convertible debenture—current	—	—	—	500	—	—	—	—
Stockholders' equity	1,034	2,631	5,451	2,126	4,051	1,406	11,333	10,333

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

The following discussion of BioSante's financial condition and results of operations should be read in conjunction with BioSante's financial statements and related notes included elsewhere in this registration statement and the cautionary statements concerning forward-looking statements presented in the sections entitled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements."

General

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

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

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

- LibiGel—a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.
- Bio-T-Gel—a transdermal testosterone gel in development for testosterone deficiency in men.
- Bio-E-Gel—a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.
- Bio-E/P-Gel—a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.
- LibiGel-E/T—a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

These gel products are designed to be quickly absorbed through the skin after application on the arms, abdomen or thighs, delivering the required hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day and to be absorbed into the skin without a trace of residue.

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

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

approximately $600,000 of manufacturing and formulation services and a license for the combination estradiol plus testosterone gel product. In August 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.

In September 2000, we sub-licensed the marketing rights to our portfolio of female hormone replacement products in Canada to Paladin Labs Inc. In exchange for the sub-license, Paladin agreed to make an initial investment in our company, make future milestone payments and pay royalties on sales of the products in Canada. The milestone payments will be in the form of a series of equity investments by Paladin in BioSante common stock at a 10 percent premium to the market price of our stock at the time the equity investment is made. Upon execution of the sub-license agreement, Paladin made an initial investment of $500,000 in our company in the form of a convertible debenture, convertible into our common stock at $10.50 per share. On August 13, 2001, BioSante exercised its right and declared the debenture converted in full. Accordingly, 47,619 shares of BioSante common stock were issued to Paladin on August 23, 2001. During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 18,939 shares of its common stock to Paladin.

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

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

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

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

license agreement covers access to Bio-Vant for a variety of cancer, infectious and auto immune disease vaccines.

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

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

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

All of our revenue to date has been derived from interest earned on invested funds and license payments earned on sub-licensing transactions. We have not commercially introduced any products. Since our inception, we have experienced significant operating losses. We incurred a net loss of $2,598,290 for the six month period ended June 30, 2002, resulting in an accumulated deficit of $20,849,323. We expect that we will incur substantial and continuing losses for the foreseeable future as our product development programs expand and various preclinical and clinical trials commence. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend upon, among other factors:

- the timing and cost of product development;
-

the progress and cost of preclinical and clinical development programs;

- the costs of licensure or acquisition of new products
- the timing and cost of obtaining necessary regulatory approvals; and
- the timing and cost of obtaining third party reimbursement.

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

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 share and per share numbers in this prospectus have been adjusted to reflect the reverse stock split.

Results of Operations

Three Months Ended June 30, 2002 Compared to Three Months Ended June 30, 2001

General and administrative expenses decreased slightly from $497,972 during the three month period ended June 30, 2001 to $491,851 during the three month period ended June 30, 2002.

Research and development expenses increased from $387,236 during the three month period ended June 30, 2001 to $987,528 during the three month period ended June 30, 2002. This increase is the result of increased expenses during the three month period ended June 30, 2002 associated with the clinical development of our hormone replacement product portfolio. As a result of our hormone replacement product clinical development, we expect that our research and development expenses will continue to increase significantly in future periods. We also 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.

Interest income decreased from $50,843 during the three month period ended June 30, 2001 to $6,712 during the three month period ended June 30, 2002 as a result of lower interest rates coupled with lower invested cash balances between the three month periods.

We incurred a net loss of $1,495,364 for the three month period ended June 30, 2002, compared to a net loss of $858,913 for the three month period ended June 30, 2001. The increase in the net loss is the result of increased expenses associated with the clinical development of our hormone replacement product portfolio. We anticipate that our operating losses will continue for the foreseeable future.

Six Months Ended June 30, 2002 Compared to Six Months Ended June 30, 2001

General and administrative expenses decreased slightly from $963,030 during the six month period ended June 30, 2001 to $950,980 during the six month period ended June 30, 2002.

Research and development expenses increased from $620,225 during the six month period ended June 30, 2001 to $1,631,922 during the six month period ended June 30, 2002. This increase is the result of increased expenses during the six month period ended June 30, 2002 associated with the clinical development of our hormone replacement product portfolio. As a result of our hormone replacement product clinical development, we expect that our research and development expenses will continue to increase significantly in future periods.

Interest income decreased from $82,952 during the six month period ended June 30, 2001 to $29,971 during the six month period ended June 30, 2002 as a result of lower interest rates coupled with lower invested cash balances between the six month periods. We expect interest income to decline in future periods as we use our cash balances for operations.

BioSante incurred a net loss of $2,598,290 for the six month period ended June 30, 2002, compared to a net loss of $1,548,813 for the six month period ended June 30, 2001. The increase in the net loss is the result of increased expenses associated with the clinical development of our hormone replacement product portfolio. We anticipate that our operating losses will continue for the foreseeable future.

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

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

Research and development expenses increased from $1,887,832 during the year ended December 31, 2000 to $2,141,944 during the year ended December 31, 2001. This overall increase is the result of increased expenses during the year ended December 31, 2001 associated with the clinical development of our hormone replacement product portfolio and payment to Antares for certain

manufacturing and formulation services, offset by a $1.0 million upfront license fee paid to Antares during the year ended December 31, 2000. 2001 also included recognition of a $250,000 credit from Antares, which represented the portion of the initial $1.0 million upfront license fee paid in 2000 which was creditable against future payments. As a result of our hormone replacement product in-license agreement with Antares, we expect to continue to incur significant expenses, primarily relating to our research and development activities. Management estimates that it is currently expending approximately $300,000 to $400,000 per month on research and development activities and approximately $400,000 to $500,000 per month in total expenses, including research and development activities. We are required under the terms of our license agreement with the University of California to have available certain amounts of funds for research and development activities. The amount of BioSante's actual research and development expenditures, however, may fluctuate from quarter-to-quarter and year-to-year depending on: (1) the resources available; (2) our development schedule; (3) results of studies, clinical trials and regulatory decisions; and (4) competitive developments.

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

Interest income decreased from $227,718 during the year ended December 31, 2000 to $174,416 during the year ended December 31, 2001 as a result of lower average cash balances in 2001 and as a result of lower interest rates on invested cash balances in 2001. We expect interest income to decline in future periods as we use our cash balances for operations.

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

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

General and administrative expenses increased from $853,389 during the year ended December 31, 1999 to $1,678,581 during the year ended December 31, 2000. This increase of approximately 97% is due primarily to expenses related to personnel-related expenses and the higher legal expenses related to the increase in our patent, collaboration and licensing activities.

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

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

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

Liquidity and Capital Resources

To date, we have raised equity financing and received licensing income to fund our operations, and we expect to continue this practice to fund our ongoing operations. Since inception, we have raised net proceeds of approximately $12.9 million from private equity financings, class A and class C stock conversions, warrant exercises and in the third quarter 2000, the issuance of a $500,000 convertible debenture, which was converted into 47,619 shares of common stock in the third quarter of 2001. In addition, as a result of licensing upfront payments and milestones, we have received an additional $2.1 million.

Six Months Ended June 30, 2002 Compared to Six Months Ended June 30, 2001

Our cash and cash equivalents were $1,704,495 and $4,502,387 at June 30, 2002 and December 31, 2001, respectively. The decrease in our cash balances is due primarily to cash used in operating activities. We used cash in operating activities of $2,725,352 for the six month period ended June 30, 2002 versus cash used in operating activities of $1,481,763 for the six month period ended June 30, 2001. This change reflects the cash expenditures associated with: (1) increased research and development and associated personnel-related expenses, (2) increased expenses related to the clinical development of our hormone replacement product portfolio and expenses related to manufacturing and formulation services provided by Antares, and (3) reduction of accounts payable and accrued expenses. Net cash used in investing activities was $25,836 for the six month period ended June 30, 2002 versus $22,546 used in investing activities for the six month period ended June 30, 2001. The uses of cash in investing activities during both six month periods ended June 30, 2002 and 2001 were capital expenditures for the purchases of computer equipment. Net cash used in financing activities was $46,704 for the six months ended June 30, 2002 compared to net cash provided by financing activities of $3,674,612 for the six months ended June 30, 2001. The net cash used in financing activities of $46,704 was the result of transaction costs associated with a current and previous financing, while the net cash provided during the six months ended June 30, 2001 was the result of the receipt of cash proceeds (net of transaction costs) from our private placement of units which closed in April 2001 and licensing milestone payments received.

