BIOSANTE PHARMACEUTICALS INC
Form S-3
June 02, 2004

Table of Contents

**As filed with the Securities and Exchange Commission on June 2, 2004**

**Registration No. 333-**

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**FORM S-3**
**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**BIOSANTE PHARMACEUTICALS, INC.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **58-2301143** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

**111 Barclay Boulevard**
**Lincolnshire, Illinois 60069**
**(847) 478-0500**
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

**Phillip B. Donenberg**
**Chief Financial Officer, Treasurer and Secretary**
**BioSante Pharmaceuticals, Inc.**
**111 Barclay Boulevard**
**Lincolnshire, Illinois 60069**
**(847) 478-0500**
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

Approximate date of commencement of proposed sale to the public:
**From time to time after this registration statement becomes effective.**

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box: o

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

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

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

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

**CALCULATION OF REGISTRATION FEE**

| Title of each class of securities to be registered | Amount to be registered (1) | Proposed maximum offering price per unit (2) | Proposed maximum aggregate offering price (2) | Amount of registration fee (2) |
|---|---|---|---|---|
| Common Stock, par value $0.0001 per share | 3,483,996 | $ 7.95 | $27,697,768 | $3,509.31 |

(1) The amount to be registered hereunder consists of an aggregate of 3,483,996 shares of common stock to be sold by the selling stockholders named in this registration statement. Of the shares of common stock, 2,949,000 shares are currently outstanding and 534,996 shares are issuable upon the exercise of warrants. In addition, pursuant to Rule 416 under the Securities Act of 1933, this registration statement includes an indeterminate number of additional shares that may be offered and sold to prevent dilution resulting from stock splits, stock dividends, or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based upon the average of the high and low sale prices of the registrant s common stock on June 1, 2004, as reported by the American Stock Exchange.

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

Table of Contents

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

Subject to Completion, dated June 2, 2004

**PRELIMINARY PROSPECTUS**

**3,483,996 Shares**

**Common Stock**

Selling stockholders of BioSante Pharmaceuticals, Inc. are offering 3,483,996 shares of common stock. These shares may be offered from time to time by the selling stockholders through public or private transactions, on or off the American Stock Exchange, at prevailing market prices or at privately negotiated prices. BioSante will not receive any proceeds from the sale of shares offered by the selling stockholders.

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

Our common stock is listed on the American Stock Exchange under the symbol BPA. On June 1, 2004, the last sale price of our common stock on the American Stock Exchange was $7.95 per share.

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

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 , 2004

**TABLE OF CONTENTS**

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

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

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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.

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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.

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Table of Contents

## WHERE YOU CAN FIND MORE INFORMATION

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

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

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

Our common stock is listed on the American Stock Exchange. Reports and other information concerning BioSante may also be inspected at the offices of the American Stock Exchange, 86 Trinity Place, Seventh Floor, New York, NY 10006 or on the American Stock Exchange website at *http://www.amex.com.*

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*.

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

We have filed a registration statement on Form S-3 with the SEC for the common stock offered by the selling stockholders under this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information that is not contained in this prospectus. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information contained in the documents we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will update and supersede this information. We are incorporating by reference the following documents:

our Annual Report on Form 10-KSB for the year ended December 31, 2003;

our Quarterly Report on Form 10-QSB for the quarter ended March 31, 2004;

our Current Reports on Form 8-K filed on May 12, 2004 and May 14, 2004; and

Table of Contents

the description of our common stock contained in our registration statement on Form 8-A and any amendments or reports filed for the purpose of updating such description.

We are also incorporating by reference any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 until this distribution is completed.

You may request of copy of these filings, at no cost, by writing to Phillip B. Donenberg, Chief Financial Officer, BioSante Pharmaceuticals, Inc., 111 Barclay Boulevard, Lincolnshire, Illinois 60069 or by telephone at (847) 478-0500 ext. 101.

Table of Contents

## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements concerning our financial condition, results of operations and business, including, without limitation, statements pertaining to:

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

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to BioSante. Below are some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described above, as well as others that we may consider immaterial or do not anticipate at this time. The foregoing risks and uncertainties are not exclusive and further information concerning the company and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission. We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Table of Contents

## SUMMARY

### Our Company

We are a development stage biopharmaceutical company that is developing a pipeline of hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CAP, for improved vaccines, drug delivery systems and the purification of the milk of transgenic animals.

