

BIOSANTE PHARMACEUTICALS INC

Form S-3

July 17, 2007

**Table of Contents**

**As filed with the Securities and Exchange Commission on July 17, 2007**

**Registration No. 333-**

**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**  
(State or other jurisdiction of  
incorporation or organization)

**58-2301143**  
(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:

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:

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.

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.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes or securities pursuant to Rule 413(b) under the Securities Act, check the following box.

**CALCULATION OF REGISTRATION FEE**

<b>Title of each class of securities to be registered</b>	<b>Amount to be registered (1)</b>	<b>Proposed maximum offering price per unit (2)</b>	<b>Proposed maximum aggregate offering price (2)</b>	<b>Amount of registration fee</b>
Common Stock, par value \$0.0001 per share	3,818,749	\$ 6.61	\$ 25,241.930	\$ 774.93

(1) The amount to be registered hereunder consists of an aggregate of 3,818,749 shares of common stock to be sold by the selling stockholders named in this registration statement. Of the shares of common stock, 3,054,999 shares are currently outstanding and 763,750 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 July 13, 2007, 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 July 17, 2007

**PRELIMINARY PROSPECTUS**

**3,818,749 Shares  
Common Stock**

Selling stockholders of BioSante Pharmaceuticals, Inc. are offering an aggregate of 3,818,749 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, but we will incur expenses in connection with the offering.

The shares of common stock offered will be sold as described under the heading **Plan of Distribution**, beginning on page 24.

Our common stock is listed on the American Stock Exchange under the symbol **BPA**. On July 16, 2007, the last sale price of our common stock on the American Stock Exchange was \$6.62 per share.

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

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

The date of this prospectus is \_\_\_\_\_, 2007

---

## TABLE OF CONTENTS

	<b>Page</b>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	1
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	1
<u>CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS</u>	3
<u>SUMMARY</u>	4
<u>RISK FACTORS</u>	6
<u>USE OF PROCEEDS</u>	19
<u>SELLING STOCKHOLDERS</u>	20
<u>PLAN OF DISTRIBUTION</u>	24
<u>LEGAL MATTERS</u>	26
<u>EXPERTS</u>	26
<u>Exhibit 5.1</u>	
<u>Exhibit 23.1</u>	

*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®, Elestrin®, Bio-E-Gel®, Bio-E/P-Gel®, LibiGel®, LibiGel-E/T®, Bio-T-Gel®, BioVant®, NanoVant®, CAP-Oral® and BioAir®.*

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.

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.

---

**Table of Contents**

**WHERE YOU CAN FIND MORE INFORMATION**

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.

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:

100 F Street, N.E.

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, 100 F Street, N.E., 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](http://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.

**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 the SEC, 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 into this prospectus:

our Annual Report on Form 10-K for the year ended December 31, 2006;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007;

our Current Reports on Form 8-K filed on January 19, 2007, March 7, 2007, April 26, 2007 and May 25, 2007;  
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 after the date of this prospectus and prior to the termination of the offering of the securities to which this prospectus relates. In no event, however, will any of the information that we furnish to the SEC in any Current Report on Form 8-K or any other report or filing be incorporated by reference into, or otherwise included in, this prospectus.

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



**Table of Contents**

**CAUTIONARY STATEMENT CONCERNING  
FORWARD-LOOKING STATEMENTS**

This prospectus and any prospectus supplement, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. All statements other than statements of historical facts included in or incorporated by reference into this prospectus that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate, words and terms of similar meaning. Our forward-looking statements generally relate to:

the timing of the commencement and completion of our clinical trials and other regulatory status of our proposed products;

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;

whether and how long our existing cash will be sufficient to fund our operations;

our need and ability to raise additional capital through future equity and other financings; and

our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. 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 are described under the heading "Risk Factors" included elsewhere in this prospectus.

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 under the heading "Risk Factors" included elsewhere in this prospectus, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading "Risk Factors" included elsewhere in this prospectus. The risks and uncertainties described under the heading "Risk Factors" included elsewhere in this prospectus are not exclusive and further information concerning us 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, except if we otherwise are required by law. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

**Table of Contents**

**SUMMARY**

**Our Company**

We are a biopharmaceutical company that licenses and develops hormone therapy products to treat men and women. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for vaccine adjuvants or immune system boosters and drug delivery systems.

Our hormone therapy products address a variety of hormone therapies for symptoms that affect both men and women, with an emphasis on women. Symptoms addressed by these hormone therapies in women include hot flashes and decreased sexual desire and sexual activity. The products are gel formulations of testosterone, estradiol, a combination of estradiol and testosterone, a combination of estradiol and progesterone and a combination of three hormones. The gels are designed to be quickly absorbed through the skin after application on the upper arm for the women's products, delivering the hormone to the bloodstream evenly and in a non-invasive, painless manner. The gels are formulated to be applied once per day, to be absorbed into the skin without a trace of residue and to dry within one to two minutes.

Our hormone therapy gel products include:

Elestrin (formerly known as Bio-E-Gel) once daily transdermal bioidentical estradiol gel FDA-approved for the treatment of vasomotor symptoms in menopausal women.

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

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

Triple Hormone Contraceptive the use of an androgen, such as LibiGel, in women using hormonal contraceptives.