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 replacement product portfolio and expenses related to manufacturing and formulation services provided by Antares. Offsetting these increased expenses for the year ended December 31, 2001 is the recognition of $1.7 million of licensing revenues pursuant to the Solvay sub-license agreement versus the year ended December 31, 2000 and the $1.0 million upfront license fee payment to Antares paid in

June 2000. Net cash used in investing activities was $86,735 for the year ended December 31, 2001 versus $43,238 for the year ended December 31, 2000. The significant uses of cash in investing activities for the year ended December 31, 2001 and 2000 included capital expenditures for computer equipment. Additionally, during the year ended December 31, 2001, we relocated our business office thus incurring the capital expenditures of used office equipment and furniture. Net cash provided by financing activities was $3,801,187 for the year ended December 31, 2001 compared to $530,045 for the year ended December 31, 2000. Net cash provided during 2001 was primarily the result of $3.7 million cash proceeds pursuant to our private placement of common stock and warrants which closed in April 2001 and licensing milestone payments received while net

cash provided during 2000 was primarily the result of a $500,000 convertible debenture issued to Paladin Labs Inc. pursuant to a sub-license agreement related to our proposed female hormone replacement products.

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

We used cash in operating activities of $3,149,604 for the year ended December 31, 2000 versus cash used in operating activities of $1,787,822 for the year ended December 31, 1999. This change was driven by the increase in research and development expenses, including the hormone product portfolio in-license upfront payment of $1.0 million to Antares Pharma, Inc. during 2000. Net cash used in investing activities was $43,238 for the year ended December 31, 2000 versus $4,219 for the year ended December 31, 1999. The significant uses of cash in investing activities for the year ended December 31, 2000 were capital expenditures for the purchase of office furniture and computer equipment. The significant uses of cash in investing activities for the year ended December 31, 1999 included capital expenditures for office furniture and a computer. Net cash provided by financing activities was $530,045 for the year ended December 31, 2000 compared to $4,225,343 for the year ended December 31, 1999. Net cash provided during 2000 was primarily the result of a $500,000 convertible debenture issued to Paladin Labs Inc. pursuant to a sub-license agreement related to our proposed female hormone replacement products. Net cash provided in 1999 was primarily the result of our private placement in May 1999.

Capital Resources

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

- research and development programs;
- pre-clinical studies and clinical trials;
- regulatory processes;
- establishment of our own marketing capabilities or a search for third party manufacturers and marketing partners to manufacture and market our products for us; and
- the licensure or acquisition of new products.

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

- progress, timing and scope of our research and development programs;
- progress, timing and scope of our pre-clinical studies and clinical trials;
- time and cost necessary to obtain regulatory approvals;

- time and cost necessary to seek third party manufacturers to manufacture our products for us;
- time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;
- time and cost necessary to respond to technological and market developments;
- changes made or new developments in our existing collaborative, licensing and other commercial relationships; and
- new collaborative, licensing and other commercial relationships that we may establish.

Commitments

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

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

- pay minimum annual royalties on February 28 of each year beginning in the year 2004 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

- maintain an annual minimum amount of available capital for development and commercialization of products incorporating the licensed technology until a product is introduced to the market; and
- pay the costs of patent prosecution and maintenance of the patents included in the agreement.

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

- enter into additional leases for new facilities and capital equipment;
- enter into additional licenses and collaborative agreements; and
- incur additional expenses associated with being a public company.

In addition to the commitments to the University of California, we also have minimum annual lease payments.

The following table summarizes the timing of these future contractual obligations and commitments:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating Leases	$ 211,292	$ 151,578	$ 59,714	$ —	$ —
Commitments Under License Agreement with UCLA	6,800,000	—	150,000	$ 350,000	$ 6,300,000
Commitments Under License Agreement with Wake Forest	1,140,000	—	55,000	145,000	940,000
Total Contractual Cash Obligations	$ 8,151,292	$ 151,578	$ 264,714	$ 495,000	$ 7,240,000

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

Outlook

We currently do not have sufficient resources to complete the commercialization of any of our proposed products. Based on our current cash resources, we believe we should be able to maintain our current pace and level of expenditures through December 2002, although no assurance can be given that we will not need additional cash prior to such time. Unexpected increases in general and administrative expenses and research and development expenses may cause us to need additional financing prior to December 2002. If we do not sell any of the shares offered in this offering, we believe our existing cash will be sufficient to fund our operations through December 2002. If we are able to sell all of the shares offered in this offering, we believe that with the net proceeds of this offering and our existing cash, we will have sufficient working capital to meet our needs through December 2003. We have based these estimates, 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. If we are unable to sell any shares offered in this offering, we will be required to seek alternative forms of equity or debt financing. Any equity financing may be dilutive to our existing shareholders, 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 required under the terms of our license agreement with the University of California, however, to have available certain amounts of funds for research and development activities.

BUSINESS

General

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

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

- accelerate the development of our hormone replacement products;
- continue to develop our nanoparticle-based platform technology, or CAP, and seek assistance in such development through corporate partner sub-licenses;
- license or otherwise acquire other drugs that will add value to our current product portfolio; and
- implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies.

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

Our proposed hormone replacement products, which we license on an exclusive basis from Antares Pharma Inc., are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone and a combination of estradiol and a progestogen. The gels are designed to be absorbed quickly through the skin after application on the arms, shoulders, abdomen or thighs, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. Human clinical trials have begun on four of our proposed hormone replacement products, a necessary step in the process of obtaining United States Food and Drug Administration, or FDA, approval to market the products.

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

- LibiGel—a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.
- Bio-T-Gel—a transdermal testosterone gel in development for testosterone deficiency in men.
- Bio-E-Gel—a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.
- Bio-E/P-Gel—a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.
- LibiGel-E/T—a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

Our CAP technology, which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call "nanoparticles," as immune system boosters, for drug delivery, 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 by selectively isolating biologically active therapeutic proteins from the transgenic milk.

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

- Bio-Vant—CAP adjuvant technology—new proprietary CAP technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases.
- Bio-Air—advanced proprietary technology using CAP as a delivery system for inhalable versions of therapies that currently must be injected.
- CAP-Oral—an advanced delivery system using proprietary CAP technology for oral administration of therapies that currently must be injected.
- CAP biotechnology production—use of CAP technology in a new patented process for extracting therapeutic proteins from transgenic milk.

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

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.

Business Strategy

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

- ***Accelerate the development of our hormone replacement products***. We are focused on building a pipeline of hormone replacement products for the treatment of human hormone deficiencies. Symptoms of hormone deficiency in men include impotence, lack of sex drive, muscle weakness and osteoporosis, and in women, menopausal symptoms, such as hot flashes, vaginal atrophy, decreased libido and osteoporosis. Human clinical trials have begun on four of our proposed hormone replacement products, a necessary step in the process of obtaining FDA approval to market the products.
- Continue to develop our nanoparticle-based CAP platform technology and seek assistance in the development through corporate partner sub-licenses. We are seeking opportunities to enter into business collaborations, joint ventures or sub-licenses with companies that have businesses or technologies complementary to our CAP technology business, such as vaccine and drug delivery pharmaceutical companies and transgenic milk companies. We believe that this partnering

strategy will enable us to capitalize on our partners' strengths in product development, manufacturing and commercialization and thereby enable us to introduce into the market products incorporating our CAP technology sooner than which we otherwise would be able. In addition, we believe these collaborations would significantly reduce our cash requirements for developing and commercializing products incorporating our CAP technology.

- ***Implement business collaborations or joint ventures with other pharmaceutical and biotechnology companies***. We intend to seek opportunities to enter into business collaborations or joint ventures with entities that have businesses or technology complementary to our business. We are particularly interested in entering into product co-development and co-marketing arrangements.
- ***License or otherwise acquire other drugs that will add value to our current product portfolio***. We intend to seek opportunities to in-license or otherwise acquire other products in the late-stage development phase or products already on the market. In seeking these opportunities, we intend to target products that cover therapeutic areas treated by a limited number of physicians and drugs that are in or require human clinical trials that involve a limited number of patients and not a significant amount of time and cost needed to complete them. We believe that targeting these products that are currently in or ready for human clinical trials would decrease the risks associated with product development and would likely shorten the time before we can introduce the products into the market. In addition to late-stage development products, we intend to seek opportunities to in-license or otherwise acquire products that (1) have FDA approval, (2) have

been or are about to be commercially introduced into the U.S. markets, (3) have a concentrated physician prescriber audience, and (4) have the potential to generate significant sales. This element of our strategy is of a lower priority than the others since we currently have a full portfolio in development.

Description of Our Proposed Hormone Replacement Products

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

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

- LibiGel—a transdermal testosterone gel in clinical development for treatment of female sexual dysfunction.
- Bio-T-Gel—a transdermal testosterone gel in development for testosterone deficiency in men.
- Bio-E-Gel—a transdermal gel containing estradiol in development for estrogen deficiency in women, including menopausal symptoms.
- Bio-E/P-Gel—a transdermal gel containing estrogen and progestogen in development for estrogen deficiency.
- LibiGel-E/T—a transdermal gel containing estrogen and testosterone in development for treatment of female sexual dysfunction.

