

BIOSANTE PHARMACEUTICALS INC

Form S-3

December 18, 2008

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As filed with the Securities and Exchange Commission on December 18, 2008

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

58-2301143

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification Number)

111 Barclay Boulevard

Lincolnshire, Illinois 60069

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(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:

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

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

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

If 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. O

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. O

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer O Accelerated filer X Non-accelerated filer O Smaller reporting company O
 (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per unit	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock, par value \$0.0001 per share	5,705,840(3)	\$ 1.40(2)	\$ 7,988,176	\$ 313.94

(1) 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 sales prices of the registrant's common stock on December 16, 2008 as reported by the NASDAQ Global Market.

(3) Includes 300,000 shares of common stock that may be issued upon the exercise of warrants.

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.

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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 December 18, 2008

PRELIMINARY PROSPECTUS

5,705,840 Shares

Common Stock

This prospectus relates to the resale of up to 5,705,840 shares of our common stock by the selling stockholder named herein. On December 15, 2008, we entered into a common stock purchase agreement with Kingsbridge Capital Limited, or Kingsbridge, pursuant to which we may issue to Kingsbridge up to 5,405,840 shares of our common stock. We are not required to sell any shares of common stock to Kingsbridge under the common stock purchase agreement. On the same date, we also issued Kingsbridge a warrant to purchase up to 300,000 shares of our common stock. To the extent that we elect to sell any shares of our common stock to Kingsbridge pursuant to the common stock purchase agreement or Kingsbridge elects to exercise the warrant to acquire shares, this prospectus may be used by the selling stockholder named under the section titled "Selling Stockholder" to resell such shares. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholder may resell its shares of our common stock in the section titled "Plan of Distribution" beginning on page 30. Kingsbridge is an underwriter within the meaning of the Securities Act with respect to any shares resold under this prospectus by the selling stockholder. Although we will pay the expenses incurred in registering the shares, we will not be paying any underwriting discounts or commissions in this offering.

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Our common stock is listed on the NASDAQ Global Market under the symbol BPAX. On December 16, 2008, the reported closing price of our common stock was \$1.38 per share.

Investing in our common stock involves a high degree of risk. We refer you to Risk Factors, beginning on page 8.

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

The date of this prospectus is _____, 2008

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

We own or have the rights to use various trademarks, trade names or service marks, including BioSante[®], 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.

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PROSPECTUS SUMMARY

The following summary highlights information contained in this prospectus or incorporated by reference. While we have included what we believe to be the most important information about BioSante and this offering, the following summary may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the risks of investing discussed under Risk Factors beginning on page 8, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering.

Our Company

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We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. Our primary products are gel formulations of testosterone and estradiol. Our key products include:

- LibiGel once daily transdermal testosterone gel in Phase III development for the treatment of female sexual dysfunction (FSD).
- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause and marketed in the U.S.
- Bio-T-Gel once daily transdermal gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.
- The Pill-Plus (triple hormone contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

With respect to LibiGel, we believe based on agreements with the FDA, including a Special Protocol Assessment (SPA) received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD). The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel. These SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD, specifically, HSDD in naturally menopausal women.

Currently, three LibiGel Phase III trials are underway: two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular safety study. Both Phase III safety and efficacy trials are double-blind, placebo-controlled trials that will enroll up to approximately 500 surgically menopausal women each for a six-month clinical trial. The Phase III cardiovascular safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular events driven study of between 2,400 and 3,100 women exposed to LibiGel or placebo for 12 months at which time we intend to submit an NDA to the FDA. Following NDA submission and potential FDA approval, we will continue to follow the subjects in

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the safety study for an additional four years. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we likely will need to raise substantial additional capital to fund our operations. Alternatively, we may choose to sublicense LibiGel or another product for development and commercialization, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations.

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 technology. First, CaP technology is being tested in the area of aesthetic medicine. Second, 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. Third, 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).

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

- **BioLook** facial line filler in development using proprietary CaP technology in the area of aesthetic medicine.
- **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. 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.

Risks Affecting Us

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You should carefully consider the matters discussed in the section **Risk Factors** beginning on page 8, including the following, before you invest in our common stock. For example:

- We have a history of operating losses, expect continuing losses and may never become profitable.
- We will need to raise substantial additional capital in the near future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.
- One of our strategic goals has been, and continues to be, to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. We believe the current domestic and worldwide economic crisis has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process.

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- Although we believe LibiGel has the potential to be a successful product, its Phase III clinical program requires significant resources and there are significant risks involved in conducting the clinical trials, obtaining regulatory approval and commercializing the product, if approved.

Corporate Information

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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. We make available on our website free of charge a link to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the Securities and Exchange Commission, or SEC. The information contained on our web site or connected to our web site is not incorporated by reference into and should not be considered part of this prospectus.

Committed Equity Financing Facility with Kingsbridge

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On December 15, 2008, we entered into a committed equity financing facility, or CEFF, with Kingsbridge, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of \$25 million or 5,405,840 shares of our common stock. In connection with the CEFF, we entered into a common stock purchase agreement and registration rights agreement with Kingsbridge, both dated December 15, 2008, and on that date we also issued a warrant to Kingsbridge to purchase up to 300,000 shares of our common stock at an exercise price of \$4.00 per share. This warrant is exercisable beginning on June 15, 2009 and for a period of five years thereafter.

