

BIOSANTE PHARMACEUTICALS INC

Form 424B5

March 05, 2010

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**PROSPECTUS SUPPLEMENT**  
**(To the prospectus dated June 9, 2009)**

**Filed Pursuant to Rule 424(b)(5)**  
**Registration No. 333-159606**

**10,404,626 Units**

**Units Consisting of**

**One Share of Common Stock and**

**a Warrant to Purchase 0.50 of a Share of Common Stock**

We are offering 10,404,626 units, with each unit consisting of one share of our common stock and a warrant to purchase 0.50 of a share of our common stock (and the shares of common stock issuable from time to time upon exercise of the offered warrants), to funds affiliated with two institutional investors pursuant to this prospectus supplement and the accompanying prospectus. Each unit will be sold at a negotiated price of \$1.73. Each warrant has an exercise price of \$2.08 per share, and is exercisable for a period of five years commencing six months and one day from the closing date. The shares of common stock and the warrants will be issued separately but will be purchased together in this offering.

The warrants will not be listed on any national securities exchange. Our common stock is listed on the NASDAQ Global Market under the symbol BPAX. On March 3, 2010, the last reported sale price of our common stock on the NASDAQ Global Market was \$1.73 per share. As of March 3, 2010, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$87.5 million based on 53,262,568 shares of outstanding common stock, of which 50,551,100 shares were held by non-affiliates, and a price of \$1.73 per share, which was the last reported sale price of our common stock as quoted on the NASDAQ Global Market on March 3, 2010.

**This investment involves a high degree of risk. Please see the section entitled Risk Factors beginning on page S-6 of this prospectus supplement and page 5 of the accompanying prospectus.**

Rodman & Renshaw, LLC acted as the placement agent on this transaction. The placement agent is not purchasing or selling any of these securities nor is it required to sell any specific number or dollar amount of securities, but has agreed to use its reasonable best efforts to sell the securities offered by this prospectus supplement. We have agreed to pay the placement agent the placement agent fees set forth in the table below.

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	Per Unit		Total	
Public offering price	\$	1.73	\$	18,000,000
Placement agent fees(1)	\$	0.04325	\$	450,000
Proceeds, before expenses, to BioSante Pharmaceuticals, Inc.(2)	\$	1.68675	\$	17,550,000

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(1) In addition, we have agreed to issue the placement agent warrants to purchase up to 208,093 shares of our common stock at an exercise price of \$2.16 per share and to reimburse the placement agent for certain of its expenses as described under "Plan of Distribution" in this prospectus supplement.

(2) The proceeds shown exclude proceeds that we may receive upon exercise of the warrants.

Delivery of the units is expected to be made on or about March 8, 2010, against payment for such units to be received by us on the same date.

**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.**

**Rodman & Renshaw, LLC**

The date of this prospectus supplement is March 4, 2010

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You should rely only on information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information that is different. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front of this prospectus supplement or the accompanying prospectus or that any document that we incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than its filing date. You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.



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**ABOUT THIS PROSPECTUS SUPPLEMENT**

We are providing this information to you about this offering in two parts. The first part is this prospectus supplement, which provides the specific details regarding the offering. The second part is the base prospectus dated June 9, 2009, included in the registration statement on Form S-3 (No. 333-159606) which we are supplementing with the information contained in this supplement. Generally, when we refer to this prospectus, we are referring to both documents combined. Some of the information in the base prospectus may not apply to this offering.

You should also read and consider the information in the documents that we have referred you to in Where You Can Find More Information on page S-33 of this prospectus supplement and the information described under Incorporation of Certain Documents by Reference on page S-34 of this prospectus supplement before investing in our securities. The information incorporated by reference is considered to be part of this prospectus supplement, and information that we file later with the Securities and Exchange Commission, or SEC, will automatically update and supersede this information.

If information in this prospectus supplement is inconsistent with the base prospectus, you should rely on this prospectus supplement. We have not authorized anyone to provide information different from that contained or incorporated in this prospectus supplement and the accompanying prospectus. We are offering to sell units only in jurisdictions where offers and sales are permitted. The information contained or incorporated in this prospectus supplement and the accompanying prospectus is accurate only as of the date of such information, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our units.

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

We own or have the rights to use various trademarks, trade names or service marks that are used in this prospectus, including BioSante®, LibiGel®, Elestrin®, Bio-T-Gel®, The Pill Plus®, BioLook®, BioVant®, Bio-Oral®, BioAir® and GVAX®. All other trademarks, trade names or service marks that are used in this prospectus are the property of their respective owners.

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**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our securities. To fully understand this offering and its consequences to you, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the information referred to under the heading "Risk Factors" in this prospectus supplement beginning on page S-6, and the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectus when making an investment decision.*

**About BioSante Pharmaceuticals, Inc.**

**Our Business**

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. In addition, we will seek opportunities for our GVAX cancer immunotherapies, 2A/Furin and other technologies we acquired in our merger with Cell Genesys, Inc. in October 2009. We also are developing our calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery.

The following is a list of our key products for female sexual health, menopause, contraception and male hypogonadism:

- LibiGel – once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment, or SPA, for the treatment of female sexual dysfunction, or FSD.
- Elestrin – once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration, or FDA, indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause, and marketed in the U.S.
- 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.
- Bio-T-Gel – once daily transdermal testosterone gel in development for the treatment of hypogonadism, or testosterone deficiency, in men.

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In order to market products in the United States, we are required to obtain approval of a new drug application, or NDA, or an abbreviated NDA, or ANDA, for each such product from the FDA. Our Elestrin is our first FDA approved product. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited for the marketing of Elestrin and the sale to Azur of certain assets related to Elestrin. Azur is marketing Elestrin in the U.S. using its women's health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an agreement with Azur to monetize our Elestrin royalty stream through a royalty buydown of approximately \$3.0 million. In addition, we maintained the right to receive up to \$140 million in sales-based milestone payments, if Elestrin reaches certain predefined sales per calendar year.

Prior to submitting an NDA or ANDA for our other products, the products must undergo human clinical trials. With respect to LibiGel, we believe, based on agreements with the FDA, including an SPA received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a

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Phase III cardiovascular and breast cancer 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, or HSDD, in menopausal women. 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 indicates that these agreed measures will serve as the basis for regulatory review and any decision by the FDA to approve an NDA for LibiGel. The LibiGel 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 studies are underway: we actively are enrolling women for two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer 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 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 after which time we intend to submit an NDA to the FDA.