Our hormone therapy products, most of which we license on an exclusive basis from Antares Pharma, Inc., address a variety of hormone therapies for symptoms that affect both men and women. Symptoms addressed by these hormone therapies include impotence, lack of sex drive, muscle weakness and osteoporosis in men and menopausal symptoms in women including hot flashes, vaginal atrophy, decreased libido and osteoporosis. The products we in-license from Antares are gel formulations of testosterone (the natural male hormone), estradiol (the natural female hormone), a combination of estradiol and testosterone, and a combination of estradiol and progestogen (another female hormone).

The gels are designed to be quickly absorbed through the skin after application on the arms, 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.

### Our Products

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

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

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

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

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

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

Our CAP technology, a portion of which we license on an exclusive basis from the University of California, is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. 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 and allow for delivery of the vaccine via non-injectable routes of administration;

Table of Contents

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

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

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

BioVant proprietary CAP adjuvant and delivery technology in development for improved versions of current vaccines and new vaccines against cancer, viral and bacterial infections and autoimmune diseases, among others including biodefense vaccines such as anthrax and ricin.

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

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

CAP biotechnology production use of CAP technology in a new patented process for purifying the milk of transgenic animals in order to extract therapeutic proteins.

**Our Business Strategy**

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

pursuing the development of our hormone therapy products;

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

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

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

**Other Information About Our Company**

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.

Table of Contents

## 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, or incorporated into this prospectus by reference, 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. The 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 $5,959,354 for the year ended December 31, 2003, and as of December 31, 2003, our accumulated deficit was $28,021,077. We incurred a net loss of $2,445,231 for the three month period ended March 31, 2004, and as of March 31 2004, our accumulated deficit was $30,466,308.

All of our revenue to date has been derived from up front and milestone payments earned on sub-licensing transactions and grant revenue earned from a government grant. 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 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

Table of Contents

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 March 31, 2004 was $8,262,453. On May 14, 2004, we completed a private placement financing raising approximately $16.5 million in net proceeds. We believe our cash will be sufficient to fund our operations through December 2006. We have based this estimate on assumptions that may prove to be wrong. As a result, we may need to obtain additional financing prior to that time. Unexpected increases in general and administrative expenses and research and development expenses may cause us to need additional financing prior to that time. In addition, we may need to raise additional capital at an earlier time to fund our ongoing research and development activities, acquire new products or take advantage of other unanticipated opportunities. We cannot be certain that any financing will be available when needed or will be on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our proposed products, prevent commercial introduction of our products altogether or restrict us from acquiring new products that we believe may be beneficial to our business.

***We are a development stage company, 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.

Table of Contents

***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.

***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 pre-clinical studies and human clinical trials are required, and the results of the studies and trials are highly uncertain.***

As part of the FDA approval process, we must conduct, at our own expense, pre-clinical studies on animals and clinical trials on humans on each of our proposed products. We expect the number of pre-clinical studies and human 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 pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. Adverse or inconclusive human clinical results

Table of Contents

would prevent us from filing for regulatory approval of our products. Additional factors that can cause delay or termination of our human clinical trials include:

slow patient enrollment;

longer treatment time required to demonstrate efficacy or safety;

adverse medical events or side effects in treated patients; and

lack of effectiveness of the product being tested.

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

In July 2002, the National Institutes of Health (NIH) released data from its Women s Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin for an average of 5.2 year follow-up among healthy postmenopausal women. Also in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom was also halted. Our proposed hormone therapy products differ from the products used in the Women s Health Initiative study and the primary products observed in the National Cancer Institute and United Kingdom studies. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. At the same time, estrogen alone did not appear to increase the risk of breast cancer. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture. Preliminary data from the memory study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment. There are, however, no studies comparing the safety of our proposed hormone therapy products against other hormone therapies.