The shares of common stock that may be issued to Kingsbridge under the common stock purchase agreement and the warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act. Pursuant to the registration rights agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. Through this prospectus, the selling stockholder may offer to the public for resale shares of our common stock that we may issue to Kingsbridge pursuant to the common stock purchase agreement, or that Kingsbridge may acquire upon exercise of the warrant.

The common stock purchase agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of two years from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, shares of our common stock for cash consideration up to an aggregate of the lesser of \$25 million or 5,405,840 shares of our common stock, subject to certain conditions and restrictions. We are not obligated to sell any shares to Kingsbridge under the common stock purchase agreement.

For a period of 24 months from the first trading day following the effectiveness of the registration statement of which this prospectus is a part, we may, from time to time, at our sole discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount ranging from eight to 14 percent of the volume weighted average of the price of our common stock for each of the eight

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consecutive trading days following our election to sell shares or draw down under the CEFF. The discount on each of these consecutive eight trading days will be determined as follows:

VWAP*	Percent of VWAP	(Applicable Discount)
Greater than \$11.00 per share	92%	(8)%
Less than or equal to \$11.00 per share but greater than \$6.75 per share	90%	(10)%
Less than or equal to \$6.75 per share but greater than \$2.75 per share	88%	(12)%
Less than or equal to \$2.75 per share but greater than or equal to \$1.15 per share	86%	(14)%

* As set forth in the common stock purchase agreement, VWAP means the volume weighted average price (the aggregate sales price of all trades of our common stock during each trading day divided by the total number of shares of common stock traded during that trading day) of our common stock during any trading day as reported by Bloomberg L.P. using the AQR function. The VWAP and corresponding discount will be determined for each of the eight trading days during a draw down pricing period.

During the eight trading day pricing period for a draw down, if the VWAP for any trading day is less than the greater of (i) \$1.15 or (ii) 90% of the closing price of our common stock for the trading day immediately preceding the beginning of the draw down pricing period, the VWAP for that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth (1/8) of the draw down amount we had initially specified. In addition, if trading in our common stock is suspended for any reason for more than three consecutive or non-consecutive hours during trading hours on any trading day during a draw down pricing period, that trading day will not be used in calculating the number of shares to be issued in connection with that draw down, and the draw down amount for that pricing period will be reduced by one-eighth (1/8) of the draw down amount we had initially specified.

The maximum number of shares of common stock that we can issue pursuant to the CEFF is 5,405,840 shares. An additional 300,000 shares of common stock are issuable if Kingsbridge exercises the warrant that we issued to it in connection with the CEFF. We intend to exercise our right to draw down amounts under the CEFF, if and to the extent available, at such times as we have a need for additional capital and when we believe that sales of stock under the CEFF provide an appropriate means of raising capital.

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. We can make individual draw downs of a maximum amount of, at our discretion, the lesser of (i)(a) 1.5% of our market capitalization as of the date the applicable drawn down notice is given if the market capitalization is equal to or greater than \$325 million, (b) 1.0% of our market capitalization as of the date of the applicable drawn down notice is given if such market capitalization is equal to or greater than \$180 million but less than \$325 million, (c) 0.5% of our market capitalization as of the date of the applicable drawn down notice is given if such market capitalization is equal to or greater than \$35 million but less than \$180 million or (d) zero if our market capitalization as of the date of the applicable drawn down notice is given is less than \$35 million and (ii) \$5 million. Unless we and Kingsbridge agree otherwise, a minimum of 15 trading days must elapse between the expiration of any draw down pricing period and the beginning of the next succeeding draw down pricing period. Kingsbridge is not obligated to purchase shares of our common stock when the volume weighted average of the price of our common stock is below \$1.15 per share.

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During the term of the CEFF, without Kingsbridge's prior written consent, we may not issue securities that are, or may become, convertible or exchangeable into shares of our common stock where the purchase, conversion or exchange price for our common stock is determined using any floating discount or other post-issuance adjustable discount to the market price of our common stock, including pursuant to an equity line or other financing that is substantially similar to the arrangement provided for in the CEFF, with certain exceptions.

The issuance of our common stock under the CEFF or upon exercise of the Kingsbridge warrant will have no effect on the rights or privileges of existing holders of common stock except that the economic and voting interests of each stockholder will be diluted as a result of any issuance. Although the number of shares of common stock that stockholders presently own will not decrease, these shares will represent a smaller percentage of our total shares that will be outstanding after any issuances of shares of common stock to Kingsbridge. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if we were to issue shares when our stock price is higher. Such issuances will have a dilutive effect and may further decrease our stock price.

Kingsbridge agreed in the common stock purchase agreement that during the term of the CEFF, neither Kingsbridge nor any of its affiliates, nor any entity managed or controlled by it, will enter into, execute, or cause or assist any other person to enter into or execute, any short sale of any of our securities, including our common stock, or engage, through related parties or otherwise, in derivative transactions directly related to shares of our common stock, except during the term of a draw down pricing period with respect to the shares that Kingsbridge purchased pursuant to the CEFF during that draw down pricing period. Subject to the foregoing restrictions, Kingsbridge has the right during any draw down pricing period to sell shares of our common stock equal in number to the aggregate number of shares of common stock purchased pursuant to the applicable draw down.