On February 22, 2010, we announced that based upon the second review of study conduct and unblinded data from the LibiGel Phase III cardiovascular and breast cancer safety study, the independent data monitoring committee (DMC) unanimously recommended continuing the study as described in the FDA-agreed study protocol, with no modifications. The DMC reviewed all unblinded adverse events in the safety study including serious adverse events and all adverse cardiovascular and breast cancer events in almost 1,200 women-years of exposure. To date, there have been no deaths, only six adjudicated cardiovascular events and only four breast cancers reported. In view of DMC recommendation, we will continue the LibiGel Phase III development program as planned. We continue to target submission to the FDA of an NDA by mid-2011. Following NDA submission and potential FDA approval, we will continue to follow the subjects in the safety study for an additional four years.

We expect the Phase III clinical trial program of LibiGel to continue to require significant resources. Therefore, we may need to raise substantial additional capital. Alternatively, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, 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 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 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.





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- 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.

As a result of our merger with Cell Genesys, we acquired a portfolio of products, including GVAX cancer immunotherapies. GVAX cancer immunotherapies are cancer treatments designed to stimulate the patient's immune system to effectively fight cancer. Multiple Phase II trials are ongoing at minimal cost to us at the Sidney Kimmel Cancer Center at The Johns Hopkins Hospital in various cancer programs, including pancreatic cancer, leukemia and breast cancer.

**Company Information**

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. In October 2009, Cell Genesys, Inc. merged with and into us, and we survived as the surviving corporation.

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.biosantepharm.com](http://www.biosantepharm.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. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

**The Offering**

Common stock offered by us	10,404,626 shares
Common stock to be outstanding after this offering	63,667,194 shares
Warrants offered by us	Warrants to purchase up to 5,202,313 shares of our common stock (excluding warrants to purchase up to 208,093 shares of our common stock to be issued to our placement agent upon the completion of this offering).

Each warrant has an exercise price of \$2.08 per share, is exercisable for a period of five years commencing six months and one day from the closing date. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants. There is currently no market for the warrants and none is expected to develop after this offering.

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Use of proceeds	We intend to use the net proceeds from the sale of the securities under this prospectus supplement for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital. Please see the section entitled "Use of Proceeds" on page S-25 of this prospectus supplement.
NASDAQ Global Market symbol	BPAX
Risk factors	This investment involves a high degree of risk. Please see the section entitled "Risk Factors" beginning on page S-6 of this prospectus supplement.

The number of shares of our common stock to be outstanding immediately after this offering is based on 53,262,568 shares of our common stock outstanding as of March 1, 2010. Unless we specifically state otherwise, the share information in this prospectus supplement does not include:

- 5,202,313 shares of our common stock issuable upon the exercise of warrants to be issued to purchasers in this offering and an additional 208,093 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in this offering;
- approximately 5.6 million shares of our common stock issuable upon the conversion of senior convertible notes of Cell Genesys assumed by us in connection with our merger with Cell Genesys;
- 5,378,955 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$8.04 per share;
- 3,408,620 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$3.88 per share;
- 661,000 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan; and
- 391,286 shares of our common stock issuable upon the one-for-one exchange of our shares of class C special stock at an exchange price of \$2.50 per share at the option of the holder of such class C special shares.

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**RISK FACTORS**

*An investment in our securities involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock and the value of the warrants offered hereby could decline, and you could lose part or all of your investment. You should carefully consider the risks described below with all of the other information included in this prospectus supplement, our annual report on Form 10-K for the fiscal year ended December 31, 2008, our subsequent quarterly reports on Form 10-Q and our other filings with the SEC. Failure to satisfactorily achieve any of our objectives or avoid any of the risks below would likely have a material adverse effect on our business, operating results and financial condition and could cause the trading price of our common stock to decrease.*

**Risks Related to this Offering, Our Common Stock and the Warrants**

*There are a substantial number of shares of our common stock eligible for future sale in the public market. The sale of these shares could cause the market price of our common stock to fall. Any future equity issuances by us may have dilutive and other effects on our existing stockholders.*

As of March 1, 2010, there were approximately 53.3 million shares of our common stock outstanding, and in addition, security holders held options, warrants or convertible notes, which, if vested, exercised or converted, would obligate us to issue up to approximately 15.2 million additional shares of common stock. A substantial number of those shares, when we issue them upon exercise or conversion, will be available for immediate resale in the public market. The market price of our common stock could fall as a result of sales of any of these shares of common stock due to the increased number of shares available for sale in the market.

We primarily have financed our operations, and we anticipate that we will have to finance a large portion of our operating cash requirements, by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. We have a shelf registration statement, which subject to certain limitations, permits us to sell up to a remaining \$57 million of our securities, some or all of which may be shares of our common stock or securities convertible into or exercisable for shares of our common stock, and all of which would be available for resale in the market. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our existing stockholders. These issuances or other dilutive issuances also would cause our net income, if any, per share to decrease in future periods. As a result, the market price of our common stock could decrease.

*The price of our common stock has been and likely will continue to be volatile. As a result, we could become subject to class action litigation, which even if without merit, could be costly to defend and could divert the time and attention of our management, which could harm our business and financial condition.*

Since January 1, 2009, the closing sale price of our common stock has ranged from a low of \$1.14 to a high of \$2.59. It is likely that the price 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 fluctuations, often unrelated to the operating performance of these companies. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including:

- general stock market and general economic conditions in the United States and abroad, not directly related to our company or our business;

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- our ability to obtain additional financing when needed and on acceptable terms;
  
- 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 current and any future clinical studies, including in particular our LibiGel Phase III clinical study program;
  
- the results of clinical trials conducted by others on products that would compete with our products;
  
- the results and timing of regulatory reviews relating to the approval of our products, including in particular LibiGel;
  
- failure of any of our products, if approved, to achieve commercial success;
  
- public concern as to the safety or efficacy of or market acceptance of products developed by the us or our competitors;
  
- the entry into, or termination of, key license and sublicense agreements;
  
- announcements by licensors or licensees of our technology;
  
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;
  
- general and industry-specific economic conditions that may affect our research and development expenditures;
  
- issues in manufacturing our products;

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- the loss of key employees;
- the introduction of technological innovations or new commercial products by our competitors;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- future sales of our securities;
- changes in the structure of health care payment systems;
- 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; and
- other potentially negative financial announcements, including delisting of our common stock from the NASDAQ Global Market, 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.