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

Table of Contents

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

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

***We have licensed two of our proposed hormone therapy products to third parties and any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect our business.***

We have licensed two of our proposed hormone therapy products to third parties that have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. Any breach by these parties of their obligations under these sublicense agreements or a termination of these sublicense agreements by these parties could adversely affect our business if we are unable to license the proposed products to another party on substantially the same or better terms or continue the work ourselves.

***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 are currently dependent upon our licensees or others for several of these functions and will likely remain dependent upon others for these functions.***

We do not have a manufacturing facility that can be used for production of our products. In addition, at this time, we have very limited sales and marketing personnel. We are currently dependent upon our licensees or others for several of these functions and in the course of our development program, we will likely be required to enter into additional arrangements with other companies or universities or clinical investigators for our animal testing, human clinical testing, manufacturing, and sales and marketing activities. If our licensees breach their obligations under our license agreements to perform these functions or we are otherwise 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.

Table of Contents

***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 will 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 before others have developed similar methods.

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

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

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

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

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

Table of Contents

***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.

**Risks Relating to Our Common Stock**

***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, other registration statements and shares available for resale under Rule 144(k) under the Securities Act, 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.***

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;

Table of Contents

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

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

developments or disputes concerning patent or proprietary rights;

actual or anticipated fluctuations in our operating results;

changes in our financial estimates by securities analysts;

general market conditions for emerging growth and pharmaceutical companies;

broad market fluctuations; and

economic conditions in the United States or abroad.

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

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

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

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

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

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

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

***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 24.7% 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

15

Table of Contents

existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

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

As of May 15, 2004, we had issued and outstanding 17,771,774 shares of common stock, 404,102 shares of our class C stock and outstanding options and warrants to purchase 4,340,870 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.

## USE OF PROCEEDS

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

Table of Contents

## SELLING STOCKHOLDERS

All of the selling stockholders named below acquired or have the right to acquire upon the exercise of warrants the shares of our common stock being offered under this prospectus directly from us in a private transaction. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of May 15, 2004 as provided by the selling stockholders. In accordance with the rules of the SEC, beneficial ownership includes the shares issuable pursuant to warrants and options that are exercisable within 60 days of May 15, 2004. Shares issuable pursuant to warrants and options are considered outstanding for computing the percentage of the person holding the warrants and options but are not considered outstanding for computing the percentage of any other person.

The percentage of beneficial ownership for the following table is based on 17,771,774 shares of common stock outstanding as of May 15, 2004. To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person.

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

| | Shares Beneficially Owned Prior to the Offering | | | | Shares Beneficially Owned After Completion of the Offering | |
|---|---|---|---|---|---|---|
| Selling Stockholder | Shares Subject to Options, Warrants, and Class C Special Stock | Total Shares Beneficially Owned | Percentage | Number of Shares Being Offered | Number | Percentage |
| Accipiter Life Sciences Fund, Ltd. (1) | 38,710 | 296,778 | 1.7% | 296,778 | 0 | |
| Accipiter Life Sciences Fund, L.P. (1) | 37,446 | 287,083 | 1.6% | 287,083 | 0 | |
| Accipiter Life Sciences Fund (QP), LP (1) | 21,344 | 163,639 | * | 163,639 | 0 | |
| FrontPoint Health Care Fund, L.P. (2) | 60,000 | 460,000 | 2.6% | 460,000 | 0 | |
| Millennium Partners, L.P. (3) | 52,500 | 402,500 | 2.3% | 402,500 | 0 | |
| Morgan Stanley & Co. | 30,000 | 230,000 | 1.3% | 230,000 | 0 | |
| Paul Scharfer | 5,625 | 43,125 | * | 43,125 | 0 | |
| Oliveira Capital, LLC (4) | 11,100 | 85,100 | * | 85,100 | 0 | |
| ProMed Offshore Fund, Ltd. (5) | 1,950 | 16,335 | * | 14,950 | 1,385 | * |
| ProMed Partners II, L.P. (5) | 2,895 | 24,235 | * | 22,195 | 2,040 | * |
| ProMed Partners, L.P. (5) | 12,030 | 100,805 | * | 92,230 | 8,575 | * |