In order to market our hormone therapy products in the United States, we are required to obtain approval of a new drug application (NDA) or an abbreviated NDA (ANDA) for each such product from the United States Food and Drug Administration (FDA). We submitted an NDA for Elestrin in February 2006 and received approval of the NDA from the FDA for Elestrin in December 2006. The Elestrin FDA approval is a non-conditional and full approval with no additional commitments. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States, which marketing began in mid-June 2007. Prior to submitting an NDA or ANDA for our other hormone therapy products, the products must undergo additional human clinical trials. Our proposed LibiGel product has successfully completed a Phase II clinical trial, and we began the first of two Phase III clinical trials in December 2006. We believe based on FDA guidance to us that two Phase III safety and efficacy trials and one year of LibiGel exposure in a separate safety trial with a four year follow-up post-NDA filing and FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel.

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. We are pursuing the development of three potential initial applications for our CaP

**Table of Contents**

technology. First, we are pursuing 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 same nanoparticles allow for delivery of the vaccine via alternative routes of administration including non-injectable routes of administration. Second, we are pursuing the creation of oral, buccal, intranasal, inhaled and longer acting delivery of drugs that currently must be given by injection (e.g., insulin). Third, our CaP technology is being tested in the area of aesthetic medicine.

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 viral and bacterial infections and autoimmune diseases, among others, including hepatitis B, avian flu and biodefense vaccines for toxins such as anthrax. BioVant also serves as a delivery system for non-injected delivery of vaccines.

**BioOral** a delivery system using CaP technology for oral/buccal/intranasal 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.

**BioCap** using CaP technology in the field of aesthetic medicine.

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, Lincolnshire, Illinois 60069. Our telephone number is (847) 478-0500 and our Internet web site address is [www.biosantepharma.com](http://www.biosantepharma.com). The information contained on our web site or connection to our web site is not incorporated by reference into and should not be considered part of this prospectus.

**The Offering**

Common stock offered by selling stockholders	3,818,749 shares, including 763,750 shares issuable upon exercise of warrants owned by the selling stockholders.
Use of proceeds.	BioSante will not receive any of the proceeds from the sale of the shares offered hereby. See Use of Proceeds.
American Stock Exchange symbol.	BPA

**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.*

***Although we were profitable for the fiscal year ended December 31, 2006, we have a history of operating losses, expect continuing losses and may never again achieve profitability.***

Although we recognized net income of \$2,791,273 for the year ended December 31, 2006, we have incurred losses in each other year since our amalgamation in 1996 and may incur substantial and continuing losses for the foreseeable future. We incurred a net loss of \$1,817,018 for the three month period ended March 31, 2007 and as of March 31, 2007, our accumulated deficit was \$48,714,065.

All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions and revenue earned from subcontracts. We have not commercially introduced any products. Although our new marketing partner, Bradley Pharmaceuticals, Inc., commercially launched Elestrin in mid-June 2007 for which we will be entitled to receive royalties on the net sales, 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 or continue, including in particular our Phase III clinical trial program for our LibiGel product which commenced in December 2006. 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 timing and cost of obtaining necessary regulatory approvals;

the commercial success and net sales of Elestrin, on which we will receive royalties; and

the costs of licensure or acquisition of new products.

In order to generate new and significant revenues, we must successfully develop our own proposed products and enter into collaborative agreements with others who can successfully 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 not generate additional revenues or achieve profitability in future years.

***We may 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 obtain regulatory approval of our other proposed products or to complete the commercialization of any of our proposed products. We expect the Phase III

**Table of Contents**

clinical trial program of LibiGel to require significant resources. Therefore, we may need to raise substantial additional capital to fund our operations. We believe that our cash and short-term investments of \$15,147,707 at March 31, 2007, together with payments we are currently entitled to receive from Bradley under our sublicense agreement with Bradley and the net proceeds of approximately \$17.3 million, after deduction of placement agent commissions and estimated transaction expenses, we received from a private placement of 3,054,999 shares of our common stock and warrants to purchase 763,750 shares of our common stock at a purchase price of \$6.00 per shares completed on June 13, 2007, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 18 months. However, we may resort to seeking additional financing prior to that time. As an alternative to raising additional financing, we may be able to license LibiGel to a third party who would finance the continued development and if approved, commercialization of LibiGel, or alternatively enter into a collaborative development agreement or other collaborative agreements with other companies of a similar size or larger than BioSante. Our future capital requirements will depend upon numerous factors, including:

the progress and costs of our research and development programs;

the scope, timing and results of our clinical trials;

patient recruitment and enrollment in our current and future clinical trials;

the cost, timing and outcome of regulatory reviews;

the commercial success and net sales of Elestrin, on which we will receive royalties;

the rate of technological advances;

ongoing determinations of the potential commercial success of our proposed products;

our general and administrative expenses;

the activities of our competitors; and

our opportunities to acquire new products or ability to take advantage of other unanticipated opportunities, including but not limited to a license to others of LibiGel or a collaborative agreement with another company.

We cannot be certain that any financing or other opportunities 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 obtain regulatory approval of our proposed products, or restrict us from acquiring new products that we believe may be beneficial to our business.

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

Our proposed products are in the development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. Other than Elestrin, which was commercially introduced in mid-June 2007 by our marketing partner, Bradley Pharmaceuticals, Inc., none of our products have been commercially introduced nor do we expect them to be for several years. We cannot assure you that any of our other proposed products will:

**Table of Contents**

be successfully developed;

prove to be safe and efficacious in clinical trials;

meet applicable regulatory standards or obtain required regulatory approvals;

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;

obtain coverage and favorable reimbursement rates from insurers and other third-party payors; or

be successfully marketed or achieve market acceptance by physicians and patients.