Testosterone deficiency in men is known as hypogonadism. Low levels of testosterone may result in lethargy, depression, decreased sex drive, impotence, low sperm count and increased irritability. Men with severe and prolonged reduction of testosterone may also experience loss of body hair, reduced

muscle mass, osteoporosis and bone fractures due to osteoporosis. Approximately five million men in the United States, primarily in the over age 40 male population group, have lower than normal levels of testosterone. Testosterone replacement therapy has been shown to restore levels of testosterone with minimal side effects.

Testosterone often is delivered through injections or dermal, or skin, patches. Delivery of testosterone through dermal patches was developed primarily to promote the therapeutic effects of testosterone replacement therapy without the often painful side effects associated with testosterone injections. Dermal patches, however, have been associated with skin irritation. Our testosterone formulated gel product for men, Bio-T-Gel, is designed to deliver the required amount of testosterone without the pain of injections and the skin irritation and discomfort associated with dermal patches. We are aware of one gel testosterone product for men currently on the market in the United States and several in development.

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

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

Through a sub-license agreement with Solvay Pharmaceuticals, B.V., we are in the process of developing a combined estrogen/progestogen formulated gel product. Women whose uterus is intact often use a combined hormone replacement therapy because evidence suggests adding progestogen to estrogen therapy may reduce the potential risks of endometrial cancer and endometrial hyperplasia associated with estrogen therapy in these women. In July 2002, the National Institutes of Health announced that it was discontinuing the estrogen-progestin oral tablet combination arm of the Women's Health Initiative study because Prempro, the combination oral HRT product used in the study, caused an increase in the risk of invasive breast cancer after an average of 5.2 years on therapy. 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 progestin in Prempro. The Women's Health Initiative 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 HRT products 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 replacement therapy can boost sexual desire and pleasure, increase bone density, raise energy levels and improve mood. Similarly, we are developing a combination gel product of testosterone and estradiol for women, LibiGel-E/T, for low libido or sex drive.

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

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

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

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

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

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

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

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

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 BioSante, regulatory milestones, maintenance payments and royalty payments by BioSante if the product gets approved and subsequently marketed.

Description of Our CAP Technology and Proposed CAP Technology Products

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our nanoparticles when combined with vaccine antigens have been shown in animal studies conducted by us and others to possess an ability to elicit a higher immune response than non-adjuvanted vaccines and an immune response of the same magnitude as alum-formulated vaccines but up to 100 times lower concentrations. These preclinical studies also have shown that our CAP nanoparticles also may sustain higher antibody levels over a longer time period than both alum-formulated vaccines and non-adjuvanted vaccines. Because our CAP nanoparticles are made of calcium phosphate, which has a chemical nature similar to normal bone material and therefore is natural to the human body, as opposed to aluminum hydroxide, or alum, which is not natural to the human body, we believe that our nanoparticles may be safer to use than alum. In our animal studies,

we observed no material adverse reactions when our CAP nanoparticles were administered at effective levels.

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

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

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

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

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

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

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

Drug delivery systems. The third field of use in which we are exploring applying our CAP technology involves creating novel and improved forms of delivery of drugs, including proteins (*e.g.*, insulin). The attachment of drugs to CAP may enhance their effects in the body or enable the addition of further protective coatings to permit oral, delayed-release and mucosal (through mucous membranes) applications. Currently, insulin is given by frequent, inconvenient and often painful injections. However, several companies are in the process of developing and testing products that will deliver insulin orally or through inhalation. We believe we may have successfully created a formulation

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

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

Sales and Marketing

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

Research and Product Development

We expect to spend a significant amount of our financial resources on research and development activities. We spent approximately $1,632,000 for the six month period ended June 30, 2002, $2,142,000 in the year ended 2001 and $1,888,000 in the year ended 2000 on research and development activities. Since we are not yet engaged in the commercial distribution of any products and we have no revenues from the sale of our products, these research and development costs must be financed by us. We estimate that we are currently spending approximately $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.

Manufacturing

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

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

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

Patents, Licenses and Proprietary Rights

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

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

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

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

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

- payment of royalties to the University based on a percentage of the net sales of any products we sell incorporating the licensed technology;
- payment of minimum annual royalties on February 28 of each year beginning in the year 2004 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 $11,358 in fiscal 2001;
- meeting performance milestones relating to:
    - hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;
    - testing proposed products;
    - conducting clinical trials;
    - obtaining government approvals;
    - introducing products incorporating the licensed technology into the market; and
- entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.

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

Patents and patent applications. We own one United States patent and no foreign patents. In June 1999, we filed a patent for our advanced method of selectively isolating biologically active therapeutic proteins from transgenic milk. This patent was issued in February 2001. In February 2000, we filed a patent application with the U.S. Patent and Trademark Office relating to our development

work with vaccine adjuvants, conventional DNA and RNA vaccines and drug delivery, including aerosol delivery into the lungs. In addition, there are two other patent applications pending for products in development.

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

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

Competition

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

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

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

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

We are aware of certain programs and products under development by others which may compete with our proposed hormone replacement products and products we may develop that incorporate our

CAP technology. Several competing companies, including Wyeth-Ayerst Pharmaceuticals, Novartis AG, Solvay Pharmaceuticals, Inc., Noven Pharmaceuticals, Inc. and Berlex Laboratories, Inc., dominate the international hormone replacement industry. The international vaccine industry is dominated by three companies: GlaxoSmithKline, Aventis (through its subsidiaries, including Institut Merieux International, Pasteur Merieux Serums et Vaccins, Connaught Laboratories Limited and Connaught Laboratories, Inc.) and Merck & Co., Inc.

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

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

Governmental Regulation

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

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

- preclinical laboratory and animal tests;
- the submission to the FDA of an investigational new drug application, commonly known as an IND application;
- clinical and other studies to assess safety and parameters of use;
- adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug product;
- the submission to the FDA of a new drug application, commonly known as an NDA; and
- FDA approval of the NDA prior to any commercial sale or shipment of the product.

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

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

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

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

A clinical trial may combine the elements of more than one Phase and typically two or more Phase III studies are required. A company's designation of a clinical trial as being of a particular Phase is not necessarily indicative that this trial will be sufficient to satisfy the FDA requirements of that Phase because this determination cannot be made

until the protocol and data have been submitted to and reviewed by the FDA. In addition, a clinical trial may contain elements of more than one Phase notwithstanding the designation of the trial as being of a particular Phase. The FDA closely monitors the progress of the phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based on the data accumulated and its assessment of the risk/benefit ratio to patients. It is not possible to estimate with any certainty the time required to complete Phase I, II and III studies with respect to a given product.

Upon the successful completion of clinical testing, an NDA is submitted to the FDA for approval. This application requires detailed data on the results of preclinical testing, clinical testing and the composition of the product, specimen labeling to be used with the drug, information on manufacturing methods and samples of the product. The FDA typically takes from six to 18 months to review an NDA after it has been accepted for filing. Following its review of an NDA, the FDA invariably raises questions or requests additional information. The NDA approval process can, accordingly, be very lengthy. Further, there is no assurance that the FDA will ultimately approve an NDA. If the FDA approves that NDA, the new product may be marketed. The FDA often approves a product for marketing with a modification to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, be conducted.

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

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

Employees

We had twelve full-time employees as of June 30, 2002, including nine in research and development and three 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 13, 2002:

Name	Age	Title
Stephen M. Simes	50	Vice Chairman, President and Chief Executive Officer
Phillip B. Donenberg	42	Chief Financial Officer, Treasurer and Secretary
Leah M. Lehman, Ph.D.	39	Vice President, Clinical Development
Steven J. Bell, Ph.D.	42	Vice President, Research and Pre-Clinical Development
Louis W. Sullivan, M.D. (1)(2)(3)	68	Chairman of the Board
Victor Morgenstern (2)	59	Director
Fred Holubow (3)	63	Director
Ross Mangano (1)	56	Director
Edward C. Rosenow III, M.D. (3)	67	Director
Angela Ho (2)	49	Director
Peter Kjaer (1)	41	Director

(1) Member of the audit and finance committee

(2) Member of the compensation committee

(3) 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. 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 Bush from 1989 to 1993. Since retiring from the Bush Administration, Dr. Sullivan is currently President Emeritus of the Morehouse School of Medicine in Atlanta, Georgia. He had previously served as President and Dean of the School from 1981 to 1985 and 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. and Household International Inc.

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. 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 Boards for Bio-Technology General Corp., ThermoRetec Corporation, Gynex Pharmaceuticals, Inc., Unimed Pharmaceuticals, Inc. and Gynex 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 is the Chairman of Cerprobe Corporation, and serves as a director for Blue Chip Casino, Inc., Orchard Software Corporation, 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 of 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 was elected to our Board of Directors as a representative of certain major investors in Hong Kong. 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 and is a representative of certain major investors in Hong Kong. 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.

Board Committees

The Board of Directors has an Audit and Finance Committee, Compensation Committee and Scientific Review Committee.