| | | | | | | |
|---|---|---|---|---|---|---|
| Quogue Capital LLC (6) | 11,250 | 86,250 | * | 86,250 | 0 | |
| Perceptive Life Sciences Master Fund, Ltd.(7) | 647,500 | 2,347,500 | 12.8% | 747,500 | 1,600,000 | 8.7% |
| The Richard H. Aldrich Living Trust dtd. 1/25/01 | 15,000 | 457,200 | 2.6% | 115,000 | 342,200 | 1.9% |
| Sonar Partners, L.P. (8) | 12,000 | 92,000 | * | 92,000 | 0 | |
| Sonar Overseas Fund Ltd.(8) | 8,100 | 62,100 | * | 62,100 | 0 | |
| Sonar Institutional Fund, L.P.(8) | 9,900 | 75,900 | * | 75,900 | 0 | |
| UBS O Connor LLC f/b/o O Connor PIPES Corporate Strategies Master Ltd. | 15,000 | 115,000 | * | 115,000 | 0 | |
| Leerink Swann & Company (9) | 45,196 | 45,196 | * | 45,196 | 0 | |
| SCO Capital Partners LLC (10) | 32,950 | 32,950 | * | 32,950 | 0 | |
| Daniel DiPietro (10) | 22,500 | 22,500 | * | 2,500 | 20,000 | * |
| Preston Tsao (10) | 22,500 | 22,500 | * | 2,500 | 20,000 | * |
| Jeffrey B. Davis (10) | 76,100 | 76,100 | * | 9,500 | 66,600 | * |

* Less than one percent (1%)

Table of Contents

(1) Gabe Hoffman is the general manager of Accipiter Life Sciences Fund, Ltd. and general partner of Accipiter Life Sciences Fund, L.P. and Accipiter Life Sciences Fund (QP), L.P., and therefore, may be deemed to have investment and voting power over the shares of BioSante common stock held by such entities.

(2) FrontPoint Healthcare Fund GP, LLC is the general partner of FrontPoint Healthcare Fund, L.P. FrontPoint Partners LLC is the sole managing member of FrontPoint Healthcare Fund GP, LLC and as such has voting and dispositive power over the securities held by FrontPoint Healthcare Fund, L.P. Phillip Duff, W. Gillespie Caffray and Paul Ghaffari are members of the Board of Managers of FrontPoint Partners LLC and are the sole members of its management committee. Messrs. Duff, Caffray and Ghaffari and FrontPoint Partners LLC and FrontPoint Healthcare Fund GP, LLC each disclaim beneficial ownership of the securities held by FrontPoint Healthcare Fund, L.P. except to the extent of their pecuniary interest therein.

(3) Millennium Management LLC, a Delaware limited liability company, is the managing partner of Millennium Partners, L.P. and consequently has voting control and investment discretion over securities owned by Millennium Partners, L.P. Israel A. Englander is the sole managing member of Millennium Management, LLC. As a result, Mr. Englander may be considered the beneficial owner of any shares deemed to be beneficially owned by Millennium Management, LLC. The foregoing should not be construed in and of itself as an admission by either Millennium Management, LLC or Mr. Englander as to beneficial ownership of the shares owned by Millennium Partners, L.P.

(4) Steven Oliveira, is the sole member of Oliveira Capital, LLC and consequently has voting and investment control over securities owned by Oliveira Capital, LLC.

(5) David Musket and Barry Kurokawa, as the two investment managers of ProMed Offshore Fund, Ltd., ProMed Partners II, L.P. and ProMed Partners, L.P., have investment and voting power over the shares of BioSante common stock held by ProMed Offshore Fund, Ltd, ProMed Partners II, L.P. and ProMed Partners, L.P.

(6) Wayne Rothbaum, a principal of Quogue Capital LLC, has voting and investment power over the securities beneficially owned by Quogue Capital LLC.

(7) Perceptive Advisors, LLC, is the investment advisor of Perceptive Life Science Master Fund, Ltd. and consequently has voting control and investment discretion over securities owned by Perceptive Life Science Master Fund, Ltd. Joseph Edelman is the managing member of Perceptive Advisors, LLC. As a result, Mr. Edelman may be considered the beneficial owner of any shares deemed to be beneficially owned by Perceptive Life Science Master Fund, Ltd. Perceptive Life Science Master Fund, Ltd. s business address is 5437 Connecticut Avenue, NW, Suite 100, Washington, DC 20015.