***If we fail to obtain regulatory approval to commercially manufacture or sell any of our future products, or if approval is delayed or withdrawn, 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. Furthermore, even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. Even after obtaining regulatory approval, we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or its manufacture are subsequently discovered. The FDA may also require us to commit to perform lengthy post-approval studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results and financial condition.

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 or the expense of current or potential licensees or collaborators, clinical trials on humans on each of our proposed products. Pre-clinical studies on animals must be conducted on some 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.

**Table of Contents**

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. We face the risk that the results of our clinical trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in early animal or human testing. Adverse or inconclusive human clinical results 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;

timely completion of clinical site protocol approval and obtaining informed consent from subjects;

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.

Delays in our clinical trials could allow our competitors additional time to develop or market competing products and thus can be extremely costly in terms of lost sales opportunities and increased clinical trial costs.

***Although Procter & Gamble (P&G) has commercially launched Intrinsa, its testosterone patch, in Europe, it is our understanding that P&G has not made any final decision as to whether it will continue to pursue regulatory approval of Intrinsa in the United States. Should P&G decide not to move forward with the development and subsequent marketing of Intrinsa in the U.S., that decision may have an adverse effect on the potential size of the U.S. female sexual dysfunction (FSD) market, the potential market for our LibiGel product and our ability to find a development partner to share in the cost of such development if we choose to seek such a partner.***

In December 2004, the FDA's Reproductive Health Drugs Advisory Committee panel voted unanimously against recommendation for approval of P&G's Intrinsa testosterone patch for hypoactive sexual desire disorder. The panel's main concern was the desire to have long-term safety data particularly as it pertains to potential increased risk of cardiovascular disease and breast cancer in women treated chronically with testosterone in combination with estrogen. Currently, the FDA has not explicitly publicly stated nor set any type of public policy or guidance document as to what size or duration of a safety trial would be required for approval.

Although P&G has commercially launched Intrinsa, its testosterone patch for FSD, in Europe, it is our understanding that P&G has not made any final decision as to whether it will continue to pursue regulatory approval of Intrinsa in the United States. It is possible that P&G will decide not to continue to develop Intrinsa in the U.S. which will adversely affect the potential size of the U.S. female sexual dysfunction market and the potential for our LibiGel product. In addition, it may adversely affect our ability to find a development partner to share in the cost of development if we decide to seek such a partner.

Some pharmaceutical products have been found to have potentially life threatening side effects and have been subsequently removed from the market. These drugs had been previously approved for sale by the

**Table of Contents**

FDA. The withdrawals of approved drugs from the market create an increased risk for the pharmaceutical industry in general in that certain proposed products may not receive the required regulatory approval on a timely basis or ever. The withdrawal of Vioxx by Merck & Co., Inc. in September 2004 has increased safety concerns of various groups including physicians, patients, members of U.S. Congress and the FDA. Although marketed product withdrawals have occurred over time, these withdrawals have resulted and may continue to result in a more cautious approach by the FDA in terms of requirements for approval of new products before approval to market is granted. These recent withdrawals could also result in additional requirements for safety monitoring called pharmacovigilance after approval to market is granted. This collective concern could result in longer, more expensive clinical trials before approval and costly post-marketing surveillance programs and at the same time could affect physicians' desire to prescribe new medication before they are on the market for a long period of time, all of which would adversely affect our business, operating results and financial condition.

***Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could adversely affect the market for hormone therapy products and the trading price of our common stock.***

The market for hormone therapy products has been negatively affected by the Women's Health Initiative study and other studies that have suggested that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among healthy postmenopausal women. In July 2002, the National Institutes of Health (NIH) released data from its Women's Health Initiative (WHI) study on the risks and benefits associated with long-term use of oral hormone therapy by healthy women. The NIH announced that it was discontinuing the arm of the study investigating the use of 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 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. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment. Researchers continue to analyze data from both arms of the WHI study and other studies. Recent reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. There currently are no studies published comparing the safety of our hormone therapy products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms have declined as a result of these published studies. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to our products, would also adversely affect our business.



**Table of Contents**

***We have entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States as a result of which we are dependent upon Bradley for the marketing and sale of our Elestrin product.***

In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Elestrin in the United States pursuant to which we received an upfront license payment and regulatory (triggered by FDA approval of Elestrin) milestone payments and have the right to receive certain sales-based milestone payments, plus royalties on sales of Elestrin. As a result of this agreement, Elestrin is subject to market acceptance of the product, and its success is also now dependent upon the success of Bradley in marketing and selling the product. We cannot assure you that Bradley will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of our agreement. Any breach by Bradley of its obligations under our agreement or a termination of the agreement could adversely affect the success of Elestrin if we are unable to sublicense the product to another party on substantially the same or better terms or continue the future commercialization of the product ourselves.

***We license the technology underlying most of our hormone therapy products and a portion of our CaP technology from third parties and may lose the rights to license them, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.***

We license most of the technology underlying our hormone therapy products from Antares Pharma IPL AG 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 sublicense agreement with a third party under which we agree to sublicense our hormone therapy technology or CaP technology for a license fee, the termination of the main license agreement with Antares Pharma IPL AG or the University of California could either, depending upon the terms of the sublicense agreement, cause us to breach our obligations under the sublicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the sublicense fees.