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 consists of Mr. Kjaer, Dr. Sullivan and Mr. Mangano.

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 as compensation to be paid to our officers and directors; and
- administers our stock option 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. Morgenstern 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, Mr. Holubow and Dr. Rosenow.

Director Compensation

We do not pay fees to our directors. We do, however, periodically compensate our directors through the granting of stock options. On January 1, 2001, we granted stock options to purchase 2,500 shares of common stock to each of our non-employee directors. These options have an exercise price of $6.70 per share, fully vest on January 1, 2002 and expire ten years from the date of grant. All directors are reimbursed for travel expenses for attending meetings of the Board of Directors and any Board committees.

Executive 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, 2001.

Summary Compensation Table

		Annual Compensation		Long-Term Compensation	
Name and Principal Position	Year	Salary ($)	Bonus ($)	Securities Underlying Options (#)	All Other Compensation ($)
Stephen M. Simes	2001	$ 291,500	$ 131,175	71,406	$ 18,388(3)
Vice Chairman, President and	2000	275,000	150,000(1)	0	29,317(3)
Chief Executive Officer	1999	248,917	125,000(2)	185,625	22,965(3)
Phillip B. Donenberg	2001	150,000	45,000	21,546	13,592(6)
Chief Financial Officer, Treasurer	2000	127,000	42,000(4)	0	13,286(6)
and Secretary	1999	110,000	33,000(5)	52,187	13,001(6)
Leah M. Lehman, Ph.D.	2001	180,000	54,000	50,000	12,450(7)
Vice President, Clinical	2000	—	—	—	—
Development	1999	—	—	—	—
Steven J. Bell, Ph.D.	2001	102,000	30,000	5,000	11,250(9)
Vice President, Research and	2000	91,521	26,000(8)	0	11,250(9)
Pre-Clinical Development	1999	85,313	10,000	12,500	6,500(9)
John E. Lee (10)	2001	146,407	—	—	9,338(11)
Former Vice President,	2000	70,833	—	50,000	81,470(11)
Commercial Development	1999	—	—	—	—

(1) Represents a cash bonus of $75,000 and a stock bonus of 12,500 shares of common stock valued at $75,000.

(2) Represents a cash bonus of $75,000 and a stock bonus of 16,385 shares of common stock valued at $50,000.

(3) Represents an auto allowance ($12,000 in 2001, $12,000 in 2000 and $12,000 in 1999), a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999) and insurance premiums and taxes associated with the premiums ($1,138 in 2001, $12,067 in 2000 and $5,965 in 1999).

(4) Represents a cash bonus of $30,000 and a stock bonus of 2,000 shares of common stock valued at $12,000.

(5) Represents a cash bonus of $25,000 and a stock bonus of 2,621 shares of common stock valued at $8,000.

(6) Represents an auto allowance ($7,200 in 2001, $7,200 in 2000 and $7,200 in 1999), a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999) and insurance premiums paid and taxes associated with the premiums ($1,142 in 2001, $836 in 2000 and $801 in 1999).

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

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

(9) Represents an auto allowance ($6,000 in 2001, $6,000 in 2000 and $1,500 in 1999) and a 401(k) matching contribution ($5,250 in 2001, $5,250 in 2000 and $5,000 in 1999).

(10) Mr. Lee was Vice President, Commercial Development from August 2000 to September 2001. Mr. Lee resigned as Vice President, Commercial Development on September 28, 2001.

(11) Represents an auto allowance ($5,400 in 2001 and $3,000 in 2000), a 401(k) matching contribution ($3,938 in 2001 and $2,188 in 2000) and relocation expenses and associated taxes of $76,282 in 2000.

Option Grants in Last Fiscal Year

The following tables summarize option grants and exercises during the fiscal year ended December 31, 2001 to or by each of the executive officers named in the Summary Compensation Table on page 57 and the potential realizable value of the options held by these persons at December 31, 2001.

	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	71,406(2)	46.32%	$ 4.00	4/5/11
Phillip B. Donenberg	21,546(2)	13.98%	$ 4.00	4/5/11
Leah M. Lehman, Ph.D.	50,000(3)	32.44%	$ 6.70	12/31/10
Steven J. Bell, Ph.D.	5,000(4)	3.24%	$ 6.70	12/31/10
John E. Lee	—	—	—	—

(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: (i) with respect to 7,460 shares on 6/30/2001 and 12/31/2001; (ii) 3,730 shares on 3/31/2002, 6/30/2002, 9/30/2002, 12/31/2002, 3/31/2003, 6/30/2003, 9/30/2003 and 12/31/2003; and (iii) 5,240 shares on 1/1/2004. 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.

(4) This option vests in equal annual installments over three years so long as the executive officer remains employed by us at that date. To the extend 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 57 at December 31, 2001. None of these executive officers exercised any stock options during 2001.

	Number of Securities Underlying Unexercised Options at December 31, 2001		Value of Unexercised In-the-Money Options at December 13, 2001(1)	
Name	Exercisable	Unexercisable	Exercisable	Unexercisable
Stephen M. Simes	287,725	69,305	$ 1,707,667	$ 328,536
Phillip B. Donenberg	87,337	20,396	$ 518,390	$ 95,934
Leah M. Lehman, Ph.D	14,920	35,080	$ 26,856	$ 63,144
Steven J. Bell, Ph.D.	25,000	5,000	$ 140,625	$ 9,000
John E. Lee	50,000	—	$ —	$ —

(1) Value based on the difference between the fair market value of one share of our common stock at December 31, 2001 ($8.50), and the exercise price of the options ranging from $2.30 to $9.10 per share. Options are in-the-money if the market price of the shares exceeds the option exercise price.

Employment and Separation 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, 2003, 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.

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. Mr. Simes is also subject to 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.

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. Mr. Donenberg is also subject to 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 by BioSante without cause, the officer will be entitled to a severance payment in an amount equal to his or her base salary for the shorter of (1) 12 months or (2) the date upon which the officer 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 assignment of inventions, confidentiality and non-competition provisions.

Separation Agreement and Mutual Release

On February 1, 2002, we entered into a separation and mutual release agreement with John E. Lee in connection with Mr. Lee's resignation as Vice President, Commercial Development and an employee of BioSante effective September 28, 2001. In connection with the separation and mutual release agreement, Mr. Lee received a severance payment of $184,166.66 on October 7, 2001 and will receive a monthly payment of $12,000 for eight months, commencing February 1, 2002 in consideration of providing marketing liaison services to BioSante during this time.

Change in Control Arrangements

Under our Amended and Restated 1998 Stock Option Plan, options 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 Option Plan

From time to time we grant options under our Amended and Restated 1998 Stock Option Plan. The option plan was approved by our Board of Directors on December 8, 1998 and approved by our stockholders on July 13, 1999. The option plan has been amended several times to increase the number of shares reserved for issuance. The option plan provides for the grant to employees, officers, directors, consultants and independent contractors of our company and our subsidiaries of options to purchase shares of common stock that qualify as "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, as well as non-statutory options that do not qualify as incentive stock options. 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 1,000,000 shares of common stock for awards under the option plan. As of August 13, 2002, options to purchase an aggregate of 776,267 shares of common stock were outstanding under the option plan, of which 588,267 were fully vested, and a total of 223,733 shares of common stock remained available for grant. As of August 13, 2002, the outstanding options under the plan were held by an aggregate of 19 individuals and were exercisable at prices ranging from $2.30 to $10.40 per share of common stock.

Incentive 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 granted to a person holding more than 10% of our voting stock, at less than 110% of fair market value). Non-statutory stock options granted under the plans may not have an exercise price less than 85% of fair market value on the date of grant. Aside from the maximum number of shares of common stock reserved under the plans, there is no minimum or maximum number of shares that may be subject to options under the plans. 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. Options generally expire when the optionee's employment or other service is terminated with us. Options 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, which is fixed by our Board of Directors at the time of grant, except that an incentive stock option may be exercisable only for 10 years and an incentive stock option granted to a person holding more than 10% of our voting stock may be exercisable only for five years.

The option plan contains provisions under which options 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 option 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.

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.

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-tenth of a share of common stock and a warrant to purchase one-twentieth of a share 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 expires on December 31, 2002.