Before Kingsbridge is obligated to buy any shares of our common stock pursuant to a draw down, the following conditions, none of which is in the control of Kingsbridge, must be met as of the date we notify Kingsbridge of our election to sell shares pursuant to the CEFF, each trading day during the draw down pricing period and the date upon which each settlement of the purchase and sale of our common stock occurs with respect to such draw down:

- Each of our representations and warranties in the common stock purchase agreement must be true and correct in all material respects as of the date when made as though made at that time, except for representations and warranties that are expressly made as of a particular date.
- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the common stock purchase agreement, the registration rights agreement and the warrant to be performed, satisfied or complied with by us.
- We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the common stock purchase agreement and the consummation of the transactions contemplated by it, except for such failures to comply as would not have a material adverse effect on the business, operations, properties or financial condition of us and our subsidiaries as a whole or prohibit or otherwise interfere with our ability to perform any of our obligations under the common stock purchase agreement, the registration rights agreement or the warrant in any material respect.

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- The registration statement, of which this prospectus is a part, must have previously become effective and must remain effective and neither us nor Kingsbridge shall have received notice that the SEC has issued or intends to issue a stop order with respect to the registration statement or that the SEC, either temporarily or permanently, intends or has threatened to do so and no other suspension of the use or withdrawal of the effectiveness of the registration statement or this prospectus shall exist.
- We must not have knowledge of any event that could reasonably be expected to have the effect of causing the registration statement, of which this prospectus is a part, to be suspended or otherwise ineffective.
- Trading in our common stock must not have been suspended by the SEC, the NASDAQ Global Market or the Financial Industry Regulatory Authority and trading in securities generally on the NASDAQ Global Market must not have been suspended or limited.
- There must not be any statute, rule, regulation, order, decree, writ, ruling or injunction enacted, entered, promulgated, endorsed or, to our knowledge, threatened by any court or governmental authority which prohibits the consummation of or would materially modify or delay any of the transactions contemplated by the common stock purchase agreement.
- There must not be any action, suit or proceeding before any arbitrator or any governmental authority that is pending, and, to our knowledge, there must not be any investigation by any governmental authority threatened, against us or any of our officers, directors or affiliates seeking to enjoin, prevent or change the transactions contemplated by the common stock purchase agreement or seeking material damages in connection with such transactions.
- We must have sufficient shares of common stock, calculated using the closing sale price of our common stock as of the trading day immediately preceding the date we notify Kingsbridge of our election to sell shares to Kingsbridge pursuant to the CEFF, registered under the registration statement of which this prospectus is a part to issue and sell such shares in accordance with such draw down.
- We must not be in default in any material respect under the warrant.
- Kingsbridge must have received an opinion of counsel as to certain legal matters regarding the transaction from our outside legal counsel.

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There is no guarantee that we will be able to meet the foregoing conditions or that we will be able to draw down any portion of the amounts available under the CEFF.

We also entered into a registration rights agreement with Kingsbridge, dated December 15, 2008. Pursuant to the registration rights agreement, we have filed the registration statement, of which this prospectus is a part, with the SEC relating to the resale by Kingsbridge of any shares of common stock purchased by it under the common stock purchase agreement or issued to it upon the exercise of its warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the common stock purchase agreement. We are entitled in certain circumstances, including the existence of certain kinds of material nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus for a period of not more than 30 days. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down or if the registration statement, of which this prospectus is a part, is not effective in circumstances not permitted by the registration rights

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agreement, then we must pay amounts to Kingsbridge or issue Kingsbridge additional shares in lieu of payment. The payment or issuance would be calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to such draw down and the change in the market price of our common stock between the date the blackout notice is delivered (or the registration statement is not effective) and the date the prospectus again becomes available.

We may terminate the CEFF upon one trading day's notice to Kingsbridge, except that we may not terminate the CEFF during any draw down pricing period. Kingsbridge may, upon one trading day's notice to us, terminate the CEFF if we enter into a transaction prohibited by the common stock purchase agreement without Kingsbridge's prior written consent or if Kingsbridge provides notice to us of a material adverse event relating to our business and the event continues for 10 trading days after the notice. Kingsbridge may also terminate the CEFF upon one trading day's notice to us at any time in the event that a registration statement is not initially declared effective in accordance with the registration rights agreement. In addition, either we or Kingsbridge may terminate the CEFF upon one trading day's notice if the other party has breached a material representation, warranty or covenant to the common stock purchase agreement and such breach is not remedied within 10 trading days after notice of such breach is delivered to the breaching party. In the event of a termination of the CEFF by Kingsbridge or us pursuant to the terms of the CEFF, Kingsbridge would retain the warrant to purchase 300,000 shares of our common stock.

The foregoing summary of the CEFF does not purport to be complete and is qualified by reference to the common stock purchase agreement, the registration rights agreement and the warrant, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part.

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RISK FACTORS

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

Risks Relating to Our Business

We have a history of operating losses, expect continuing losses and may never become profitable.

We have a history of operating losses. We incurred a net loss of \$7.6 million for the year ended December 31, 2007 and a net loss of \$16.3 million for the nine months ended September 30, 2008. As of September 30, 2008, our accumulated deficit was \$70.7 million. All of our revenue to date has been derived from upfront and milestone payments earned on licensing and sub-licensing transactions, revenue earned from subcontracts with various parties and royalty revenue. 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 LibiGel. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
- the timing and cost of obtaining necessary regulatory approvals for our proposed products;
- the commercial success and net sales of Elestrin, on which we receive royalties and potentially may receive sales-based milestones;
- the timing and cost of obtaining third party reimbursement for our products; and

- the progress, timing and costs of our business development efforts to implement business collaborations, joint ventures, licenses and other business combinations or transactions with entities that have businesses or technologies complementary to our business.

In order to generate new and significant revenues, we successfully must develop our own proposed products and enter into collaborative agreements with others who successfully can commercialize them. Even if our proposed products and the products we may license or otherwise acquire are introduced commercially, they may never achieve market acceptance and we may not generate additional revenues or achieve profitability in future years.