***We have licensed four of our 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 the development and marketing of our licensed products. In addition, these third parties also may compete with us with respect to some of our proposed products.***

We have licensed four of our hormone therapy product to third parties, Bradley Pharmaceuticals, Inc., Solvay Pharmaceuticals, B.V., Teva Pharmaceuticals USA, Inc. and Pantarhei Bioscience B.V. Solvay, Teva and Pantarhei have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. In addition, we may in the future enter into additional similar license agreements. Our partnered products that we have licensed to others are thus subject to not only customary and inevitable uncertainties associated with the drug development process, regulatory approvals and market acceptance of products, but also depend on the respective licensees for

**Table of Contents**

timely development, obtaining required regulatory approvals, commercialization and otherwise continued commitment to the products. Our current and future licensees may have different and, sometimes, competing priorities. We cannot assure you that our partners or any future third party to whom we may license our proposed products will remain focused on the development and commercialization of our partnered products or will not otherwise breach the terms of our agreements with them, especially since these third parties may also compete with us with respect to some of our proposed products. Any breach by our partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could adversely affect development of the products in these agreements if we are unable to sublicense the proposed products to another party on substantially the same or better terms or continue the development and future commercialization of the proposed products ourselves.

***Elestrin, which is now FDA approved, and our other proposed products, if they receive FDA approval, may not achieve expected levels of market acceptance, which could have a material adverse effect on our business, financial position and operating results and could cause the market value of our common stock to decline.***

The commercial success of our FDA-approved product, Elestrin, and our other proposed products, if they receive the required regulatory approvals, is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our products could be affected by several factors, including:

the availability of alternative products from competitors;

the price of our products relative to that of our competitors;

the timing of market entry; and

the ability to market our products effectively.

Some of these factors are not within our control, especially if we transfer all of the marketing rights associated with the product to others, as we have with Elestrin to Bradley Pharmaceuticals, Inc. Elestrin and our proposed products may not achieve expected levels of market acceptance. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

***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, many 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, some of whom are our development partners, will not succeed in developing similar technologies and products more rapidly than we do, commercially

**Table of Contents**

introducing such technologies and products to the marketplace prior to us, or that these competing technologies and products will not be more effective or successful than any of those that we currently are developing or will develop. ***Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply, we could experience material adverse effects on our business, financial position and results of operations, and the market value of our common stock could decline.***

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For example, we must comply with FDA requirements with respect to the development of our proposed products and our clinical trials, and if any of our proposed products are approved, the manufacture, labeling, sale, distribution, marketing, advertising and promotion of our products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Despite our efforts at compliance, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, our business, financial position and results of operations could be materially affected and the market value of our common stock could decline.

***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. 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 licensor's patent applications will result in issued patents.

Competitors may interfere with our patents and 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 have our patents reexamined by showing the patent examiner that the invention was not original or novel or was obvious.

We are engaged 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.

**Table of Contents**

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 protection on products covered by 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 efforts to secure 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 resulting in a loss of protection. 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 business, financial condition and operating results.***

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 and also are maintained in secrecy outside the United States until the application is published. Accordingly, we can conduct only limited searches to determine whether our technology infringes the patents or patent applications of others. Any claims of patent infringement asserted by third parties 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.

**Table of Contents**

***We have very limited staffing and will continue to be dependent upon key employees.***

Our success is dependent upon the efforts of a small management team and staff. We have employment arrangements in place with both of our two executive officers, but neither of our executive officers is legally bound to remain employed for any specific term. Although we have key man life insurance on our President and Chief Executive Officer, Stephen M. Simes, we do not have key man life insurance policies covering our other executive officer or any of our other employees. If key individuals leave BioSante, we could be adversely affected if suitable replacement personnel are not quickly recruited.

There is competition for qualified personnel in all functional areas, which makes it difficult to attract and retain the qualified personnel necessary for the development and growth of our business. Our future success depends upon our ability to continue to attract and retain qualified personnel.

***The price and trading volume of our common stock has been, and may continue to be, volatile.***

Historically, the market price and trading volume of our common stock has fluctuated over a wide range. During the past 12 months, our common stock traded in a range from a low of \$1.48 to a high of \$8.00, and our daily trading volume ranged from 6,300 shares to 3,015,500 shares. It is likely that the price and trading volume of our common stock will continue to fluctuate in the future. The securities of small capitalization, biopharmaceutical companies, including our company, from time to time experience significant price and volume fluctuations, often unrelated to the operating performance of these companies. In particular, the market price and trading volume of our common stock may fluctuate significantly due to a variety of factors, including:

governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products or our competitors' products;

the results of our clinical trials or those of our competitors;

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

announcements by licensors or licensees of our technology;

public concern as to the safety or efficacy of or market acceptance of products developed by us or our competitors;

developments or disputes concerning patents or other proprietary rights;

our ability to obtain needed financing;

period-to-period fluctuations in our financial results, including our cash, cash equivalents and short-term investment balance, operating expenses, cash burn rate or revenues;

loss of key management;

common stock sales in the public market by one or more of our larger stockholders, officers or directors;

other potentially negative financial announcements, including delisting of our common stock from the American Stock Exchange, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results or delays in our filings with the SEC; and

**Table of Contents**

economic conditions in the United States and abroad.