(8) Neil Druker, as the sole member of Sonar Capital Management, LLC, the general partner of Sonar Partners, L.P. and Sonar Institutional Fund, L.P. and the investment manager of Sonar Overseas Fund Ltd., may be deemed to have investment and voting power over the shares of BioSante common stock held by Sonar Partners, L.P., Sonar Institutional Fund, L.P. and Sonar Overseas Fund Ltd.

(9) Leerink Swann & Company acted as agent in connection with BioSante s May 2004 private placement. In connection with the May 2004 private placement, Leerink received a commission of approximately $996,230 and a warrant to purchase an aggregate of 45,196 shares of common stock.

(10) SCO Securities, LLC acted as agent in connection with BioSante s August 2003 private placement. In connection with the May 2004 private placement, SCO Securities received a commission of approximately $170,820 and a warrant to purchase an aggregate of 47,450 shares of common stock. In connection with the August 2003 private

placement, SCO Securities received a warrant to purchase 371,373 shares of common stock. SCO Securities assigned its rights under the warrant to SCO Capital Partners LLC and the following employees of SCO Securities: Daniel DiPietro, Preston Tsao and Jeffrey B. Davis.

Table of Contents

## PLAN OF DISTRIBUTION

We are registering the shares of common stock on behalf of the selling security holders. Sales of shares may be made by selling security holders, including their respective donees, pledges, transferees or other successors-in-interest directly to purchasers or to or through underwriters, broker-dealers or through agents. As used herein, selling security holders includes donees, pledges, transferees or other successors-in-interest selling shares received after the date of this prospectus from a selling security holder as a gift, pledge, partnership distribution or other non-sale related transfer.

Sales may be made from time to time on the American Stock Exchange or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

- a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction (including crosses in which the same broker acts as agent for both sides of the transaction);
- purchases by a broker-dealer as principal and resale by such broker-dealer, including resales for its account, pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchases;
- through options, swaps or derivatives;
- in privately negotiated transactions;
- in making short sales or in transactions to cover short sales; and
- put or call option transactions relating to the shares.

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

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

The selling security holders and any broker-dealers that act in connection with the sale of shares may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while

Table of Contents

acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling security holders and each selling security holder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act.

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

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

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

- the name of each such selling security holder and of the participating broker-dealer(s);
- the number of shares involved;
- the initial price at which the shares were sold;
- the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and
- other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the Commission, we will file a supplement to this prospectus when a selling security holder notifies us that a donee, pledge, transferee or other successor-in-interest intends to sell more than 500 shares of common stock.

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

Table of Contents

## LEGAL MATTERS

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

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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

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

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

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to BioSante s directors, officers or persons controlling BioSante pursuant to the foregoing provisions,

Table of Contents

BioSante is aware that in the opinion of the Securities and Exchange Commission that this indemnification is against public policy as expressed in the Securities Act of 1933 and is therefore unenforceable.

## EXPERTS

The financial statements as of December 31, 2003 and 2002 and for each of the three years in the period ended December 31, 2003, incorporated by reference in this prospectus by reference to our Annual Report on Form 10-KSB for the year ended December 31, 2003, have been audited by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, (which report expresses an unqualified opinion and includes an explanatory paragraph indicating that BioSante Pharmaceuticals, Inc. is in the development stage), and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

Table of Contents

## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 14. Other Expenses of Issuance and Distribution.

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

| | |
|---|---|
| SEC registration fee | $ 3,509 |
| Printing expenses | 1,000 |
| Fees and expenses of legal counsel for BioSante | 25,000 |
| Fees and expenses of accountants for BioSante | 20,000 |
| Blue sky fees and expenses | 2,000 |
| Miscellaneous | 10,000 |
| *Total | $61,509 |