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

We currently do not have sufficient resources to obtain regulatory approval of our proposed products or to complete the commercialization of any of our proposed products. We expect the Phase III clinical trial program of LibiGel to require significant resources. Therefore, we will need to raise substantial additional capital to fund our operations. We believe that our cash, cash equivalents and short-term investments of \$17.5 million at September 30, 2008 will be sufficient to meet our liquidity requirements through at least the next twelve months. However, we may seek to obtain additional financing prior to that time. As an alternative to raising additional financing, we may choose to sublicense LibiGel or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization, sell certain assets or rights we have under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company.

Our future capital requirements will depend upon numerous factors, including:

- the success, progress, timing and costs of our business development efforts to implement business collaborations, licenses and other business combinations or transactions, including our efforts, with the assistance of Deutsche Bank Securities, to continue to evaluate various strategic alternatives available with respect to our products and our company;
- the progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical trial program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel;
- the commercial success and net sales of Elestrin;
- our ability to license LibiGel or our other products for development and commercialization;
- the cost, timing and outcome of regulatory reviews of our proposed products;
- the rate of technological advances;

- the commercial success of our proposed products;
- our general and administrative expenses;
- the timing and cost of obtaining third party reimbursement for our products; and
- the activities of our competitors.

Due to market conditions and the status of our product development programs, we cannot assure you that additional financing will be available on terms favorable to us, or at all. If adequate funds are not available or are not available on acceptable terms when we need them, we may be required to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our proposed products or to relinquish greater or all rights to our proposed products at an earlier stage of development or on less favorable terms than we otherwise would choose. Failure to obtain adequate financing also

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may adversely affect our ability to operate as a going concern and cause us to significantly curtail or cease ongoing operations.

If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we incur debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities, and we could be subject to covenants that restrict our ability to operate our business and make distributions to our stockholders.

The current adverse domestic and worldwide economic conditions have adversely affected our ongoing exploration of strategic alternatives process.

General domestic and worldwide economic conditions have experienced a significant downturn due to the effects of the subprime lending crisis, general credit market crisis, collateral effects on the finance and banking industries, concerns about inflation, slower economic activity, decreased consumer confidence, reduced corporate profits and capital spending, adverse business conditions and liquidity concerns. Our company is not immune to these adverse conditions. We believe the current domestic and worldwide economic crisis has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. One of our strategic goals has been, and continues to be, to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor to assist us in our efforts to explore strategic alternatives. Strategic alternatives we may pursue could include, but are not limited to, licenses, partnering or other collaboration agreements, a sale of some or all of our assets, a merger or sale of the entire company, continued execution of our operating plan, or other strategic transaction. While no timetable has been set for the completion of our exploration of strategic alternatives process, we believe that it is likely that the process will take significantly longer than we originally anticipated. We believe this is due, in significant part, to a currently very challenging capital markets environment and uncertain general domestic and worldwide economic conditions, both of which have reduced companies' willingness to use their cash and/or stock to acquire other companies and products, especially development stage products that involve risk. We believe based on sales data for male sexual dysfunction products as well as published papers and independent market research that the estimated market for an FDA approved female sexual dysfunction product could reach more than \$2.0 billion, and that if approved by the FDA, LibiGel could become the first FDA approved treatment specifically indicated for hypoactive sexual desire disorder in menopausal women. However, we expect the Phase III clinical trial program of LibiGel to require significant resources. We also understand the significant risks involved in conducting clinical trials, obtaining regulatory approvals and commercializing a product that could be the first product of its kind to reach the market. While we continue in our ongoing efforts to explore strategic alternatives, we are mindful of these risks and the general economic environment which currently exists, both of which we believe has adversely affected, and may continue to adversely affect, our strategic alternatives process and the results of that process. Accordingly, we cannot provide any assurance as to when or if our exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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

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than Elestrin, none of our products have been introduced commercially nor do we expect them to be for several years. Some of our products are not in active development. For example, at this time, we believe that our estrogen/progestogen combination transdermal hormone therapy gel product sublicensed to Solvay is not in active development by Solvay, and we do not expect its active development to occur at any time in the near future. We cannot assure you that any of our proposed products will:

- be successfully developed;
- prove to be safe and effective 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

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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, 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.

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We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

After we have conducted pre-clinical studies in animals, we must demonstrate that our products are safe and effective for use on the target human patients in order to receive regulatory approval for commercial sale. The data obtained from pre-clinical and human clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. 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 we successfully have completed and reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trials for LibiGel, we still may not obtain FDA approval of LibiGel within a reasonable period of time or ever, which would harm our business and likely decrease our stock price.

We anticipate that LibiGel if approved by the FDA, could be a very successful product. However, LibiGel has not been approved for marketing by the FDA and is still subject to risks associated with its clinical development and obtaining regulatory approval. We believe based on agreements with the FDA, including a Special Protocol Assessment (SPA) received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular safety study with a four-year follow-up post-NDA filing and potentially

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post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD). The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it provides assurance that these agreed measures will serve as the basis for regulatory review and the decision by the FDA to approve an NDA for LibiGel. These SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD, specifically, HSDD in naturally menopausal women. The SPA agreements, however, are not guarantees of LibiGel approval by the FDA

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or approval of any permissible claims about LibiGel. In particular, SPA agreements are not binding on the FDA if previously unrecognized public health concerns later comes to light, other new scientific concerns regarding product safety or effectiveness arise, we fail to comply with the protocol agreed upon, or the FDA's reliance on data, assumptions or information are determined to be wrong. Even after an SPA agreement is finalized, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. In addition, the data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA regulatory approval.