Also, certain dilutive securities such as warrants can be used as hedging tools which may increase volatility in our stock and cause a price decline. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor's ability to



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sell our common stock, which could result in substantial economic loss as well. In addition, due in large part to the current global economic crisis many institutional investors that historically had invested in specialty pharmaceutical companies have ceased operations or further investment in these companies, which has had negatively impacted trading volume for our stock. In addition, the occurrence of any of the risks described 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.

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.

***Since we have broad discretion in how we use the proceeds from this offering, we may use the proceeds in ways in which you disagree.***

We intend to use the net proceeds from the sale of the securities under this prospectus supplement for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital. Because we have not allocated specific amounts of the net proceeds from this offering for any specific purposes, our management will have significant flexibility in applying the net proceeds of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for our company. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

***Investors in this offering may pay a higher price than the book value of our stock.***

If you purchase securities in this offering, you will incur an immediate and substantial dilution in net tangible book value, after giving effect to the sale by us of 10,404,626 shares of common stock offered in this offering at the price to public of \$1.73 per share.

***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.

***There is no public market for the warrants to purchase common stock being offered in this offering.***

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There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

*The warrants are not immediately exercisable.*

The warrants, which have an exercise price of \$2.08 per share, are exercisable commencing six months and one day from the issuance date and will terminate five years after the date the warrants first

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become exercisable. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

***Holders of our warrants will have no rights as a common stockholder until such holders exercise their warrants and acquire our common stock.***

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***Our common stock may be delisted from the NASDAQ Global Market which could have a material adverse effect on the liquidity of our common stock.***

In order for our securities to be eligible for continued listing on the NASDAQ Global Market, we must remain in compliance with certain listing standards, including a \$1.00 minimum closing bid price per share requirement, a \$50 million market capitalization and a \$15 million public float requirement or a \$12 million minimum stockholders' equity requirement, and certain corporate governance standards. If our common stock were to be delisted from the NASDAQ Global Market, we could apply to list our common stock on the NASDAQ Capital Market or our common stock could be traded in the over-the-counter market on an electronic bulletin board established for unlisted securities, such as the Pink Sheets or the OTC Bulletin Board. Any delisting could adversely affect the market price of, and liquidity of the trading market for, our common stock, our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors.

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

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

- authorizing the issuance of blank check preferred shares that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of our stockholders to elect director candidates; and

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- 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.

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**Risks Related to Our Financial Condition and Capital Requirements**

*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 \$15.0 million for the nine months ended September 30, 2009 and a net loss of \$17.4 million for the year ended December 31, 2008. As of September 30, 2009, our accumulated deficit was \$86.9 million. Although we have not finalized our financial statements for the year ended December 31, 2009, we expect a significant net loss. Substantially 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 and royalty revenue. We expect to incur substantial and continuing losses for the foreseeable future as our own product development programs continue and various preclinical and clinical trials commence or continue, including in particular our Phase III clinical study 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 study program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;
- our ability to license LibiGel or our other products for development and commercialization;
- the cost, timing and outcome of regulatory reviews of our products;
- the rate of technological advances;
- ongoing determinations of the potential markets for and commercial success of our products;
- the timing and cost of various cash and non-cash general and administrative expenses;

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- 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 to evaluate various strategic alternatives available with respect to Cell Genesys' s GVAX cancer immunotherapies and other technologies that we acquired in connection with our merger with Cell Genesys and our products and our company;
- the activities of our competitors; and
- our opportunities to acquire new products or take advantage of other unanticipated opportunities.

In order to generate new and significant revenues, we must develop our own products and enter into collaborative agreements with others who successfully can commercialize them. Even if our products 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 may need to raise substantial additional capital 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 products or to complete the commercialization of any of our products. We expect the Phase III clinical study program of LibiGel to continue to require significant resources. We had cash and cash equivalents of approximately \$13.2 million at September 30, 2009. Subsequent to September 30, 2009, we completed our merger with Cell Genesys on October 14, 2009. One of the primary reasons we merged with Cell Genesys was our need for additional funding to continue our Phase III clinical studies for LibiGel and the lack of other available acceptable alternatives for us to access capital at the time the merger agreement was entered into by the parties in June 2009, especially in light of the then state of the markets for equity offerings, which historically had been our primary method for raising additional financing. As of the completion of the merger on October 14, 2009, Cell Genesys had approximately \$23.2 million in cash, cash equivalents and short-term investments, after deducting anticipated estimated merger-related and other expenses. As of such date, Cell Genesys also had, and we assumed by virtue of the merger, \$1.2 million in principal amount of 3.125% convertible senior notes due in November 2011 and \$20.8 million in principal amount of 3.125% convertible senior notes due in May 2013.

We expect our cash and cash equivalent balance to decrease as we continue to use cash to fund our operations, including in particular our LibiGel clinical development program. We expect that our current cash resources, including the cash, cash equivalents and short-term investments acquired as a result of our recent merger with Cell Genesys, together with other revenues from the royalty stream monetization of Elestrin that we have received, will provide us sufficient capital to maintain our business operations through at least the next 12 months, although if we do not raise additional financing or secure another funding source for our clinical study program prior to the end of 2010, we may need to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our products, including most importantly, our Phase III clinical study program for LibiGel, or otherwise make changes to our operations to cut costs. This estimate may prove incorrect or we, nonetheless, may choose to raise additional financing earlier. If we need to delay or cease enrollment in our Phase III clinical study program for LibiGel, it would be our intention to continue the clinical program for those women already enrolled. Certain changes in our Phase III clinical study program of LibiGel could delay the eventual submission of an NDA for LibiGel beyond mid-2011, which is when we are targeting to submit an NDA. As an alternative to raising additional financing, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights 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 progress, timing, cost and results of our preclinical and clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;
- patient recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel;
- our ability to license LibiGel or our other products for development and commercialization;

- 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, to continue to evaluate various strategic alternatives available with respect to our products and our company



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- the cost, timing and outcome of regulatory reviews of our products;
- the rate of technological advances;
- the commercial success of our products;
- our general and administrative expenses; and
- the timing and cost of obtaining third party reimbursement for our products; and
- the activities of our competitors.