In July 2001, Avi Ben-Abraham, M.D., a former 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 13, 2002 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		Common Stock and Common Stock Equivalents	Percent of Total Voting Power(1)
Name	Number	Percent	Number	Percent		
Stephen M. Simes(2)	394,562(3)	5.9%	—	—	394,562	5.5%
Louis W. Sullivan, M.D.(2)	15,000(4)	*	100,000	21.4%	115,000	1.7%
Edward C. Rosenow III, M.D.(2)	12,500(5)	*	—	—	12,500	*
Victor Morgenstern(2)	512,500(6)	7.9%	—	—	512,500	7.4%
Fred Holubow(2)	66,250(7)	1.0%	—	—	66,250	1.0%
Ross Mangano(2)	1,505,499(8)	22.1%	—	—	1,505,499	20.7%
Angela Ho(2)	75,000(9)	1.2%	100,000	21.4%	175,000	2.6%
Peter Kjaer(2)	10,000(10)	*	—	—	10,000	*
Phillip B. Donenberg(2)	99,865(11)	1.6%	—	—	99,865	1.5%
Leah M. Lehman, Ph.D.(2)	74,900(12)	1.2%	—	—	74,900	1.1%
Steven J. Bell, Ph.D.(2)	28,228(13)	*	—	—	28,228	*
JO & Co.	1,155,000(14)	17.2%	—	—	1,155,000	16.1%
Hans Michael Jebsen	425,000(15)	6.6%	100,000	21.4%	525,000	7.6%
King Cho Fung	370,000(16)	5.8%	62,500	13.4%	432,500	6.3%
Marcus Jebsen	175,000(17)	2.8%	50,000	10.7%	225,000	3.3%
Avi Ben-Abraham, M.D.	1,047,980(18)	16.6%	—	—	1,047,980	15.4%
All executive officers and directors as a group (11 persons)	2,794,304(19)	37.0%	200,000	42.9%	2,994,304	37.3%

* 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, Suite 280, Lincolnshire, Illinois 60069.

(3) Mr. Simes' beneficial ownership includes 309,427 shares of common stock issuable upon exercise of stock options and 18,750 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) 95,000 shares of common stock issuable upon exercise of warrants, (3) 32,500 shares of common stock issuable upon exercise of warrants and 80,000 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 20,000 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 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.

(8) Mr. Mangano's beneficial ownership includes: (1) 10,000 shares of common stock issuable upon exercise of a stock option, (2) 375,000 shares of common stock issuable upon exercise of a warrant and 780,000 shares of common stock held by JO & Co., of which Mr. Mangano is President, and (3) an aggregate of 225,000 shares of common stock and an aggregate of 112,499 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 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 93,369 shares of common stock issuable upon exercise of stock options and 625 shares of common stock issuable upon exercise of a warrant.

(12) Dr. Lehman's beneficial ownership includes 18,650 shares of common stock issuable upon exercise of a stock option and 18,750 shares of common stock issuable upon exercise of a warrant.

(13) Dr. Bell's beneficial ownership includes 26,666 shares of common stock issuable upon exercise of stock options and 187 shares of common stock issuable upon exercise of a warrant.

(14) Includes 375,000 shares of common stock issuable upon exercise of a warrant. Ross Mangano, a director of BioSante, has sole voting 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) 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.

(16) 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.

(17) 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.

(18) Dr. Ben-Abraham's beneficial ownership includes 5,000 shares of common stock issuable upon exercise of a stock option. Mr. Ben-Abraham's address is 22 Maskit Street, Suite MB-12550, Lumir Bldg., Herzelya Pituach, 46733, Israel.

(19) The amount beneficially owned by all current directors and executive officers as a group includes 682,672 shares issuable upon exercise of warrants and stock options held by these individuals and 554,999 shares issuable upon exercise of warrants held by entities 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 6,321,458 shares were issued and outstanding as of August 13, 2002. 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 13, 2002. 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 13, 2002, we had outstanding options to purchase an aggregate of 771,267 shares of common stock at a weighted average exercise price of $3.88 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 1,643,750 shares of common stock at a weighted average exercise price of $3.70 per share with a majority of those warrants having a five-year term. The warrants 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 $4.00 per share.

Registration Rights

The holders of the common stock and warrants purchased in our April 2001 private placement are entitled to certain 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 shares of BioSante common stock underlying the shares of common stock and 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 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 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 shares of BioSante common stock underlying the shares of common stock and warrants purchased in our April 2001 private placement and the 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.

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 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.

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.

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 Trust Company of Canada, formerly Montreal Trust of Canada.

LEGAL MATTERS

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

EXPERTS

The financial statements as of December 31, 2001 and 2000 and for each of the three years in the period ended December 31, 2001, 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 referring to the development stage nature of BioSante). This report has been included in reliance upon the report of such firm given upon its authority as an expert 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 facilities maintained by the SEC:

Judiciary Plaza 450 Fifth Street, N.W. Washington, D.C. 20549	175 W. Jackson Blvd. Suite 900 Chicago, Illinois 60604	233 Broadway Woolworth Building New York, New York 10279

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.

We have filed a registration statement on Form SB-2, as amended, with the SEC for the common stock offered 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

PART I—FINANCIAL INFORMATION

ITEM 1—FINANCIAL STATEMENTS

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
June 30, 2002 and December 31, 2001 (Unaudited)

	June 30, 2002	December 31, 2001
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 1,704,495	$ 4,502,387
Prepaid expenses and other sundry assets	72,213	91,859
	1,776,708	4,594,246
PROPERTY AND EQUIPMENT, NET	365,473	384,996
	$ 2,142,181	$ 4,979,242
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 287,236	$ 90,653
Accrued compensation	98,982	379,346
Other accrued expenses	61,277	24,444
Due to Antares	288,200	433,319
	735,695	927,762
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Capital stock		
Issued and Outstanding 466,602 (2001—466,602) Class C special stock	467	467
6,321,458 (2001—6,321,880) Common stock	22,255,342	22,302,046
	22,255,809	22,302,513
Deficit accumulated during the development stage	(20,849,323)	(18,251,033)
	1,406,486	4,051,480
	$ 2,142,181	$ 4,979,242

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Three and six months ended June 30, 2002 and 2001 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002
	2002	2001	2002	2001	
REVENUE					
Licensing income	$ —	$ —	$ —	$ —	$ 1,747,386
Interest income	6,712	50,843	29,971	82,952	950,923
	6,712	50,843	29,971	82,952	2,698,309

EXPENSES					
Research and development	987,528	387,236	1,631,922	620,225	8,058,238
General and administration	491,851	497,972	950,980	963,030	9,059,877
Depreciation and amortization	22,697	24,548	45,359	48,510	519,753
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
	1,502,076	909,756	2,628,261	1,631,765	23,547,632
NET LOSS	$ (1,495,364)	$ (858,913)	$ (2,598,290)	$ (1,548,813)	$ (20,849,323)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.22)	$ (0.13)	$ (0.38)	$ (0.25)	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	6,788,343	6,648,403	6,788,412	6,208,676	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Six months ended June 30, 2002 and 2001 and the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002
(Unaudited)

	Six Months Ended June 30,		Cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002
	2002	2001	
CASH FLOWS USED IN OPERATING ACTIVITIES			
Net loss	**$ (2,598,290)**	**$ (1,548,813)**	**$ (20,849,323)**
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	**45,359**	**48,510**	**519,753**
Amortization of deferred unearned compensation	**—**	**18,000**	**42,290**
Repurchase of licensing rights	**—**	**—**	**125,000**
Employee compensation paid in shares of common stock	**—**	**—**	**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	**19,646**	**1,078**	**(69,245)**
Accounts payable and accrued expenses	**(46,948)**	**(538)**	**(292,692)**
Due to licensors	**(145,119)**	**—**	**288,200**
Due from SBI	**—**	**—**	**(128,328)**
Net cash used in operating activities	**(2,725,352)**	**(1,481,763)**	**(14,678,800)**
CASH FLOWS USED IN INVESTING ACTIVITIES			
Purchase of capital assets	**(25,836)**	**(22,546)**	**(1,008,661)**
CASH FLOWS (USED IN) PROVIDED BY FINANCING ACTIVITIES			
Issuance of convertible debenture	**—**	**—**	**500,000**
Proceeds from sales or conversion of shares	**(46,704)**	**3,674,612**	**16,891,956**
Net cash (used in) provided by financing activities	**(46,704)**	**3,674,612**	**17,391,956**
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	**(2,797,892)**	**2,170,303**	**1,704,495**
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	**4,502,387**	**2,611,755**	**—**
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**$ 1,704,495**	**$ 4,782,058**	**$ 1,704,495**
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION			

Acquisition of SBI			
Purchased in-process research and development	$ —	$ —	$ 5,377,000
Other net liabilities assumed	—	—	(831,437)
	—	—	4,545,563
Less: common stock issued therefor	—	—	4,545,563
	$ —	$ —	$ —
Income tax paid	$ —	$ —	$ —
Interest paid	$ —	$ —	$ —

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.

Notes to Financial Statements (Unaudited)
June 30, 2002

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. as of June 30, 2002, the results of operations for the three and six months ended June 30, 2002 and 2001 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002, and the cash flows for the six months ended June 30, 2002 and 2001 and for the cumulative period from August 29, 1996 (date of incorporation) to June 30, 2002, 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, 2002 are not necessarily indicative of the results that may be expected for the year ending December 31, 2002.

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 plans 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.

On May 31, 2002, BioSante 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 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 BioSante's Annual Report on Form 10-KSB for the year ended December 31, 2001.