In addition, the occurrence of any of the risks described above or elsewhere in this report or otherwise in reports we file with or submit to the SEC from time to time could have a material and adverse impact on the market price of our common stock. For example, in December 2004, primarily as a result of the unanimous vote by the FDA's Reproductive Health Drugs Advisory Committee panel against recommendation for approval of Procter & Gamble's Intrinsic testosterone patch for hypoactive sexual desire disorder, the price of our common stock decreased over 35% in one trading day and over 50% over the course of three trading days. In addition, on the day of and first two trading days after the public announcement of FDA advisory panel's recommendation, the daily trading volume of our common stock went from an average of approximately 166,000 shares per day to an average of over approximately 3 million shares per day for those same three days and then back down to an average of approximately 140,000 shares per day. Our current trading volume is approximately 300,000 shares per day.

Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. We may become the target of similar litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business and financial condition, as well as the market price of our common stock.

***We received an inquiry from the Securities and Exchange Commission in connection with a complaint by a former officer.***

The staff of the Securities and Exchange Commission's Division of Enforcement is conducting an investigation arising out of allegations contained in a complaint made by a former officer of our company to the U.S. Department of Labor, Occupational Safety & Health Administration in February 2006 under the whistleblower provision of the Sarbanes-Oxley Act of 2002, which complaint was subsequently closed by OSHA in August 2006. Although we believe the allegations in the complaint are without merit, it is possible that the staff of the SEC's Division of Enforcement may disagree with our conclusion.

On March 28, 2007, we received notice that the staff of the Securities and Exchange Commission's Division of Enforcement is conducting an investigation arising out of allegations contained in a complaint made by a former officer of our company to the U.S. Department of Labor, Occupational Safety & Health Administration in February 2006 under the whistleblower provision of the Sarbanes-Oxley Act of 2002. Immediately upon notice of the former officer's intent to file the SOX complaint in January 2006, the Board of Directors of our company directed that an investigation be made into the allegations of securities and other law violations contained in the former officer's SOX complaint. The results of the investigation led to the conclusion by us and our outside legal counsel that the allegations in the SOX complaint were without merit. OSHA closed its investigation into the SOX complaint in August 2006. The Staff has informed us that the Staff's inquiry into the matter should not be construed as an indication by the SEC or the Staff that any violation of law has occurred. We intend to fully cooperate with the Staff. Although we believe the allegations in the complaint are without merit, it is possible that the Staff may disagree with our conclusion.

***Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.***

We are in the process of documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act requires our management to assess and our independent registered public accounting firm to provide an opinion on the effectiveness of our internal controls over financial reporting (ICFR) beginning with our

**Table of Contents**

fiscal year ended December 31, 2007. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. While we feel that our key controls are currently effective, we have not yet completed a formal assessment of our ICFR. We continue to enhance our ICFR by adding additional resources in key functional areas and bringing all of our operations up to the level of documentation, segregation of duties, and systems security necessary, as well as transactional control procedures required, which we believe to be necessary under current and proposed standards issued by the Public Company Accounting Oversight Board and the SEC.

We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effects on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the American Stock Exchange. Any such action could adversely affect our financial results, financial position and the market price of our common stock. In addition, if one or more material weaknesses is identified in ICFR, we will be unable to assert that our ICFR is effective. If we are unable to assert that our ICFR is effective (or if our independent registered public accounting firm is unable to express an opinion or issues an adverse opinion on the effectiveness of our ICFR), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective ICFR in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective ICFR could have an adverse effect on our common stock price.

***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.

***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:

**Table of Contents**

authorizing the issuance of blank check preferred shares 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.

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

As of June 13, 2007, we had issued and outstanding 26,743,349 shares of common stock, 391,286 shares of our class C stock and outstanding options and warrants to purchase 3,835,676 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 may issue additional equity securities which would dilute your share ownership.***

We may 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 would dilute your share ownership.



**Table of Contents**

**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 placement completed in June 2007. The following table sets forth information known to us with respect to the beneficial ownership of our common stock as of June 13, 2007 as provided by the selling stockholders. In accordance with the rules of the SEC, beneficial ownership includes the shares issuable pursuant to warrants that are exercisable within 60 days of June 13, 2007. Shares issuable pursuant to warrants are considered outstanding for computing the percentage of the person holding the warrants but are not considered outstanding for computing the percentage of any other person. The warrants issued in June 2007 become exercisable on December 14, 2007 and are subject to a conversion cap which precludes the holder thereof from exercising such warrants to the extent that such owner would beneficially own in excess of 4.99% or 9.99% of BioSante's common stock. These warrants are included in shares beneficially owned prior to the offering.

The percentage of beneficial ownership for the following table is based on 26,743,349 shares of common stock outstanding as of June 13, 2007. To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person.

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

Selling Stockholder	Shares Beneficially Owned Prior to the Offering			Number of Shares Being Offered	Shares Beneficially Owned After Completion of the Offering	
	Shares Subject to Options, Warrants, and Class C Special Stock	Total Shares Beneficially Owned	Percentage		Number	Percentage
Amatine Limited Partnership (1)	17,500	87,500	*	87,500	0	
Anova Underwriting Ltd. (2)	22,500	153,500	*	112,500	41,000	*
Roni Ben-David	12,500	62,500	*	62,500	0	
Bristol Investment Fund, Ltd. (3)	10,417	52,084	*	52,084	0	
Cranshire Capital, L.P. (4)	20,833	104,166	*	104,166	0	
Crescent International Ltd. (5)	12,500	62,500	*	62,500	0	
Diamond Opportunity Fund, LLC (6)	54,167	95,834	*	52,084	43,750	*
Excellence Kupot Mizrahi Lesheavar Ltd. (7)	45,000	500,675	1.9%	225,000	275,675	1.0%