Delays in the completion of these clinical trials, which can result from unforeseen issues, FDA interventions, problems with enrolling patients and other reasons, could significantly delay commercial launch and affect our product development costs. Moreover, results from these clinical studies may not be as favorable as the results we obtained in prior, completed studies. We cannot ensure that, even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

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 affected negatively by the Women's Health Initiative study and other studies that have found that the overall health risks from the use of certain hormone therapy products 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 affects from hormone therapy, including in particular, hormone therapies similar to our products, would also adversely affect our business.

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If clinical trials for our proposed products are prolonged or delayed, we may be unable to commercialize our proposed products on a timely basis, which would require us to incur additional costs and delay our receipt of any revenue from potential product sales or licenses.

We may encounter problems with our completed, ongoing or planned clinical trials for our proposed products that will cause us or any regulatory authority to delay or suspend those clinical trials or delay the analysis of data derived from them. A number of events, including any of the following, could delay the completion of, or terminate, our ongoing and planned clinical trials for our proposed products and negatively impact our ability to obtain regulatory approval or enter into collaborations for, or market or sell, a particular proposed product:

- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delay in developing, or our inability to obtain, a clinical dosage form, insufficient supply or deficient quality of our proposed products or other materials necessary to conduct our clinical trials;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical study or termination of a clinical program;
- serious and/or unexpected product-related side effects experienced by subjects in clinical trials; or
- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which our clinical trials are conducted all have the power to stop our clinical trials prior to completion. Our clinical trials for our proposed products may not begin as planned, may need to be restructured, and may not be completed on schedule, if at all.

We entered into an exclusive sublicense agreement with Azur Pharma International II, Ltd. for the marketing of Elestrin in the United States as a result of which we are dependent upon Azur for the marketing and sale of our Elestrin product.

In December 2008, we entered into an exclusive sublicense agreement with Azur Pharma International II, Ltd. for the marketing of Elestrin in the United States pursuant to which we received an upfront license payment 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 not only general market acceptance of the

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product, but also the success of Azur in marketing and selling the product. Sales of Elestrin by our former sublicensee, Nycomed US Inc. (which acquired Bradley Pharmaceuticals, Inc. in February 2008), were minimal and did not result in our receipt of any meaningful royalty revenue. We cannot assure you that Azur will be successful in marketing Elestrin or that Azur will remain focused on the commercialization of Elestrin or will not otherwise breach the terms of our agreement, especially if Azur does not experience significant Elestrin sales. Any breach by Azur 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.

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Elestrin, which is 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 impacted 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 have transferred all of the marketing rights associated with the product, as we have with Elestrin to Azur. 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.

We and our sublicensees depend on third-party manufacturers to produce our proposed products and if these third parties do not successfully manufacture these products our business would be harmed.]

We have no manufacturing experience or manufacturing capabilities for the production of our proposed products for clinical trials or commercial sale. In order to continue to develop proposed products, apply for regulatory approvals and commercialize our proposed products following approval, we or our sublicensees must be able to manufacture or contract with third parties to manufacture our products in clinical and commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our products may be complex, difficult to accomplish and difficult to scale-up when large-scale production is required. Manufacture may be subject to delays, inefficiencies and poor or low yields of quality products. The cost of manufacturing our products may make them prohibitively expensive. If supplies of any of our products become unavailable on a timely basis or at all or are contaminated or otherwise lost, clinical trials by us could be seriously delayed.

To the extent that we or our sublicensees seek to enter into manufacturing arrangements with third parties, we and such sublicensees will depend upon these third parties to perform their obligations in a timely and effective manner and in accordance with government regulations. Contract manufacturers may breach their manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us. If third-party manufacturers fail to perform their obligations, our competitive position and ability to generate revenue may be adversely affected in a number of ways, including:

- we and our collaborators may not be able to initiate or continue clinical trials of product candidates that are under development;

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- we and our collaborators may be delayed in submitting applications for regulatory approvals for our product candidates; and
- we and our collaborators may not be able to meet commercial demands for any approved products.

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 Vice Chairman, 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 recruited quickly.

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.

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

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. The Committee of Sponsoring Organizations of the Treadway Commission provides a framework for companies to assess and improve their internal control systems. If we are unable to maintain effective internal controls, we might be subject to sanctions or investigations by regulatory authorities, such as the Securities and Exchange Commission or the NASDAQ Stock Market. 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 our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting is effective. If we are unable to assert that our internal controls over financial reporting 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 internal controls over financial reporting), 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 internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal controls over financial reporting could have an adverse effect on our common stock price.

Risks Relating to Our Industry

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

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development,

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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 collaborators, will not succeed in developing similar technologies and products more rapidly than we do, commercially 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.

Risks Relating to Our Intellectual Property

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, Inc. and a portion of our CaP technology from the University of California. We may lose our right to license these technologies if we breach our obligations under the license agreements. Although we intend to use our reasonable best efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements or with respect to the University of California's license agreement within 60 days after written notice from the University of California, the other party to these agreements may terminate these agreements or certain projects contained in these agreements. The termination of these agreements, however, will not relieve us of our obligation to pay any royalty or license fees owed 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 a 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, Inc. 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.