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

### Item 15. Indemnification of Directors and Officers.

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

BioSante s Certificate of Incorporation provides for indemnification of BioSante s directors and officers. Specifically, Article VI provides that BioSante shall indemnify, to the fullest extent authorized or permitted by law, as the same exists or may thereafter be amended, any person who was or is made or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of BioSante), by reason of the fact that such person is or was a director or officer of BioSante, or is or was serving at the request of BioSante as a director, officer, employee or agent of any other company, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise; provided, however, that BioSante shall not indemnify any director or officer in connection with any action by such director or officer against BioSante unless BioSante shall have consented to such action. BioSante may, to the extent authorized from time-to-time by BioSante s Board of Directors, provide rights to indemnification to employees and

agents of BioSante similar to those conferred in Article VI to directors and officers of

Table of Contents

BioSante. No amendment or repeal of Article VI shall apply to or have any effect on any right to indemnification provided thereunder with respect to any acts or omission occurring prior to such amendment or repeal.

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

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

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

**Item 16. Exhibits.**

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

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

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

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

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

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

provided, however, that clauses (i) and (ii) do not apply if the information required to be included in a post-effective amendment by those clauses is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

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

Table of Contents

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

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

Table of Contents

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lincolnshire, State of Illinois on June 2, 2004.

**BIOSANTE PHARMACEUTICALS, INC.**

By /s/ Stephen M. Simes

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

By /s/ Phillip B. Donenberg

Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

## POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated, on a June 2, 2004.

| Name and Signature | Title |
|---|---|
| /s/ Stephen M. Simes<br>Stephen M. Simes | Vice Chairman, President and Chief Executive Officer (Principal Executive Officer) |
| /s/ Phillip B. Donenberg | |

| | |
|---|---|
| Phillip B. Donenberg | Chief Financial Officer, Treasurer and Secretary<br>(Principal Financial and Accounting Officer) |

Table of Contents

| | |
|---|---|
| /s/ Louis W. Sullivan, M.D. | Chairman of the Board |
| Louis W. Sullivan, M.D. | |
| /s/ Edward C. Rosenow, III, M.D. | Director |
| Edward C. Rosenow, III, M.D. | |
| /s/ Victor Morgenstern | Director |
| Victor Morgenstern | |
| /s/ Ross Mangano | Director |
| Ross Mangano | |
| | Director |
| Peter Kjaer | |
| /s/ Fred Holubow | Director |
| Fred Holubow | |
| | Director |
| Angela Ho | |

Table of Contents

**BIOSANTE PHARMACEUTICALS, INC.**
**REGISTRATION STATEMENT ON FORM S-3**
**EXHIBIT INDEX**

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 2.1 | Arrangement Agreement, dated October 23, 1996, between Structured Biologicals Inc. and BioSante Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 2.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637). |
| 4.1 | Amended and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 3.1 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218). |
| 4.2 | Amendment to Amended and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 3.2 contained in BioSante s Registration Statement on Form 8-A (File No. 1-31812). |
| 4.3 | Bylaws of BioSante Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 3.2 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218). |
| 4.4 | Form of Warrant issued in connection with May 1999 Private Placement | Incorporated by reference to Exhibit 4.1 contained in BioSante s Registration Statement on Form 10-SB, as amended (File No. 0-28637). |

Table of Contents

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|---|---|---|
| 4.5 | Form of Warrant issued in connection with April 2001 Private Placement | Incorporated by reference to Exhibit 4.2 contained in BioSante s Registration Statement on Form SB-2, as amended (Reg. No. 333-64218). |
| 4.6 | Form of Warrant issued in connection with the August 2003 Private Placement | Incorporated by reference to Exhibit 10.2 contained in BioSante s Current Report on Form 8-K, filed on August 6, 2003 (File No. 0-28637). |
| 4.7 | Form of Warrant issued in connection with the May 2004 Private Placement | Incorporated by reference to Exhibit 10.2 contained in BioSante s Current Report on Form 8-K, filed on May 12, 2004 (File No. 001-31812). |
| 5.1 | Opinion of Oppenheimer Wolff & Donnelly LLP | Filed herewith electronically. |
| 23.1 | Consent of Deloitte & Touche LLP | Filed herewith electronically. |
| 23.2 | Consent of Oppenheimer Wolff & Donnelly LLP (included in Exhibit 5.1) | Included in Exhibit 5.1. |
| 24.1 | Power of Attorney | Included on page 26 of this Registration Statement. |