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form S-3

Excellence Nessuah Gemel Ltd. (7)	22,500	923,881	3.5%	112,500	811,381	3.0%
Excellence Phoenix Insurance Company Ltd. (7)	3,750	95,450	*	18,750	76,700	*
Fort Mason Master, L.P. (8)	78,258	391,291	*	391,291	0	
Fort Mason Partners, L.P. (8)	5,075	25,375	*	25,375	0	
GCA Strategic Investment Fund Limited (9)	20,833	104,166	*	104,166	0	
Hudson Bay Fund LP (10)	53,750	268,750	*	268,750	0	
Hudson Bay Overseas Fund LTD (10)	71,250	356,250	*	356,250	0	
Ion Israel Fund (11)	11,500	251,500	*	57,500	194,000	*
Ion Israel Partners (11)	38,500	278,500	*	192,500	86,000	*
Iroquois Master Fund Ltd. (12)	64,583	147,916	*	104,166	43,750	*
Machshava Management & Consultant LTD (13).	22,500	172,300	*	112,500	59,800	*
Menora Mivtachim Gemel Ltd. (14)	18,000	90,000	*	90,000	0	

20

**Table of Contents**

	Shares Beneficially Owned Prior to the Offering			Shares Beneficially Owned After Completion of the Offering		
	Shares Subject to Options, Warrants, and Class C Special Stock	Total Shares Beneficially Owned	Percentage	Number of Shares Being Offered	Number	Percentage
<b>Selling Stockholder</b>						
Menora Mivtachim Gemel Ltd. (14)	7,000	35,000	*	35,000	0	
Menora Mivtachim Insurance Ltd. (14)	25,000	125,000	*	125,000	0	
Menora Mivtachim Pension Fund Ltd. (15)	4,250	21,250	*	21,250	0	
Menora Mivtachim Provider Fund Ltd. (15)	45,750	228,750	*	228,750	0	
Otago Partners, LLC (16)	8,750	43,750	*	43,750	0	
Pansk Assets A.Y. Ltd. (17)	31,250	156,250	*	156,250	0	
Portside Growth and Opportunity Fund (18)	10,417	52,084	*	52,084	0	
Rockmore Investment Master Fund Ltd. (19)	10,417	52,083	*	52,083	0	
Sheffield Partners, L.P. (20)	11,246	152,031	*	1,165	150,866	*
Sheffield Institutional Partners, L.P. (20)	32,660	311,720	1.2%	77,908	233,812	*
Sheffield International Partners, Ltd. (20)	19,844	235,370	*	20,927	214,443	*
Tao Tsuot Ltd. (21)	37,500	232,900	*	187,500	45,400	*
The Consilience Fund Ltd. (22)	3,750	18,750	*	18,750	0	
Y.A.Z. Investments & Assets Ltd. (23)	31,250	156,250	*	156,250	0	
Zetto Investments S.A. (24)	10,000	70,000	*	50,000	20,000	*

\* Less than one percent (1%)

1. Eran Wiss is the general partner of Amatrine Limited Partnership and has sole voting

control and investment control over the securities held by Amatrine Limited Partnership. Eran Wiss disclaims beneficial ownership of the shares held by Amatrine Limited Partnership.

2. Ze'ev Cohen has sole voting and investment control over the shares held by Anova Underwriting Ltd.

3. Bristol Capital Advisors, LLC is the investment advisor to Bristol Investment Fund, Ltd. Paul Kessler is the manager of Bristol Capital Advisors, LLC and as such has voting and investment control over the securities held by Bristol Investment Fund, Ltd. Mr. Kessler disclaims beneficial ownership of these securities. Bristol Capital

Advisors, LLC was an investor in our July 2006 private placement.

4. Mitchell P. Kopin, the president of Downsview Capital, Inc., the general partner of Cranshire Capital, L.P., has sole voting control and investment control over the securities held by Cranshire Capital, L.P. Each of Mitchell P. Kopin and Downsview Capital, Inc. disclaims beneficial ownership of the securities held by Cranshire Capital, L.P.
5. Cantara (Switzerland) SA is the investment advisor to Crescent International Ltd. Maxi Brezzi and Bachir Taleb-Ibrahimi are managers of Cantara (Switzerland) SA, and as such have authority to vote and

dispose of the securities held by Crescent International Ltd. Messrs. Brezzi and Taleb-Ibrahimi disclaim beneficial ownership of such securities. Crescent International Ltd. was an investor in our July 2006 private placement.

6. David Hokin, Rob Rubin and Richard Marks, in their respective capacity as manager and managing Directors of Diamond Opportunity Fund, LLC, have shared voting and investment control over the securities held by Diamond Opportunity Fund, LLC. Messrs. Hokin, Rubin and Marks disclaim beneficial ownership of such securities. Diamond Opportunity Fund, LLC was an investor in our July 2006 private

placement.

7. Gili Cohen is the investment advisor to each of Excellence Kupot Mizrahi Lesheavar Ltd., Excellence Nessuah Gemel Ltd. and Excellence Phoenix Insurance Company Ltd. Gili Cohen is the manager of the Funds Providence and as such has voting and investment control over the securities held by each of Excellence Kupot



**Table of Contents**

Mizrahi  
Lesheavar Ltd.,  
Excellence  
Nessuah Gemel  
Ltd. and  
Excellence  
Phoenix  
Insurance  
Company Ltd.  
Gili Cohen  
disclaims  
beneficial  
ownership of  
these securities.