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We have licensed some 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 some of our hormone therapy product to third parties, Azur, Solvay Pharmaceuticals, B.V., Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA. All of these parties, except for Azur and PharmaSwiss, 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 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 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. For example, at this time, we believe that our estrogen/progestogen combination transdermal hormone therapy gel product licensed to Solvay is not in active development by Solvay, and we do not expect its active development to occur at any time in the near future. As an additional example, in 2005, we were notified that Teva USA had discontinued development of our male testosterone gel, Bio-T-Gel, product and indicated to us a desire to formally terminate the agreement. Although in June 2007, we signed an amendment to the agreement under which we and Teva reinitiated our collaboration on the development of Bio-T-Gel for the U.S. market and Teva withdrew its previous notice of its desire to terminate the agreement and reinitiated funding and development of the product, prior to such time, no third party was developing our Bio-T-Gel. Any future breach of this agreement by Teva or any other 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.

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 licensors' 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

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under our patent. Competitors may also have our patents reexamined by demonstrating to 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.
- 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 financial condition.

The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Patent applications are maintained in secrecy in the United States 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.

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

Risks Relating to Our Common Stock

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 closing price has fluctuated over a wide range. To date in 2008, our common stock closed in a range from a low of \$1.34 to a high of \$5.85, and our daily trading volume ranged from 11,755 shares to 1,782,159 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 NASDAQ Global Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of previously reported financial results, delays in our filings with the SEC or our failure to maintain effective internal control over financial reporting; and

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- general stock, market and general economic conditions in the United States and abroad, not directly related to BioSante.

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 percent in one trading day and over 50 percent 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 110,000 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.

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.

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

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

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- 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 December 17, 2008, we had issued and outstanding 27,042,764 shares of common stock, 391,286 shares of our class C stock and outstanding options and warrants to purchase 4,750,229 additional shares of common stock, including the warrant issued to Kingsbridge. 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.

Risks Relating to the Committed Equity Financing Facility with Kingsbridge

The Committed Equity Financing Facility that we entered into with Kingsbridge may not be available to us if we elect to make a draw down.

In December 2008, we entered into a CEFF with Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of two years, shares of our common stock for cash consideration, subject to certain conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless certain conditions are met, which include a minimum price for our common

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stock of \$1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; effectiveness of the registration statement of which this prospectus is a part; and the continued listing of our stock on the NASDAQ Global Market. In addition, Kingsbridge is permitted to terminate the CEFF if it determines that a material and adverse event has occurred affecting our business, operations, properties or financial condition and if such condition continues for a period of 10 trading days from the date Kingsbridge provides us notice of such material and adverse event. If we are unable to access funds through the CEFF, or if the CEFF is terminated by Kingsbridge, we may be unable to access capital on favorable terms or at all.

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The CEFF that we entered into with Kingsbridge may require us to make additional blackout or other payments to Kingsbridge.

In connection with our CEFF with Kingsbridge, we are entitled in certain circumstances to deliver a blackout notice to Kingsbridge to suspend the use of the registration statement of which this prospectus is a part and prohibit Kingsbridge from selling shares under this prospectus. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement is not effective in circumstances not permitted by the agreement, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of the number of shares held by Kingsbridge (exclusive of shares that Kingsbridge may hold pursuant to exercise of the Kingsbridge warrant) and the change in the market price of our common stock during the period in which the use of the registration statement is suspended. If the trading price of our common stock declines during a suspension of the registration statement, the blackout or other payment could be significant.

The CEFF that we entered into with Kingsbridge may result in dilution to our stockholders if we sell shares to Kingsbridge under the CEFF or issue shares in lieu of a blackout payment.

Should we sell shares to Kingsbridge under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders, and may result in downward pressure on the price of our common stock. If we draw down under the CEFF, we will issue shares to Kingsbridge at a discount of up to 14 percent from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our share price is decreasing, we will need to issue more shares to raise the same amount than if we were to issue shares when our stock price is higher. Such issuances will have a dilutive effect and may further decrease our stock price.

**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, approximate, contemplate or continue and other 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, licensure or acquisition of new products;

- our engagement of Deutsche Bank Securities and our efforts, with the assistance of Deutsche Bank Securities, to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market and market acceptance of our products;

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- the effect of new accounting pronouncements;
- whether and how long our existing cash will be sufficient to fund our operations;
- our need, ability and expected timing of any actions 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 SEC.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholder pursuant to this prospectus. Any issuance of shares by us to Kingsbridge under the common stock purchase agreement or in connection with the exercise of the Kingsbridge warrant will be made pursuant to an exemption from the registration requirements of the Securities Act. To the extent the warrant held by the selling stockholder is exercised at its current exercise price, we would receive approximately \$1.2 million in cash proceeds, unless such warrant is exercised on a cashless basis pursuant to its terms.

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Unless otherwise provided in the applicable prospectus supplement, we intend to use the proceeds from our sales, if any, to Kingsbridge to finance our Phase III clinical trials for LibiGel and for general corporate purposes, including capital expenditures and working capital. We may also use a portion of the proceeds to acquire or invest in complementary businesses or products or to obtain rights to additional product candidates and other technologies. We have no commitments with respect to any such acquisitions or investments. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in, and costs of, our Phase III clinical trials for LibiGel, the timing of revenues, if any, from any future collaborations or similar transactions and the amount of cash used by our operations. We therefore cannot estimate the amount of proceeds to be used for all of the purposes

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described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the proceeds. Pending the uses described above, we intend to invest the proceeds temporarily in short-term or marketable securities until we use them for their stated purpose.