We have on file an effective shelf registration statement that allows us to raise up to \$75.0 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. However, we have used \$18.0 million of this amount and under applicable SEC rules, if we have a public float of less than \$75 million, we can only offer to sell under the registration statement up to one-third of our public float during any 12 month period. We can provide no assurance 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 need to delay, scale back or eliminate some or all of our programs designed to obtain regulatory approval of our products, including most importantly, as mentioned above, our Phase III clinical study program for LibiGel. If we need to delay or cease enrollment in our Phase III clinical study program for LibiGel, it would be our intention to continue the clinical program for those women already enrolled. Certain changes in our Phase III clinical study program of LibiGel could delay the eventual submission of an NDA for LibiGel beyond mid-2011, which is when we are targeting to submit an NDA. As an alternative to raising additional financing, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, sell certain assets or rights under our existing license agreements or enter into other business collaborations or combinations, including the possible sale of our company. Failure to obtain adequate financing also may cause us to curtail significantly or even cease our ongoing operations.

***Raising additional funds by issuing securities or through licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

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 our existing stockholders. If we incur additional 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. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on the ability of us to create liens, pay dividends, redeem our stock or make investments. As an alternative to raising additional financing by issuing securities, we may choose to sublicense LibiGel, Elestrin (outside

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the territories already sublicensed) or another product to a third party who may finance a portion or all of the continued development and, if approved, commercialization of that licensed product, 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. If we raise additional funds through licensing arrangements, we may be required to relinquish greater or all rights to our products at an earlier stage of development or on less favorable terms than we otherwise would choose.

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***The committed equity financing facility that we entered into with Kingsbridge Capital Limited may not be available to us if we elect to make a draw down.***

In December 2008, we entered into a committed equity financing facility, or CEFF, with Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of two years, up to the lesser of (i) an aggregate of \$25 million in or (ii) 5,405,840 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 stock of \$1.15 per share; the accuracy of representations and warranties made to Kingsbridge; compliance with laws; continued effectiveness of the registration statement registering the resale of shares of our common stock issued or issuable to Kingsbridge; 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. As of the date of this prospectus supplement, we have not sold any shares to Kingsbridge under the CEFF.

***The report of our independent registered public accounting firm prior to our merger with Cell Genesys which resulted in \$23.3 million net in cash gained by us, expressed substantial doubt about our ability to continue as a going concern which may adversely affect our ability to raise additional financing.***

Because of continuing expenditures related to our research and development activities, including in particular the Phase III clinical study program for LibiGel, as well as additional expenditures incurred due to our efforts at pursuing strategic alternatives, including in particular our merger with Cell Genesys, we have incurred higher than anticipated expenses and liabilities. As a result, in connection with the re-issuance of our financial statements for the year ended December 31, 2008 as a result of the filing of the Form S-4 registration statement on August 7, 2009 to register the shares of our common stock issued in connection with the Cell Genesys merger, our independent registered public accounting firm modified their report on our financial statements for the year ended December 31, 2008 to include an explanatory paragraph that expresses substantial doubt regarding our ability to continue as a going concern. Our financial statements for the year ended December 31, 2008 and our unaudited condensed financial statements for the three and nine months ended September 30, 2009, which are incorporated by reference into this prospectus supplement, have been prepared assuming that we will continue as a going concern since at this time we believe we have enough funds for the next 12 months, which contemplates the realization of assets and the settlement of liabilities in the normal course of business.

***As a result of our merger with Cell Genesys, we have substantial indebtedness, which increases our vulnerability to general adverse economic and industry conditions and may limit our ability to pursue strategic alternatives and react to changes in our business and industry.***

As a result of our merger with Cell Genesys, we assumed \$20.8 million aggregate principal amount of convertible senior notes due in May 2013 and an additional \$1.2 million aggregate principal amount of convertible senior notes due in November 2011. The annual interest payment on these notes is anticipated to be approximately \$0.7 million. This substantial indebtedness could harm our business, results of operations, financial condition, cash flow and future prospects. For example, it could:

- make it more difficult for us to pay our debts and meet other financial obligations as they become due;

- require us to dedicate a portion of our cash flows to make principal and interest payments which will reduce our cash flow available for operations and future business opportunities;

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- limit our ability to raise or borrow additional funds for future working capital, capital expenditures, research and development and other general corporate requirements;
- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to pursue strategic alternatives, including merger or acquisition transactions; and
- limit our flexibility to react to changes in our business and the industry in which we operate.

***We may not have sufficient funds to pay principal and interest on our outstanding convertible notes as they become due, which would have a material adverse effect on our financial condition.***

As a result of our merger with Cell Genesys, we assumed \$22.0 million aggregate principal amount of outstanding convertible notes, \$1.2 million of which will be due in November 2011 and \$20.8 million of which will be due in May 2013. The annual interest payment on these notes is anticipated to be approximately \$0.7 million. We do not have any significant source of revenues and do not anticipate any significant source of revenues for the near future. Although we intend to continue to seek additional financing to support our operations, it is possible that we may not have sufficient funds to pay the principal and interest on our convertible notes when they become due (\$1.2 million in November 2011 and \$20.8 million in May 2013), especially if an event of default were to occur under the indentures governing the convertible notes.

***The indentures governing our assumed convertible notes contain covenants, which if not complied with, could result in an event of default and the acceleration of all amounts due under the notes.***

The indentures governing our assumed convertible notes contain covenants, such as the requirement to pay accrued interest on May 1 and November 1 of each year, the requirement to repurchase the notes upon a fundamental change, as defined in the indenture, if a note holder so elects and the requirement to file periodic reports electronically with the SEC. If we do not comply with the covenants in the indentures, an event of default could occur and all amounts due under the notes could become immediately due and payable. Upon the occurrence of an event of default under the indentures, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Upon the occurrence of an event of default under the indentures, the trustee has available a range of remedies customary in these circumstances, including declaring all such indebtedness, together with accrued and unpaid interest thereon, to be due and payable. Although it is possible we could negotiate a waiver with the trustee and the holders of the notes, such a waiver likely would involve significant costs. It is also possible that we could refinance our obligations under the notes; however, such a refinancing also would involve significant costs and likely result in increased interest rates.

***As a result of our merger with Cell Genesys, we possess not only all of the assets but also all of the liabilities of Cell Genesys. Discovery of previously undisclosed liabilities could have an adverse effect on our business, operating results and financial condition.***

Acquisitions often involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. In October 2008, in view of the termination of both its VITAL-1 and VITAL-2 Phase III clinical trials, Cell Genesys discontinued further development of GVAX immunotherapy for prostate cancer. Cell Genesys subsequently implemented a substantial restructuring plan to wind down its business operations and seek strategic alternatives. Under the restructuring plan, Cell Genesys terminated approximately 280 employees, closed two facilities and terminated two leases. As a result of the completion of our merger with Cell Genesys in October 2009, we possess not only all of the assets, but also all of the potential liabilities of Cell Genesys. Although we conducted a due diligence investigation of Cell Genesys

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and its known and potential liabilities and obligations, it is possible that, undisclosed, contingent or other liabilities or problems may arise, which could have an adverse effect on our business, operating results and financial condition.