8. Fort Mason  
Capital, LLC  
serves as the  
general partner  
of each of Fort  
Mason Master,  
L.P. and Fort  
Mason Partners,  
L.P. and, in  
such capacity,  
exercises sole  
voting and  
investment  
authority over  
the securities  
held by Fort  
Mason Master,  
L.P. and Fort  
Mason Partners,  
L.P. Daniel  
German serves  
as the sole  
managing  
member of Fort  
Mason Capital,  
LLC. Fort  
Mason Capital,  
LLC and  
Mr. German  
each disclaim  
beneficial  
ownership of  
these securities,  
except to the

extent of its or his pecuniary interest therein, if any.

9. Lewis N. Lester and Michael S. Brown are Directors of GCA Strategic Investment Fund Limited and as such have voting and investment control over the securities held by GCA Strategic Investment Fund Limited. Lewis N. Lester and Michael S. Brown disclaim beneficial ownership of these securities. GCA Strategic Investment Fund Limited is an affiliate of a registered broker dealer and has indicated to us that it purchased the securities being offered under this prospectus in the ordinary course of business and, at the time of purchase, had no agreements or understandings to distribute the securities.

10. Sander Gerber, Yoav Roth and John Doscas share voting and investment control over the securities held by Hudson Bay Fund, L.P. and Hudson Bay Overseas Fund, Ltd. Each of Sander Gerber, Yoav Roth and John Doscas disclaim beneficial ownership over these securities. Each of Hudson Bay Fund, L.P. and Hudson Bay Overseas Fund, Ltd. are affiliates of a registered broker-dealer and each have indicated to us that it purchased the securities being offered under this prospectus in the ordinary course of business and, at the time of purchase, had no agreements or understandings to distribute the securities.
  
11. Ion Asset Management Ltd. is the investment advisor to Ion Israel Fund and

Ion Israel Partners. Ion Asset Management (Israel) Ltd. is the manager of Ion Asset Management Ltd. Stephen Levey and Jonathan Half are managing directors of Ion Asset Management Ltd. and as such have voting and investment control over the securities held by each of Ion Israel Fund and Ion Israel Partners. Each of Stephen Levey and Jonathan Half disclaim beneficial ownership of these securities.

12. Joshua Silverman has voting and investment control over the shares held by Iroquois Master Fund Ltd. Mr. Silverman disclaims beneficial ownership of such securities. Iroquois Master Fund Ltd. was an investor in our July 2006 private placement.

13. Ze'ev Cohen has sole voting and investment control over the securities held by Machshava Management & Consultant LTD.
  
14. Yori Tal and Avi Sternschuss are investment directors to each of Menora Mivtachim Gemel Ltd. and Menora Mivtachim Insurance Ltd. and as such have voting and investment control over the securities held by each of Menora Mivtachim Gemel Ltd. and Menora Mivtachim Insurance Ltd. Yori Tal and Avi Sternschuss disclaim beneficial ownership of these securities.
  
15. Rami Armon is investment director of each of Menora Mivtachim Pension Fund Ltd. and Menora Mivtachim Provider Fund Ltd. and as such has voting and

investment  
control over the  
securities held  
by each of  
Menora  
Mivtachim  
Pension Fund  
Ltd. and Menora  
Mivtachim  
Provider Fund  
Ltd. Rami  
Armon  
disclaims  
beneficial  
ownership of  
these securities.

16. Lindsay A. Rosenwald, M.D., is the managing and sole member of Otago Partners, LLC, and as such has authority to vote and dispose of the securities held by Otago Partners, LLC. Dr. Rosenwald is the sole shareholder and chairman of Paramount BioCapital, Inc., a registered broker-dealer and Paramount BioCapital Asset Management, Inc., an investment advisor. Otago Partners, LLC has indicated to us that it purchased the shares being offered under

this prospectus  
in the ordinary  
course of  
business and, at  
the time of  
purchase, had  
no agreements  
or  
understandings  
to distribute the  
shares.

17. Yehuda Zadik is  
the manager of  
Pansk Assets  
A.Y. Ltd. and as  
such has voting  
and investment  
control over the  
securities held  
by Pansk Assets  
A.Y. Ltd.  
Yehuda Zadik  
disclaims  
beneficial  
ownership of  
these securities.

**Table of Contents**

18. Ramius Capital Group, L.L.C. is the investment adviser of Portside Growth and Opportunity Fund and consequently has voting control and investment discretion over the securities held by Portside Growth and Opportunity Fund. Ramius Capital Group, L.L.C. disclaims beneficial ownership of the securities held by Portside Growth and Opportunity Fund. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S & Co., L.L.C., the sole managing member of Ramius Capital Group, L.L.C. As a result, Messrs. Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any securities deemed to be beneficially owned by Ramius Capital Group, L.L.C. Messrs. Cohen, Stark, Strauss and Solomon disclaim



beneficial ownership of these securities. Portside Growth and Opportunity Fund is an affiliate of a registered broker dealer and has indicated to us that it purchased the securities being offered under this prospectus in the ordinary course of business and, at the time of purchase, had no agreements or understandings to distribute the securities.

