BIOSANTE PHARMACEUTICALS INC
Form 424B1
September 06, 2002

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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

TABLE OF CONTENTS

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) 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:								

							Six Months Ended June 30,	
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 assi