*Charges resulting from the allocation of the purchase consideration in connection with our merger with Cell Genesys may adversely affect the market value of our common stock.*

Our merger with Cell Genesys has been accounted for under U.S. generally accepted accounting principles, or U.S. GAAP, as an acquisition of the net assets of Cell Genesys, whereby the individual assets and liabilities of Cell Genesys have been recorded by us as of the completion of the merger based on their estimated fair values. The future net income (loss) of the combined company will reflect charges resulting from the purchase price allocation related to the merger, which will include adjustments to carrying values of the acquired net assets based on the fair value of consideration measured as of October 14, 2009, the date of the completion of the merger. The purchase price adjustments and potential corresponding charges could have a material impact on our current results of operations which may have had an adverse impact on the market value of our common stock.

**Risks Related to Our Business**

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

Our products are in the development stages and will require further development, preclinical and clinical testing and investment prior to commercialization in the United States and abroad. Other than Elestrin, 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 and as previously disclosed, we believe that our estrogen/progestogen combination transdermal gel product sublicensed to Solvay Pharmaceuticals, B.V. is not in active development by Solvay, and we do not expect its active development to occur at any time in the near future, especially in light of Solvay's recent acquisition by Abbott Laboratories. We cannot assure you that any of our products will:

- be developed successfully;
- prove to be safe and effective in clinical studies;
- 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 manufacture commercially 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



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commercialize. The FDA approval process typically is lengthy and expensive, and approval never is 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 eventually are approved for sale. Because of the risks and uncertainties in biopharmaceutical development, our 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, the credibility of our management, the value of our company and our operating results and liquidity would be affected adversely. Even if a product gains regulatory approval, the product and the manufacturer of the product may be subject to continuing regulatory review. In addition, 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 our manufacture subsequently are discovered. The FDA also may 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 many of 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 in human subjects on each of our products. Pre-clinical studies on animals must be conducted on some of our products. We expect the number of pre-clinical studies and human clinical trials that the FDA will require will vary depending on the product, the disease or condition the product is being developed to address and regulations applicable to the particular product. We may need to perform multiple pre-clinical studies using various doses and formulations before we can begin human clinical trials, which could result in delays in our ability to market any of our products. Furthermore, even if we obtain favorable results in pre-clinical studies on animals, the results in humans may be different.

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

- lack of effectiveness of the product being tested; and
- lack of funding.

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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 trial program 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 received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer 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, HSDD in menopausal women. 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 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 delay significantly 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 (WHI) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the NIH released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by 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



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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 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 also was halted. Our products differ from the products used in the WHI 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 products against other hormone therapies. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies, although the market now seems to have stabilized. 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, also could affect adversely our business and likely decrease our stock price.

***If clinical trials for our products are prolonged or delayed, we may be unable to commercialize our 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 products that may cause us or a 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 products and negatively impact our ability to obtain regulatory approval or enter into collaborations for, or market or sell, a particular 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 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

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- 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 products may not begin as planned, may need to be restructured, and may not be completed on schedule, if at all. This is particularly true if we no longer have the financial resources to dedicate to our clinical trial program.

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***We entered into an exclusive sublicense agreement with Azur Pharma International II, Limited 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 Elestrin.***

In December 2008, we entered into an exclusive sublicense agreement with Azur 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, after having sold our royalty stream on sales of Elestrin to Azur. As a result of this agreement, Elestrin is subject to not only general market acceptance of the product, but also the success of Azur in marketing and selling the product. Azur launched sales and marketing activities related to Elestrin in April 2009. We recognized royalty and other revenue from sales of Elestrin of \$90,934 for the nine months ended September 30, 2009. In December 2009, we entered into an agreement with Azur to monetize our Elestrin royalty stream through a royalty buydown. In addition, we maintained the right to receive up to \$140 million in sales-based milestone payments, if Elestrin reaches certain predefined sales per calendar year. We cannot assure you that Azur will be successful in marketing Elestrin or that Azur will remain focused on the commercialization of Elestrin, especially if Azur does not experience significant Elestrin sales.

***Our other 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 products, if they receive the required FDA or other regulatory approvals, is dependent upon market acceptance by physicians and patients. Levels of market acceptance for our products could be affected by several factors, including:

- the availability of alternative products from competitors;
- the price of our products relative to that of our competitors;
- the timing of market entry; and
- the ability to market our products effectively.

Some of these factors are not within our control, especially if we have transferred all of the marketing rights associated with the product, as we have with Elestrin to Azur. Our 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 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 products for clinical trials or commercial sale. In order to continue to develop products, apply for regulatory approvals and commercialize our 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



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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, our clinical trials 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 our 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;
- 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 relatively 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 bound legally to remain employed for any specific term. We do not have key man life insurance policies covering our executive officers or any of our other employees. If key individuals leave our company, our business could be affected adversely 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.

**Risks Related 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 products and bringing them to market.*

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Competition in the pharmaceutical industry is intense. Potential competitors in the United States and abroad are numerous and include pharmaceutical and biotechnology companies, most of which have substantially greater capital resources and more experience in research and development, manufacturing and marketing than us. Academic institutions, hospitals, governmental agencies and other public and private research organizations also are conducting research and seeking patent protection and may develop and commercially introduce competing products or technologies on their own or through joint ventures. We cannot assure you that our potential 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.

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***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 products and our clinical trials, and if any of our 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 Related to Our Intellectual Property**

***We license rights to the technology underlying most of our products and a portion of our CaP technology and GVAX cancer immunotherapies from third parties and may lose these rights, 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 rights to certain of the technology underlying our hormone therapy products from Antares Pharma, Inc., our GVAX cancer immunotherapies from Johns Hopkins University and The Whitehead Institute for Biomedical Research, a portion of our CaP technology from the University of California and the Pill Plus from Wake Forest University. We may lose our rights to these technologies if we breach our obligations under the license agreements. Although we intend to use commercially reasonable efforts to meet these obligations, if we violate or fail to perform any term or covenant of the license agreements, the other party to these agreements under certain circumstances 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 these technologies 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 rights to our hormone therapy technology, GVAX cancer immunotherapies or CaP technology for a sublicense fee, the termination of the main license agreement with Antares Pharma, Inc., Johns Hopkins University and The Whitehead Institute for BioMedical Research, the University of California or Wake Forest University could either, depending upon the terms of the sublicense agreement, cause us to breach our obligations under the sublicense agreement or give the other party a right to terminate that agreement, thereby causing us to lose future revenue generated by the sublicense fees.