19. Rockmore Capital, LLC and Rockmore Partners, LLC, serve as the investment manager and general partner, respectively, to Rockmore Investments (US) LP, which invests all of its assets through Rockmore Investment Master Fund Ltd. By reason of such relationships, Rockmore Capital, LLC and Rockmore Partners, LLC may be deemed to share dispositive power over the securities owned

by Rockmore  
Master Fund Ltd.  
Rockmore  
Capital, LLC and  
Rockmore  
Partners, LLC  
disclaim  
beneficial  
ownership of  
these securities.  
Rockmore  
Partners, LLC has  
delegated  
authority to  
Rockmore  
Capital, LLC  
regarding the  
portfolio  
management  
decisions with  
respect to the  
securities owned  
by Rockmore  
Master Fund Ltd.  
Bruce T.  
Bernstein and  
Brian Daly, as  
officers of  
Rockmore  
Capital, LLC, are  
responsible for the  
portfolio  
management  
decisions of the  
securities owned  
by Rockmore  
Master Fund Ltd.  
By reason of such  
authority, Messrs.  
Bernstein and  
Daly may be  
deemed to share  
dispositive power  
over the securities  
owned by  
Rockmore Master  
Fund Ltd.  
Messrs. Bernstein  
and Daly disclaim  
beneficial  
ownership of such

securities and neither of such persons has any legal right to maintain such authority. No other person has sole or shared voting or dispositive power with respect to the securities owned by Rockmore Master Fund Ltd.

20. Brian J. Feltzin and Craig C. Albert are the members of Sheffield Asset Management, L.L.C., the general partner of Sheffield Partners, L.P. and Sheffield Institutional Partners, L.P. and the investment advisor to Sheffield International Partners, Ltd., and consequently have voting control and investment discretion over securities owned by Sheffield Partners, L.P., Sheffield Institutional Partners, L.P. and Sheffield International Partners, Ltd. As a result, Brian J. Feltzin and Craig C. Albert may be considered the beneficial owners of any shares

deemed to be  
beneficially  
owned by  
Sheffield Partners,  
L.P., Sheffield  
Institutional  
Partners, L.P. and  
Sheffield  
International  
Partners, Ltd.  
Sheffield Partners,  
L.P., Sheffield  
Institutional  
Partners, L.P. and  
Sheffield  
International  
Partners, Ltd.  
were investors in  
our July 2006  
private placement.

21. Ilan Ben-Dov is the Chairman and Yossi Arad is the Chief Executive Officer of Tao Tsuot Ltd. and as such have voting and investment control over the securities held by Tao Tsuot Ltd. Ilan Ben-Dov and Yossi Arad disclaim beneficial ownership of these securities.
22. Amit Snir is the director of The Consilience Fund and as such has voting and investment control over the securities held by The Consilience Fund Ltd. Amit Snir disclaims beneficial

ownership of  
these securities.

23. Yehuda Zadik is the manager of Y.A.Z. Investments & Assets Ltd. and as such has voting and investment control over the securities held by Y.A.Z. Investments & Assets Ltd. Yehuda Zadik disclaims beneficial ownership of these securities.

24. Arie Weber is the investment advisor to Zetto Investments S.A. and is the manager of Director and as such has voting and investment control over the securities held by Zetto Investments S.A. Arie Weber disclaims beneficial ownership of these securities.

Information concerning the selling stockholders may change from time to time and any such changed information will be set forth in supplements to this prospectus, if and when necessary.

**Table of Contents**

**PLAN OF DISTRIBUTION**

Each selling stockholder of the common stock and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the American Stock Exchange or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

In connection with the sale of the common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such

**Table of Contents**

broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

**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.

**EXPERTS**

The financial statements incorporated in this prospectus by reference from BioSante Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2006, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, and have 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	\$ 775
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	500
Miscellaneous	10,000
*Total	 \$ 57,275

\* 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. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective 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

**Table of Contents**

by reference in the registration statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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

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

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) The undersigned registrant hereby undertakes 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.

(c) The undersigned registrant hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a-3 or Rule 14c-3 under the Securities Exchange Act of 1934, as amended and, where interim financial information required to be presented by Article 3 of Regulation S-X are not set forth in the prospectus, to deliver or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

(d) 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 July 17, 2007.

**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 July 17, 2007.

<b>Name and Signature</b>	<b>Title</b>
/s/ Stephen M. Simes Stephen M. Simes	Vice Chairman, President and Chief Executive Officer (Principal Executive Officer)
/s/ Phillip B. Donenberg Phillip B. Donenberg	Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)
/s/ Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Chairman of the Board

**Table of Contents**

<b>Name and Signature</b>	<b>Title</b>
/s/ Fred Holubow	Director
Fred Holubow	
/s/ Peter Kjaer	Director
Peter Kjaer	
/s/ Ross Mangano	Director
Ross Mangano	
/s/ Edward C. Rosenow, III, M.D.	Director
Edward C. Rosenow, III, M.D.	

II-5

---

**Table of Contents**

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

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
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 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).
4.5	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).
4.6	Form of Warrant issued in connection with the July 2006 Private Placement.	Incorporated by reference to Exhibit 10.2 contained in BioSante's Current Report on Form 8-K, filed on July 24, 2006 (File No. 001-31812).

**Table of Contents**

<b>Exhibit No.</b>	<b>Exhibit</b>	<b>Method of Filing</b>
4.7	Form of Warrant issued in connection with the June 2007 Private Placement.	Incorporated by reference to Exhibit 10.2 contained in BioSante's Current Report on Form 8-K, filed on June 14, 2007 (File No. 001-31812).
5.1	Opinion of Oppenheimer Wolff & Donnelly LLP.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith.
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 II-4 of this Registration Statement.

E-2