Table of Contents**SELLING STOCKHOLDER**

This prospectus relates to the possible resale by the selling stockholder, Kingsbridge, of shares of common stock that we may issue pursuant to the common stock purchase agreement we entered into with Kingsbridge on December 15, 2008, or upon exercise of the warrant that we issued to Kingsbridge on December 15, 2008. We are filing the registration statement, of which this prospectus is a part, pursuant to the provisions of the registration rights agreement we entered into with Kingsbridge on December 15, 2008. The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the common stock purchase agreement or upon exercise of the warrant.

The following table presents information regarding Kingsbridge, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of December 17, 2008. As used in this prospectus, the term "selling stockholder" includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column "Number of Shares Being Offered" represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares of common stock beneficially owned prior to the offering shown in the table below is based both on an aggregate of 27,042,764 shares of our common stock outstanding on December 17, 2008, and on the assumption that all shares of common stock issuable under the common stock purchase agreement with Kingsbridge and all shares of common stock issuable upon exercise of the warrant are outstanding as of that date.

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	Percent		Number	Percent
Kingsbridge Capital Limited (1)	300,000	5,705,840(2)	17.4%	5,705,840	0	

* Less than one percent (1%)

- (1) The business address of Kingsbridge Capital Limited is P.O. Box 1075, Elizabeth House, 9 Castle Street, St. Helier, Jersey, JE42QP, Channel Islands.
- (2) Consists of 5,405,840 shares of common stock, the maximum number of shares of common stock issuable under the common stock purchase agreement we entered into with Kingsbridge on December 15, 2008. For the purposes hereof, we assume the issuance of all 5,405,840 shares. Adam Gurney, Tony Gardner-Hillman and Maria O Donoghue have shared voting and investment control of the securities held by Kingsbridge. Kingsbridge does not accept any third party investments.

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PLAN OF DISTRIBUTION

To the extent that we issue shares to Kingsbridge under the CEFF or Kingsbridge acquires shares upon exercise of its warrant, the selling stockholder may offer such shares for resale under this prospectus. Except as described below, to our knowledge, the selling stockholder has not entered into any agreement, arrangement or understanding with any particular broker or market maker with respect to the shares of common stock offered hereby, nor, except as described below, do we know the identity of the brokers or market makers that will participate in the resale of the shares.

The selling stockholder may decide not to sell any shares. The selling stockholder may from time to time offer some or all of the shares of common stock through brokers, dealers or agents who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of common stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Kingsbridge is an underwriter within the meaning of the Securities Act. Any brokers, dealers or agents who participate in the distribution of the shares of common stock by the selling stockholder may also be deemed to be underwriters, and any profits on the sale of the shares of common stock by them and any discounts, commissions or concessions received by any such brokers, dealers or agents may be deemed to be underwriting discounts and commissions under the Securities Act. To the extent the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale by it. Such sales may be made on the NASDAQ Global Market, on the over-the-counter market, otherwise, or in a combination of such methods of sale, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares of common stock may be sold by the selling stockholder according to one or more of the following methods:

- a block trade in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus;
- an over-the-counter distribution in accordance with the rules of the NASDAQ Stock Market;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- privately negotiated transactions;
- a combination of such methods of sale; and
- any other method permitted pursuant to applicable law.

Any shares covered by this prospectus which qualify for sale pursuant to Rule 144 of the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus. In addition, the selling stockholder may transfer the shares by other means not described in this prospectus.

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Any broker-dealer participating in such transactions as agent may receive commissions from Kingsbridge (and, if they act as agent for the purchaser of such shares, from such purchaser). Broker-dealers may agree with Kingsbridge to sell a specified number of shares at a stipulated price per share, and, to the extent such a broker-dealer is unable to do so acting as agent for Kingsbridge, to purchase as principal any unsold shares at the price required to fulfill the broker-dealer commitment to Kingsbridge. Broker-dealers who acquire shares as principal may thereafter resell such shares from time to time in transactions (which may involve crosses and block transactions and which may involve sales to and through other broker-dealers, including transactions of the nature described above) on the NASDAQ Global Market, on the over-the-counter market, in privately-negotiated transactions or otherwise at market prices prevailing at the time of sale or at negotiated prices, and in connection with such resales may pay to or receive from the purchasers of such shares commissions computed as described above. To the extent required under the Securities Act, an amendment to this prospectus or a supplemental prospectus will be filed, disclosing:

- the name of any such broker-dealers;
- the number of shares involved;
- the price at which such shares are to be sold;
- the commission paid or discounts or concessions allowed to such broker-dealers, where applicable;
- that such broker-dealers did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, as supplemented; and
- other facts material to the transaction.

Underwriters and purchasers that are deemed underwriters under the Securities Act may engage in transactions that stabilize, maintain or otherwise affect the price of the securities, including the entry of stabilizing bids or syndicate covering transactions or the imposition of penalty bids. Kingsbridge and any other persons participating in the sale or distribution of the shares will be subject to the applicable provisions of the Exchange Act and the rules and regulations thereunder including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of, purchases by the selling stockholder or other persons or entities. Under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to such securities for a specified period of time prior to the commencement of such distributions, subject to special exceptions or exemptions. Regulation M may restrict the ability of any person engaged in the distribution of the securities to engage in market-making and certain other activities with respect to those securities. The anti-manipulation rules under the Exchange Act may apply to sales of the securities in the market. All of these limitations may affect the marketability of the shares and the ability of any person to engage in market-making activities with respect to the securities.