***We have licensed some of our 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 products.***

We have licensed our CaP technology for use as a facial line filler to MATC and some of our hormone therapy product to third parties, including Azur, Solvay Pharmaceuticals, B.V. (which was recently acquired by Abbott Laboratories), Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA. All of these parties, except for Azur have agreed to be responsible for continued development, regulatory filings and manufacturing and marketing associated with the products. In addition,



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we in the future may enter into additional similar license agreements. Our products that we have licensed to others thus are 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 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 also may compete with us with respect to some of our products. For example, at this time and as previously disclosed, 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, especially in light of Abbott's recent acquisition of Solvay. 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 license the products to another party on substantially the same or better terms or continue the development and future commercialization of the 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. We rely on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our proprietary technology. These legal means, however, afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Where appropriate, we seek patent protection for certain aspects of our technology. Our owned and licensed patents and patent applications, however, 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. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Competitors also may 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 products. Even if we receive a patent, it may not provide much practical protection. There is no assurance that third parties will not be able to design around our patents. 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 products is successful and approval for sale is obtained, there can be no assurance that applicable



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patent coverage, if any, will not have expired or will not expire shortly after this approval. Though patent term extension may be possible for particular products, any expiration of the applicable patent could have a material adverse effect on the sales and profitability of our products.

- Litigation also may be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may adversely affect our operating results. Such litigation also 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.

We also rely on unpatented proprietary technology. It is unclear whether efforts to secure our trade secrets will provide useful protection. We rely on the use of registered trademarks with respect to the brand names of some of our products. We also rely on common law trademark protection for some brand names, which are not protected to the same extent as our rights in the use of our registered trademarks. We cannot assure you that we will be able to meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop and obtain patent protection substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with our employees and consultants. Such agreements, however, may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. 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.

***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 cannot determine whether our technology would infringe on patents arising from these unpublished 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

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- require us to enter into royalty or licensing agreements.

Although patent and intellectual property disputes in the pharmaceutical industry often have been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and often require the payment of ongoing royalties, which could hurt our potential 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.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

This prospectus supplement, the accompanying prospectus and the documents that we incorporate by reference herein and therein, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts included in or incorporated by reference into this prospectus supplement and any accompanying prospectus supplement that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Our forward-looking statements generally include statements about our plans, objectives, strategies and prospects regarding, among other things, our business, results of operations, liquidity and financial condition. Some of the forward-looking statements included or incorporated by reference into this prospectus supplement include statements regarding:

- the timing of the commencement, enrollment and successful completion of our clinical studies, the submission of new drug applications and other regulatory status of our products in development;
- approval by the U.S. Food and Drug Administration of our products that are currently in clinical development;
- our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;
- our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- the future market size and market acceptance of our products;
- the effect of new accounting pronouncements and future health care, tax and other legislation;
- 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.

In some cases, we have identified forward-looking statements with words like believe, may, could, might, possible, potential, project, should, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate or continue or the negative of these words and terms of similar meaning.



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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 section entitled "Risk Factors" included elsewhere in this prospectus supplement and in the accompanying prospectus and under similar sections in the documents we incorporate by reference into 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 section entitled "Risk Factors" included elsewhere in this prospectus supplement and in the accompanying prospectus and under similar sections in the documents we incorporate by reference into 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. 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**



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We expect the net proceeds from this offering to be up to approximately \$17.5 million after deducting the placement agent fees (excluding the cost of the warrants issued to the placement agent), as described in Plan of Distribution, and other estimated offering expenses payable by us, which include legal, accounting, filing fee and various other fees and expenses associated with registering the securities and listing the common stock, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering. We intend to use the net proceeds from the sale of the securities under this prospectus supplement for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital.

As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses of the proceeds from this offering. Accordingly, we will retain broad discretion over the use of such proceeds. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in, and costs of, our Phase III clinical studies for LibiGel, the timing of revenues, if any, from any future collaborations or similar transactions and the amount of cash used by our operations. Pending the uses described above, we intend to deposit the proceeds temporarily in our non-interest bearing 100% FDIC-insured checking account or to invest them temporarily in short-term or marketable securities until we use them for their stated purpose.

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**DILUTION**





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Our net tangible book value on September 30, 2009 was approximately \$11.2 million, or approximately \$0.34 per share of common stock. Net tangible book value per share is determined by dividing our net tangible book value, which consists of tangible assets less total liabilities, by the number of shares of common stock outstanding on that date. Without taking into account any other changes in our net tangible book value after September 30, 2009, including in particular the completion of our merger with Cell Genesys on October 14, 2009, other than to give effect to our receipt of the estimated net proceeds from the sale of 10,404,626 units at an offering price of \$1.73 per unit, less the placement agent fees and our estimated offering expenses, our net tangible book value as of September 30, 2009, after giving effect to the items above, would have been approximately \$28.7 million, or \$0.66 per share. This represents an immediate increase in net tangible book value of \$0.32 per share of common stock to our existing stockholders and an immediate dilution in net tangible book value of \$1.07 per share of common stock to purchasers of units in this offering. The following table illustrates this per share dilution:

Public offering price per unit		\$	1.73
Net tangible book value per share as of September 30, 2009	\$	0.34	
Increase in net tangible book value per share attributable to this offering		0.32	
Pro forma net tangible book value per share as of September 30, 2009, after giving effect to this offering			0.66
Dilution in net tangible book value per share to new investors in this offering	\$		1.07

The above table is based on 33,042,764 shares of our common stock outstanding as of September 30, 2009 and excludes, as of September 30, 2009:

- 5,202,313 shares of our common stock issuable upon the exercise of warrants to be issued to purchasers in this offering and an additional 208,093 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in this offering;
- approximately 20.2 million shares of our common stock issued in connection with our merger with Cell Genesys and an additional approximately 6.2 million shares of our common stock issuable upon the exercise of options and warrants and the conversion of senior convertible notes of Cell Genesys assumed by us in connection with the merger;
- 4,983,709 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$5.47 per share;
- 2,736,691 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$2.90 per share;
- 1,098,500 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan; and
- 391,286 shares of our common stock issuable upon the one-for-one exchange of our shares of class C special stock at an exchange price of \$2.50 per share at the option of the holder of such class C special shares.