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 BioSante 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 AND SUPPLY AGREEMENTS

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

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

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

In April 2002, BioSante 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 BioSante of $100,000, regulatory milestones, maintenance payments and royalty payments by BioSante if the product gets approved and subsequently marketed.

4. FINANCING

In April 2001, BioSante closed a private placement raising $3.7 million upon the issuance of units, which consisted of an aggregate of 925,000 shares of common stock and five-year warrants to purchase an aggregate of 462,500 shares of common stock. 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 $4.00, the approximate market price of BioSante's common stock at closing. The exercise price of the warrant is $5.00 per full share. Transaction costs related to the private placement have been netted against the proceeds.

In May 2002, BioSante filed a registration statement on Form SB-2 with the Securities and Exchange Commission. The filing relates to a proposed best-efforts, self underwritten offering by BioSante of up to $10 million in shares of common stock. The per share public offering price will be determined shortly after the registration statement is declared effective.

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

Therefore, the Company needs to raise additional capital to fund operations sometime in the near future. BioSante cannot be certain that any financing will be available when needed. If BioSante fails to raise additional financing as needed, it may have to delay or terminate product development programs or pass on opportunities to in-license or otherwise acquire new products that BioSante believes may be beneficial to its business.

5. COMMITMENTS

University of California License

BioSante's license agreement with the University of California requires BioSante 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

- Development of products incorporating the licensed technology until a product is introduced to the market;
- Payment of the costs of patent prosecution and maintenance of the patents included in the agreement, which for the year ended December 31, 2001 amounted to $11,358;
- 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 exercise of the license agreement, including but not limited to, any product liability claims.

Antares Pharma, Inc. License

BioSante's license agreement with Antares required BioSante to make a $1.0 million upfront payment to Antares. $250,000 of this upfront payment was creditable against future milestone or other payments and was utilized in the third quarter of 2001. The result was a $250,000 reduction in research and development expense in the statement of operations during the quarter ended September 30, 2001 as the initial $1.0 million payment had been expensed in its entirety in 2000. BioSante expects to fund the development of the products, make milestone payments and once regulatory approval to market is received and sales of the products commence, pay royalties on the sales of products. BioSante must also make cash payments to Antares for manufacturing and formulation services performed by Antares at BioSante's request, related to the products and must pay Antares a portion of any up front sublicense or milestone payment received by BioSante from the sublicense of the products.

6. NEW ACCOUNTING PRONOUNCEMENTS

On July 20, 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets." These statements establish new accounting and reporting standards for business combinations and associated goodwill and intangible assets. They require, among other things, elimination of the pooling of interests method of accounting, no amortization of acquired goodwill, and a periodic assessment for impairment of all goodwill and intangible assets acquired in a business combination. SFAS 141 is effective for all business combinations accounted for by the purchase method that are completed after June 30, 2001. SFAS 142 was adopted on January 1, 2002. There was no impact on BioSante's financial statements as a result of the adoption of SFAS 142.

Independent Auditors' Report

Board of Directors
BioSante Pharmaceuticals, Inc.
Lincolnshire, Illinois

We have audited the accompanying balance sheets of BioSante Pharmaceuticals, Inc. (a development stage company) as of December 31, 2001 and 2000 and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001, and for the period from August 29, 1996 (date of incorporation) through December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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, 2001 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, and for the period from August 29, 1996 (date of incorporation) through December 31, 2001 in conformity with accounting principles generally accepted in the United States of America.

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

/s/ DELOITTE & TOUCHE LLP

February 15, 2002
(May 31, 2002 as to Note 14)
Chicago, Illinois

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Balance Sheets
December 31, 2001 and 2000

	2001	2000
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 4,502,387**	**$ 2,611,755**
Prepaid expenses and other sundry assets	**91,859**	**64,341**
	4,594,246	**2,676,096**
PROPERTY AND EQUIPMENT, NET (Note 5)	**384,996**	**390,821**
	$ 4,979,242	**$ 3,066,917**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable (Note 12)	**$ 90,653**	**$ 44,746**
Accrued compensation	**379,346**	**258,598**
Other accrued expenses	**24,444**	**137,919**
Due to Antares (Note 4)	**433,319**	**—**
Convertible debenture (Notes 7 and 13)	**—**	**500,000**
	927,762	**941,263**
COMMITMENTS (Notes 11 and 13)		
STOCKHOLDERS' EQUITY (Note 8)		

Capital stock		
Issued and Outstanding		
2001—466,602; 2000—468,768 Class C special stock	**467**	**469**
2001—6,321,880; 2000—5,295,294 Common stock	**22,302,046**	**17,782,857**
	22,302,513	**17,783,326**
Deferred unearned compensation	**—**	**(18,000)**
Deficit accumulated during the development stage	**(18,251,033)**	**(15,639,672)**
	4,051,480	**2,125,654**
	$ 4,979,242	**$ 3,066,917**

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Operations
Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	Year ended December 31, 2001	Year ended December 31, 2000	Year ended December 31, 1999	Cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001
REVENUE				
Licensing income, net (Note 4)	**$ 1,747,386**	**$ —**	**$ —**	**$ 1,747,386**
Interest income	**174,416**	**227,718**	**198,683**	**920,952**
	1,921,802	**227,718**	**198,683**	**2,668,338**
EXPENSES				
Research and development	**2,141,944**	**1,887,832**	**660,588**	**6,426,316**
General and administration	**2,298,659**	**1,678,581**	**853,389**	**8,108,897**
Depreciation and amortization	**92,560**	**98,500**	**90,965**	**474,394**
Loss on disposal of capital assets	**—**	**—**	**—**	**157,545**
Costs of acquisition of Structured Biologicals Inc.	**—**	**—**	**—**	**375,219**
Purchased in-process research and development	**—**	**—**	**—**	**5,377,000**
	4,533,163	**3,664,913**	**1,604,942**	**20,919,371**
NET LOSS	**$ (2,611,361)**	**$ (3,437,195)**	**$ (1,406,259)**	**$ (18,251,033)**
BASIC AND DILUTED NET LOSS PER SHARE (Note 2)	**$ (0.40)**	**$ (0.60)**	**$ (0.28)**	
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	**6,485,349**	**5,753,676**	**4,942,414**	

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Stockholders' Equity
Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	Class A Special Shares		Class C Special Shares		Common Stock			
	Shares	Amount	Shares	Amount	Shares	Amount	Deferred Unearned Compensation	Deficit Accumulated During the Development Stage

Balance, August 29, 1996, Date of incorporation	—	$ —	—	$ —	—	$ —	$ —	$ —
Issuance of Class "C" shares August 29, 1996 ($0.0001 per share)	—	—	415,000	415	—	—	—	—
Issuance of Class "A" shares September 23, 1996 ($0.0001 per share)	2,000,000	2,000	—	—	—	—	—	—
Issuance of common shares								
September 23, 1996	—	—	—	—	410,000	4,100,000	—	—
Financing fees accrued	—	—	—	—	—	(410,000)	—	—
November 27, 1996—issued as consideration upon acquisition of SBI (Note 3)	—	—	—	—	743,432	4,545,563	—	—
Exercise of Series "X" warrants (Note 7)	—	—	—	—	21,571	275,387	—	—
Exercise of Series "Z" warrants (Note 7)	—	—	—	—	143	2,553	—	—
Net loss	—	—	—	—	—	—	—	(6,246,710)
Balance, December 31, 1996	2,000,000	2,000	415,000	415	1,175,146	8,513,503	—	(6,246,710)
Conversion of shares								
January 13, 1997	—	—	(28,285)	(28)	28,285	70,741	—	—
January 13, 1997	—	—	(9,428)	(9)	9,429	23,580	—	—
December 2, 1997	—	—	(10,639)	(11)	10,639	26,607	—	—
December 2, 1997	—	—	(10,000)	(10)	10,000	25,010	—	—
Exercise of Series "V" warrants (Note 7)	—	—	—	—	2,400	36,767	—	—
Exercise of Series "X" warrants (Note 7)	—	—	—	—	2,857	36,200	—	—
Exercise of Series "W" warrants (Note 7)	—	—	—	—	2,000	25,555	—	—
Adjustment for partial shares issued upon amalgamation	—	—	—	—	13	—	—	—
Financing fees reversed	—	—	—	—	—	410,000	—	—
Net loss	—	—	—	—	—	—	—	(1,890,093)
Balance, December 31, 1997	2,000,000	2,000	356,648	357	1,240,769	9,167,963	—	(8,136,803)
Conversion of shares								
March 4, 1998	—	—	(2,000)	(2)	2,000	5,002	—	—
March 16, 1998	—	—	(1,000)	(1)	1,000	2,501	—	—
May 8, 1998	(1,500,000)	(1,500)	—	—	1,500,000	3,751,500	—	—
June 1, 1998	(100,000)	(100)	—	—	100,000	250,100	—	—
June 1, 1998	(100,000)	(100)	—	—	100,000	250,100	—	—
Return of shares to treasury								
May 8, 1998	(146,861)	(147)	—	—	—	—	—	—
May 8, 1998	—	—	(25,000)	(25)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(2,659,415)
Balance, December 31, 1998	153,139	153	328,648	329	2,943,769	13,427,166	—	(10,796,218)
Conversion of shares								
February 2, 1999	—	—	(1,000)	(1)	1,000	2,501	—	—
Private placement of common shares, net								
May 6, 1999	—	—	—	—	2,312,500	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	—	—
Net loss	—	—	—	—	—	—	—	(1,406,259)
Balance, December 31, 1999	—	—	480,787	481	5,264,269	17,652,510	—	(12,202,477)
Conversion of shares								
March 17, 2000	—	—	(1,000)	(1)	1,000	2,501	—	—
March 24, 2000	—	—	(3,184)	(3)	3,184	7,963	—	—
June 12, 2000	—	—	(5,000)	(5)	5,000	12,505	—	—
July 13, 2000	—	—	(2,835)	(3)	2,834	7,088	—	—
Issuance of common shares								
July 18, 2000	—	—	—	—	19,007	58,000	—	—
Issuance of warrants for services received	—	—	—	—	—	42,290	(42,290)	—
Amortization of deferred unearned compensation	—	—	—	—	—	—	24,290	—
Net loss	—	—	—	—	—	—	—	(3,437,195)
Balance, December 31, 2000	—	—	468,768	469	5,295,294	17,782,857	(18,000)	(15,639,672)
Conversion of shares								
September 15, 2001	—	—	(1,166)	(1)	1,166	2,916	—	—
December 15, 2001	—	—	(1,000)	(1)	1,000	2,501	—	—
Private placement of common shares, net								
April 4, 2001	—	—	—	—	925,000	3,659,408	—	—
Issuance of common shares								
August 15, 2001	—	—	—	—	15,500	93,000	—	—
August 15, 2001	—	—	—	—	47,619	500,000	—	—
September 15, 2001	—	—	—	—	17,361	125,000	—	—
September 15, 2001	—	—	—	—	18,940	136,364	—	—
Amortization of deferred unearned compensation	—	—	—	—	—	—	18,000	—
Net loss	—	—	—	—	—	—	—	(2,611,361)
Balance, December 31, 2001	—	$ —	466,602	$ 467	6,321,880	$ 22,302,046	$ —	$ (18,251,033)