We have agreed to pay the expenses of registering the shares of common stock under the Securities Act, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees, as well as certain fees of counsel for the selling stockholder incurred in the preparation and negotiation of the CEFF agreements and the registration statement of which this prospectus forms a part. The selling stockholder will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as transfer taxes and certain other expenses associated with its sale of securities.

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Under the terms of the Kingsbridge common stock purchase agreement and the registration rights agreement, we have agreed to indemnify the selling stockholder and certain other persons against certain liabilities in connection with the offering of the shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute toward amounts required to be paid in respect of such liabilities.

At any time a particular offer of the shares of common stock is made by the selling stockholder, a revised prospectus or prospectus supplement, if required, will be distributed. Such prospectus supplement or post-effective amendment will be filed with the SEC, to reflect the disclosure of required additional information with respect to the distribution of the shares of common stock. We may suspend the sale of shares by the selling stockholder pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

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 the BioSante Pharmaceuticals, Inc. Annual Report on Form 10-K, and the effectiveness of BioSante's internal control over financial reporting have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a public company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. Our SEC filings are also available to the public at the SEC's web site at <http://www.sec.gov>.

Our common stock is listed on the NASDAQ Global Market. Reports and other information concerning BioSante may also be inspected at the offices of the NASDAQ OMX Group, Inc., 9600 Blackwell Road, Rockville, MD 20850 or on the NASDAQ OMX Group, Inc. website at <http://www.nasdaq.com>.

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

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

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We have filed a registration statement on Form S-3 with the SEC for the common stock offered by the selling stockholder 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. You may:

- inspect a copy of this prospectus, including the exhibits and schedules, without charge at the public reference room;
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC; or
- obtain a copy from the SEC website.

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, 2007 (including information specifically incorporated by reference into our Form 10-K from our Proxy Statement for our 2008 Annual Meeting of Stockholders);
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2008, June 30, 2008 and September 30, 2008;
- our Current Reports on Form 8-K filed on January 18, 2008, April 21, 2008, June 13, 2008, July 18, 2008, December 5, 2008 and December 18, 2008; and
- 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 access our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statement, and amendments, if any, to those documents filed or furnished pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act with the SEC free of charge at the SEC's website or our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You may request a 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

pdonenberg@biosantepharma.com.

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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. The selling stockholder will not bear any portion of such expenses. All such expenses are estimated except for the SEC registration fee.

SEC registration fee	\$	314
Fees and expenses of legal counsel for BioSante		20,000
Fees and expenses of accountants for BioSante		10,000
Printing expenses		1,000
Transfer agent fees		500
Miscellaneous		10,000
*Total	\$	41,814

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

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

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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

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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 entered into agreements with its directors and officers regarding indemnification, in addition to indemnification provided for in BioSante's Certificate of Incorporation, Bylaws and the Delaware General Corporation Law and intends to enter into indemnification agreements with any new directors and officers in the future. Under these agreements, BioSante is required to indemnify its current and former directors and officers against expenses, judgments, penalties, fines, settlements and other amounts actually and reasonably incurred, including expenses of a derivative action, in connection with an actual or threatened proceeding if any of them may be made a party because he or she is or was one of BioSante's directors or officers. BioSante will be obligated to pay these amounts only if the director or officer acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to BioSante's best interests. With respect to any criminal proceeding, BioSante will be obligated to pay these amounts only if the director or officer had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

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

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

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to 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.

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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 paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement 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

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in

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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 effective date, supersede or modify any statement that was made in the registration

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statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, 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.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(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 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 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) 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,

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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.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus 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.

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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 December 18, 2008.

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 the dates indicated.

Name and Signature	Title	Date
/s/ Stephen M. Simes	Vice Chairman, President and Chief	December 18, 2008
Stephen M. Simes	Executive Officer (Principal Executive Officer)	
/s/ Phillip B. Donenberg	Chief Financial Officer, Treasurer and	December 18, 2008
Phillip B. Donenberg	Secretary (Principal Financial and Accounting Officer)	

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/s/ Louis W. Sullivan, M.D.	Chairman of the Board	December 16, 2008
Louis W. Sullivan, M.D.		

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Name and Signature	Title	Date
/s/ Fred Holubow Fred Holubow	Director	December 17, 2008
/s/ Peter Kjaer Peter Kjaer	Director	December 17, 2008
/s/ Ross Mangano Ross Mangano	Director	December 18, 2008
/s/ Edward C. Rosenow, III, M.D. Edward C. Rosenow, III, M.D.	Director	December 17, 2008

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REGISTRATION STATEMENT ON FORM S-3
EXHIBIT INDEX**

Exhibit No.	Exhibit	Method of Filing
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	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).
4.3	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).
4.4	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).
4.5	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).
4.6	Warrant to purchase common stock issued to Kingsbridge Capital Limited on December 15, 2008	Incorporated by reference to Exhibit 4.1 contained in BioSante's Current Report on Form 8-K, filed on December 18, 2008 (File No. 001-31812).
5.1	Opinion of Oppenheimer Wolff & Donnelly LLP	Filed herewith.
10.1	Common Stock Purchase Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.1 contained in BioSante's Current Report on Form 8-K, filed on December 18, 2008 (File No. 001-31812).

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Exhibit No.	Exhibit	Method of Filing
10.2	Registration Rights Agreement dated as of December 15, 2008 between BioSante Pharmaceuticals, Inc. and Kingsbridge Capital Limited	Incorporated by reference to Exhibit 10.2 contained in BioSante's Current Report on Form 8-K, filed on December 18, 2008 (File No. 001-31812).
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-5 of this Registration Statement.