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To the extent that any of these shares are issued or options or warrants are exercised, new options or other equity incentive awards are issued under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan or we otherwise issue additional shares of common stock in the future, there will be further dilution to the new investors.

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**DESCRIPTION OF SECURITIES WE ARE OFFERING**



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In this offering, we are offering a maximum of 10,404,626 units, consisting of 10,404,626 shares of common stock and warrants to purchase 5,202,313 shares of common stock. Each unit consists of one share of common stock and warrants to purchase 0.50 of a share of common stock at an exercise price of \$2.08 per share. The shares of common stock and the warrants will be issued separately but will be purchased together in this offering. This prospectus supplement also relates to the offering of shares of our common stock upon the exercise, if any, of the warrants issued in this offering.

### **Common Stock**

The following description of our common stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of our common stock that we may offer under this prospectus. For the complete terms of our common stock, please refer to our certificate of incorporation and bylaws, which are incorporated by reference into the registration statement which includes this prospectus. Copies of our certificate of incorporation and bylaws are on file with the SEC as exhibits to registration statements previously filed by us. See *Where You Can Find More Information*. The terms of our common stock also may be affected by Delaware law.

*Authorized Common Stock.* We are authorized to issue 200,000,000 shares of common stock, \$0.0001 par value per share.

*Voting Rights.* For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in the holder's name on our books. Our common stock does not have cumulative voting rights. The holders of a majority of the shares of our common stock and class C special stock entitled to vote in any election of directors, voting together as a single class, can elect all of the directors standing for election, if they so choose.

*Dividends.* Subject to limitations under Delaware law and preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by our board of directors out of legally available funds.

*Liquidation.* Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of our company, subject to the prior rights of any preferred stock then outstanding.

*Fully Paid and Nonassessable.* All shares of our outstanding common stock are fully paid and nonassessable and any additional shares of common stock that we issue will be fully paid and nonassessable.

*Other Rights and Restrictions.* Holders of our common stock do not have preemptive or subscription rights, and they have no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of preferred stock which we may designate in the future. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the holder's shares of common stock.

*Listing.* Our common stock is listed on the Nasdaq Global Market under the symbol *BPAX*.

*Transfer Agent and Registrar.* The transfer agent and registrar for our common stock is Computershare Investor Services, LLC.

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**Warrants**

The material terms and provisions of the warrants being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. A form of the warrants is being filed as an exhibit to our current report on Form 8-K that we will file with the SEC in connection with this offering and reference is made thereto for a complete description of the warrants.

*Term; Exercise Price and Exercisability.* The warrants to be issued in this offering represent the rights to purchase up to 5,202,313 shares of our common stock at an exercise price of \$2.08 per share. Each warrant will be exercisable for a period of five years commencing six months and one day from the closing date. The number of warrant shares that may be acquired by any holder upon any exercise of the warrant will be limited to the extent necessary to insure that, following such exercise (or other issuance), the total number of shares of common stock then beneficially owned by such holder and its affiliates and any other persons whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, does not exceed 9.99% of the total number of issued and outstanding shares of common stock (including for such purpose the shares of common stock issuable upon such exercise), or beneficial ownership limitation. The holder may elect to change this beneficial ownership limitation upon 61 days' prior written notice.

*Manner of Exercise.* Holders of the warrants may exercise their warrants to purchase shares of our common stock on or before the expiration date by delivering (i) notice of exercise, appropriately completed and duly signed, and (ii) if such holder is not utilizing the cashless exercise provisions with respect to the warrants, payment of the exercise price for the number of shares with respect to which the warrant is being exercised. Warrants may be exercised in whole or in part, but only for full shares of common stock. We provide certain buy-in rights to a holder if we fail to deliver the shares of common stock underlying the warrants by the third trading day after the date on which delivery of the stock certificate is required by the warrant. The buy-in rights apply if after the third trading day on which delivery of the stock certificate is required by the warrant, the holder purchases (in an open market transaction or otherwise) shares of our common stock to deliver in satisfaction of a sale by the holder of the warrant shares that the holder anticipated receiving from us upon exercise of the warrant. In this event, we will:

- pay in cash to the holder the amount equal to the excess (if any) of the buy-in price over the product of (A) such number of shares of common stock, times (B) the price at which the sell order giving rise to holder's purchase obligation was executed; and
- at the election of holder, either (A) reinstate the portion of the warrant as to such number of shares of common stock, or (B) deliver to the holder a certificate or certificates representing such number of shares of common stock.

In addition, the warrant holders are entitled to a cashless exercise option. This option entitles the warrant holders to elect to receive fewer shares of common stock without paying the cash exercise price. The number of shares to be issued would be determined by a formula based on the total number of shares with respect to which the warrant is being exercised, the daily volume weighted average price for the shares of our common stock on the trading day immediately prior to the date of exercise and the applicable exercise price of the warrants.

The shares of common stock issuable on exercise of the warrants will be, when issued and paid for in accordance with the warrants, duly authorized, validly issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise of all outstanding warrants.





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*Fundamental Transaction.* If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding common stock, (4) we effect any reclassification or recapitalization of our common stock or any compulsory share exchange pursuant to which our common stock is converted into or exchanged for other securities, cash or property, (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of the outstanding shares of our common stock, or (6) there is a liquidation, bankruptcy, insolvency, dissolution or winding-up (or the occurrence of any analogous proceeding) affecting our company each, a Fundamental Transaction, then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction. Any successor to us or surviving entity will assume the obligations under the warrant.

*Certain Adjustments.* The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock. If the holders of our common stock shall have received or become entitled to receive, without payment therefor, (1) common stock or any shares of stock or other securities which are at any time directly or indirectly convertible into or exchangeable for our common stock, or any rights or options to subscribe for, purchase or otherwise acquire any of the foregoing by way of dividend or other distribution, (2) any cash paid or payable otherwise than as a cash dividend; or (3) common stock or additional stock or other securities or property (including cash) by way of spinoff, split-up, reclassification, combination of shares or similar corporate rearrangement, then and in each such case, the holder of the warrants will, upon the exercise of the warrant, be entitled to receive, in addition to the number of shares of our common stock receivable thereupon, and without payment of any additional consideration therefor, the amount of stock and other securities and property (including cash in the cases referred to in clauses (2) and (3) above) which such holder would hold on the date of such exercise had such holder been the holder of record of such common stock as of the date on which holders of common stock received or became entitled to receive such shares or all other additional stock and other securities and property.