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Statements of Cash Flows
Years ended December 31, 2001, 2000 and 1999
and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

	Year ended December 31, 2001	Year ended December 31, 2000	Year ended December 31, 1999	Cumulative period from August 29, 1996 (date of incorporation) to

				December 31, 2001
CASH FLOWS USED IN OPERATING ACTIVITIES				
Net loss	$ (2,611,361)	$ (3,437,195)	$ (1,406,259)	$ (18,251,033)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization	92,560	98,500	90,965	474,394
Amortization of deferred unearned compensation	18,000	24,290	—	42,290
Repurchase of licensing rights	125,000	—	—	125,000
Employee compensation paid in shares of common stock	—	93,000	58,000	151,000
Purchased in-process research and development	—	—	—	5,377,000
Loss on disposal of equipment	—	—	—	157,545
Changes in other assets and liabilities affecting cash flows from operations				
Prepaid expenses and other sundry assets	(27,518)	(5,347)	16,272	(88,891)
Accounts payable and accrued expenses	146,180	102,148	(444,483)	(245,744)
Due to licensor (Antares/Regents)	433,319	(25,000)	(102,317)	433,319
Due from SBI	—	—	—	(128,328)
Net cash used in operating activities	(1,823,820)	(3,149,604)	(1,787,822)	(11,953,448)
CASH FLOWS USED IN INVESTING ACTIVITIES				
Purchase of capital assets	(86,735)	(43,238)	(4,219)	(982,825)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES				
Issuance of convertible debenture	—	500,000	—	500,000
Proceeds from sale or conversion of shares	3,801,187	30,045	4,225,343	16,938,660
Net cash provided by financing activities	3,801,187	530,045	4,225,343	17,438,660
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,890,632	(2,662,797)	2,433,302	4,502,387
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,611,755	5,274,552	2,841,250	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 4,502,387	$ 2,611,755	$ 5,274,552	$ 4,502,387
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION				
Acquisition of SBI				
Purchased in-process research and development	$ —	$ —	$ —	$ 5,377,000
Other net liabilities assumed	—	—	—	(831,437)
	—	—	—	4,545,563
Less: subordinate voting shares issued therefor	—	—	—	4,545,563
	$ —	$ —	$ —	$ —
Income tax paid	$ —	$ —	$ —	$ —
Interest paid	$ —	$ —	$ —	$ —

See accompanying notes to the financial statements.

BIOSANTE PHARMACEUTICALS, INC.
(a development stage company)
Notes to Financial Statements
For the years ended December 31, 2001, 2000 and 1999, and the cumulative period from August 29, 1996 (date of incorporation) to December 31, 2001

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").

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

The Company has been in the development stage since its inception. The Company's successful completion of its development program and its transition to profitable operations is dependent upon obtaining regulatory approval from the United States (the "U.S.") Food and Drug Administration ("FDA") prior to selling its products within the U.S., and foreign regulatory approval must be obtained to sell its products internationally. There can be no assurance that the Company's products will receive regulatory approvals, and a substantial amount of time may pass before the achievement of a level of sales adequate to support the Company's cost structure. The Company will also incur substantial expenditures to achieve regulatory approvals and will need to raise additional capital during its developmental period. Obtaining marketing approval will be directly

dependent on the Company's ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries. It is not possible at this time to predict with assurance the outcome of these activities.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

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

statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

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

Property and Equipment

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

Long-Lived Assets

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

Research and Development

Research and development costs are charged to expense as incurred.

Basic and Diluted Net Loss Per Share

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

Stock-based Compensation

The Company follows the provisions of APB Opinion No. 25, which requires compensation cost for stock-based employee compensation plans be recognized based on the difference, if any, between the quoted market price of the stock on the date of grant and the amount the employee must pay to acquire the stock. As a result of the Company's application of APB No. 25, SFAS No. 123, "Accounting for Stock-Based Compensation," requires certain additional disclosures of the pro forma compensation expense arising from the Company's fixed and performance stock compensation plans. The expense is measured as the fair value of the award at the date it was granted using an option-pricing model that takes into account the exercise price and the expected term of the option, the current price of the underlying stock, its expected volatility, expected dividends on the stock and the expected risk-free rate of return during the term of the option. The compensation cost is recognized over the service period, usually the period from the grant date to the vesting date. The Company has disclosed the required pro forma net loss and loss per share data in Note 9 as if the Company had recorded compensation expense using the fair value method per SFAS No. 123. Warrants issued to non-employees as compensation for services rendered are valued at their fair value on the date of issue.

Revenue Recognition

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

New Statements of Financial Accounting Standards

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

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

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

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

3. ACQUISITION

Pursuant to the shareholders meeting to approve the arrangement held on November 27, 1996 and the subsequent filing of the articles of arrangement December 6, 1996, the Company completed the acquisition of 100% of the outstanding shares of SBI. The acquisition was effected by a statutory amalgamation wherein the stockholders of the Company were allotted a significant majority of the shares of the amalgamated entity. Upon amalgamation, the then existing shareholders of SBI received 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 for the six indications was expected to be received at various dates between 2002 and 2004, however, there are many competitive products in development. There are also many requirements that must be met before FDA approval is secured. There is no assurance that the products will be successfully developed, proved to be safe in clinical trials, meet applicable regulatory standards, or demonstrate substantial benefits in the treatment or prevention of any disease.
- The estimated additional research and development expenditures required before FDA approval was $26.5 million, to be incurred over 8 to 10 years.
- Future cash flows were estimated based on estimated market size, with costs determined based on industry norms, an estimated annual growth rate of 3%.
- The cash flows were discounted at 25%. The rate was preferred due to the high-risk nature of the biopharmaceutical business.
- The Company is continuing to develop the technology related to five of the six indications.
- In June 1997, the Company exercised its option and entered into a license agreement with UCLA for the technology that it had previously supported.

4. LICENSE AND SUPPLY AGREEMENTS

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

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

During the third quarter 2001, Paladin made a series of equity investments in BioSante as a result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 18,939 shares of its common stock to Paladin at a 10 percent premium to BioSante's market price. The dollar value of the premium, $39,394, is recorded as licensing income in the statements of operations.

In a series of amendments executed during 2001 between BioSante and Antares, BioSante returned to Antares the license rights to one of the four previously licensed hormone products, namely the estradiol patch, in all countries of the licensed territory. Additionally, BioSante returned to Antares the license rights to the single entity estrogen and testosterone gel products in Malaysia and Australia. In exchange for the return to Antares of the estradiol patch in all the countries and the estradiol and testosterone gel products in Malaysia and Australia, Antares granted BioSante a credit for approximately $600,000 of manufacturing and formulation services and a license for an undisclosed transdermal hormone replacement gel product. During the third quarter of 2001, Antares informed the Company that the total costs for manufacturing and formulation services had exceeded the $600,000 credit. Accordingly, beginning in third quarter of 2001 and going forward, the Company will be required to reimburse Antares for such services. At December 31, 2001, the amount owed to Antares for such services was $433,319.

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

On October 1, 2001, BioSante sub-licensed its Bio-Vant calcium phosphate based vaccine adjuvant on a non-exclusive basis to Corixa Corporation for use in several potential vaccines to be developed by

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

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

The license agreement with the University of California requires us to undertake various obligations as described in Note 13.

5. PROPERTIES AND EQUIPMENT

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

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

6. INCOME TAXES

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

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

The Company has no current tax provision due to its accumulated losses, which result in net operating loss carryforwards. At December 31, 2001, the Company had approximately $13,140,000 of net operating loss carryforwards that are available to reduce future taxable income for a period of up to 20 years. The net operating loss carryforwards expire in the years 2011-2021. The net operating loss carryforwards as well as amortization of various intangibles, principally acquired in-process research and development, generate deferred tax benefits, which have been recorded as deferred tax assets and are

entirely offset by a tax valuation allowance. The valuation allowance has been provided at 100% to reduce the deferred tax assets to zero, the amount management believes is more likely than not to be realized. Additionally, the Company has approximately $580,000 of research and development credits available to reduce future income taxes through the year 2014.

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

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

7. CONVERTIBLE DEBENTURE

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

8. STOCKHOLDERS' EQUITY

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

a) Authorized

Preference shares

An unlimited number of preference shares issuable in series subject to limitation, rights, and privileges as determined by the directors. No preference shares have been issued as of December 31, 2001.

Special Shares

An unlimited number of Class C special shares without par value, convertible to common stock on the basis of one Class C special share and U.S. $2.50. These shares are not entitled to a dividend and carry one vote per share.

Common Stock

An unlimited number of common shares of stock without par value, which carry one vote per share.

Significant Equity Transactions

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

- Prior to the Amalgamation on December 6, 1996, the Company issued 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 director and a founder of the Company and the Company's then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. Pursuant to the agreement, Dr. Ben-Abraham converted shares of the Company's Class A stock held by him into 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, 19,008 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 BioSante as result of certain sub-licensing transactions and BioSante reaching certain milestones. These equity investments resulted in BioSante issuing an additional 18,939 shares of its common stock to Paladin at a 10 percent premium to BioSante's market price on the date of the transactions. The dollar value of the premium is recorded as licensing income in the statements of operations.

- On August 7, 2001, BioSante entered into a sub-license agreement with Solvay Pharmaceuticals, B.V. (Solvay) covering the U.S. and Canadian rights to the estrogen/progestogen combination transdermal hormone replacement gel product licensed from Antares in June 2000. The Canadian rights to this product had previously been sub-licensed to Paladin as part of that

sub-license arrangement and were repurchased by the Company prior to the Solvay transaction in exchange for $125,000, paid by the issuance of 17,361 shares of BioSante 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.

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, 2001.

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. The warrant vests quarterly over the first year. As of December 31, 2001, all 25,000 of these shares were exercisable. The Company recognized expense of approximately $18,000 for this warrant grant in 2000 and 2001.

Pursuant to the Company's private placement financing in April 2001, warrants to purchase an aggregate of 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, 2001.

9. STOCK OPTIONS

The Company has a stock option plan for certain officers, directors and employees whereby 850,000 shares of common stock have been reserved for issuance. Options for 699,466 shares of common stock have been granted as of December 31, 2001 at prices equal to either the ten-day weighted average closing price, or the closing price of the stock at the date of the grant, and are exercisable and vest in a range substantially over a three-year period. The options expire either in five or ten years from the date of the grants.

The Company applies APB Opinion No. 25 and related interpretations in accounting for its plan. Accordingly, no compensation cost has been recognized for the plan. Had the compensation cost for the Company's plan been determined based on the fair value of the awards under the plan consistent

with the method of SFAS No. 123 the Company's net loss, cumulative net loss, and basic net loss per common share would have been increased to the pro forma amounts indicated below:

	2001	2000	1999
Net loss			
As reported	**$ (2,611,361)**	$ (3,437,195)	$ (1,406,259)
Pro forma	**$ (3,501,822)**	$ (3,960,210)	$ (1,713,693)
Basic and diluted net loss per share			
As reported	**$ (0.40)**	$ (0.60)	$ (0.28)
Pro forma	**$ (0.54)**	$ (0.69)	$ (0.35)
Cumulative net loss			
As reported	**$ (18,251,033)**		
Pro forma	**$ (20,318,982)**		

The weighted average fair value of the options at the date of the grant for options granted during 2001, 2000 and 1999 was $5.00, $8.96 and $3.30 was estimated using the Cox Rubinstein binomial model and the Black-Scholes option-pricing model with following weighted average assumptions:

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

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

Options outstanding, Beginning of period	**526,312**	$ 3.30	497,312	$ 3.00	246,500	$ 3.70
Options granted	**174,153**	$ 5.20	51,000	$ 9.10	306,812	$ 2.40
Options cancelled/expired	**(1,000)**	$ 7.50	(22,000)	$ 10.00	(56,000)	$ 3.10
Options exercised	**—**	—	—	—	—	—
Options outstanding, End of period	**699,465**	$ 3.80	526,312	$ 3.30	497,312	$ 3.00
Options exercisable, End of year	**542,483**	$ 3.40	386,502	$ 2.80	211,711	$ 3.50

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

	Outstanding Options			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Avg. Remaining Contractual Life	Weighted Avg. Exercise Price	Number Outstanding	Weighted Avg. Exercise Price
$ 2.30	237,812	2.2 years	$ 2.30	225,571	$ 2.30
$ 2.80 — $2.90	232,500	2.1 years	$ 2.80	231,500	$ 2.80
$ 4.00 — $6.70	174,153	9.2 years	$ 5.20	30,412	$ 5.30
$ 9.10 — $10.40	55,000	8.5 years	$ 9.20	55,000	$ 9.20
	699,465			542,483	

10. RETIREMENT PLAN

In July 1998, the Company began offering a discretionary 401(k) Plan (the Plan) to all of its employees. Under the Plan, employees may defer income on a tax-exempt basis, subject to IRS

limitation. Under the Plan the Company can make discretionary matching contributions. Company contributions expensed in 2001, 2000 and 1999 totaled $30,743, $26,296 and $23,899, respectively.

11. LEASE ARRANGEMENTS

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

Year	Minimum Annual Royalty Due
2002	**$ 142,811**
2003	**131,877**
Thereafter	**—**
	$ 274,688

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

12. RELATED PARTY TRANSACTIONS

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

Prior to the Amalgamation on December 6, 1996, the Company issued 2,000,000 shares of class A stock and 415,000 shares of class C stock for $0.001 per share. 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 director and a founder of the Company and the Company's then Chief Executive Officer and Chairman of the Board, entered into an agreement pursuant to which Dr. Ben-Abraham would relinquish his executive position and remain as a director of the Company. See Note 8.

In connection with the May 1999 private placement of 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.

13. COMMITMENTS

University of California License

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

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

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

- Development of products incorporating the licensed technology until a product is introduced to the market;
- Payment of the costs of patent prosecution and maintenance of the patents included in the agreement which for the year ended December 31, 2001 have amounted to $11,358 and which management estimates will equal approximately $15,000 per year;
- Meeting performance milestones relating to:
  - Hiring or contracting with personnel to perform research and development, regulatory and other activities relating to the commercial launch of a proposed product;
  - Testing proposed products;
  - Obtaining government approvals;
  - Conducting clinical trials; and
  - Introducing products incorporating the licensed technology into the market.
- Entering into partnership or alliance arrangements or agreements with other entities regarding commercialization of the technology covered by the license.
- The Company has agreed to indemnify, hold harmless and defend the University of California and its affiliates, as designated in the license agreement, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from or arising out of exercise of the license agreement, including but not limited to, any product liability claims.

Antares Pharma, Inc. License

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

The Company's sub-license agreement in Canada (of the Antares license) with Paladin Labs Inc. required Paladin to make an initial investment in the Company of $500,000 in the form of a convertible debenture. On August 13, 2001, the Company exercised its right and declared the convertible debenture converted in full at a price of $10.50 per share. Accordingly, 47,619 shares of the Company's common stock were issued to Paladin.

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

14. SUBSEQUENT EVENT

On May 21, 2002, the Board of Directors authorized a reverse stock split of the issued and outstanding shares of BioSante's common stock and class C special stock. All share and per share numbers have been adjusted to reflect the one-for-ten reverse stock split effected May 31, 2002.

5,000,000 Shares

Common Stock

Prospectus

September 5, 2002

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