*Delivery of Certificates.* Upon the holder's exercise of a warrant, we will promptly, but in no event later than three trading days after the exercise date (referred to as the exercise share delivery date), issue and deliver, or cause to be issued and delivered, a certificate for the shares of common stock issuable upon exercise of the warrant. In addition, we will, if the holder provides the necessary information to us, issue and deliver the shares electronically through The Depository Trust Corporation through its Deposit Withdrawal Agent Commission System (DWAC) or another established clearing corporation performing similar functions.

*Notice of Corporate Action.* We will provide at least 20 days prior notice to holders of the warrants to provide them with the opportunity to exercise their warrants and hold common stock in order to participate in or vote on the following corporate events:

- if we shall take a record of the holders of our common stock for the purpose of entitling them to receive a dividend or other distribution, or any right to subscribe for or purchase any shares of stock of any class or any other right;

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- if we authorize or approve, enter into any agreement contemplating, or solicit stockholder approval for any transaction that would be deemed a Fundamental Transaction as described above; or
  
- a voluntary dissolution, liquidation or winding up of our company.

*Additional Provisions.* We are not required to issue fractional shares upon the exercise of the warrants. No holders of the warrants will possess any rights as a stockholder under those warrants until the holder exercises those warrants. The warrants may be transferred independent of the common stock they were issued with, on a form of assignment, subject to all applicable laws.

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**PLAN OF DISTRIBUTION**

We have entered into a placement agency agreement, dated as of March 4, 2010, with Rodman & Renshaw, LLC, as placement agent which we refer to as the placement agency agreement. Subject to the terms and conditions contained in the placement agency agreement, Rodman & Renshaw, LLC has agreed to act as our placement agent in connection with this offering. In addition, we have retained JMP Securities LLC as a financial advisor in connection with the offering. The placement agent is not purchasing or selling any securities offered by this prospectus supplement and the accompanying prospectus, nor is the placement agent required to arrange the purchase or sale of any specific number or dollar amount of the securities, but the placement agent has agreed to use its reasonable best efforts to arrange for the sale of all of the securities in this offering. There is no requirement that any minimum number of units or dollar amount of units be sold in this offering and there can be no assurance that we will sell all or any of the units being offered.

The placement agency agreement provides that the obligations of the placement agent and the investors are subject to certain conditions precedent, including, among other things, the absence of any material adverse change in our business and the receipt of certain opinions, letters and certificates from us or our counsel.

We currently anticipate that the closing of this offering will take place on or about March 8, 2010. Prior to or at the closing, the funds will be deposited into an independent escrow account with a commercial bank. On the closing date, the following will occur:

- we will receive funds in the amount of the aggregate purchase price;
  
- the placement agent will receive the placement agent fees in accordance with the terms of the placement agency agreement; and
  
- we will deliver the units to the investors.

The placement agent proposes to arrange for the sale to one or more purchasers of the securities offered pursuant to this prospectus supplement and the accompanying prospectus.

We will pay the placement agent an aggregate cash commission equal to 2.5% of the gross proceeds from the sale of the units in this offering. JMP Securities LLC will be paid \$100,000 out of the placement agent's commission. Subject to compliance with Financial Industry Regulatory Authority, or FINRA, Rule 5110(f)(2)(D), we will also reimburse the placement agent for legal and other expenses incurred by it in connection with this offering in an amount equal to 0.8% of the aggregate offering proceeds but in no event more than \$30,000. The placement agent also will receive warrants to purchase up to 208,093 shares of our common stock or 2% of the aggregate number of shares of common stock included in the units that are sold in the offering with an exercise price of \$2.16 per share (125% of the public offering price) and an expiration date of June 9, 2014 (the five year anniversary of the effective date of the registration statement). Pursuant to FINRA Rule 5110(g), for a period of six months after the issuance date of the placement agent warrants, neither the placement agent warrants nor any shares issued upon exercise of the placement agent warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale,

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derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security:

- (i) by operation of law or by reason of reorganization of the Company;
  
- (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period;

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(iii) if the aggregate amount of securities of the Company held by the holder of the Rodman warrant or related person do not exceed 1% of the securities being offered;

(iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or

(v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

Under no circumstances will the fee, commission or discount received by the placement agent or any other member of FINRA or independent broker-dealer exceed 8% of the gross proceeds to us in this offering or any other offering in the United States pursuant to this prospectus supplement and the accompanying prospectus. The number of placement agent warrants may be reduced to the extent necessary to comply with the overall limit on placement agent compensation of 8%.

The estimated offering expenses payable by us, in addition to the aggregate fee of \$450,000 due to the placement agent, are approximately \$50,000 which includes legal, accounting and filing fees various other fees and expenses associated with registering the securities and listing the common stock. After deducting certain fees due to the placement agent and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$17.5 million if the maximum number of units are sold.

The following table shows the per unit and total commissions we will pay to the placement agent in connection with the sale of the units offered pursuant to this prospectus supplement and the accompanying prospectus, assuming the purchase of all of the units offered hereby and excluding proceeds that we may receive upon exercise of the warrants.

Per unit placement agent fees	\$	0.04325
Maximum offering total	\$	450,000.00

We have agreed to indemnify the placement agent and certain other persons against certain liabilities relating to or arising out of the placement agent's activities under the placement agency agreement. We also have agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

From time to time in the ordinary course of business, the placement agent or its affiliates may in the future engage in investment banking and/or other services with us for which they may receive compensation, but we have no current agreement in place with the placement agent.

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A copy of the placement agency agreement, the form of securities purchase agreement we entered into with the purchasers and the form of warrant will be included as exhibits to our current report on Form 8-K that will be filed with the SEC in connection with the consummation of this offering.

The placement agent has informed us that it will not engage in over allotment, stabilizing transactions or syndicate covering transactions in connection with this offering.

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The transfer agent for our common stock to be issued in this offering is Computershare Investor Services, LLC. We will act as transfer agent for the warrants being offered hereby.

Our common stock is traded on the NASDAQ Global Market under the symbol BPAX. The warrants to purchase common stock issued to the investors in this offering are not expected to be eligible for trading on any market.

The purchase price per unit and the exercise price for the warrants were determined based on negotiations with the purchasers and discussions with the placement agent based on current market factors.

**LEGAL MATTERS**

The validity of the issuance of the securities offered hereby will be passed upon for us by Oppenheimer Wolff & Donnelly LLP, Minneapolis, Minnesota. The placement agent is being represented in connection with this offering by Weinstein Smith LLP, New York, New York.

**EXPERTS**

The financial statements of BioSante Pharmaceuticals, Inc. as of December 31, 2008 and 2007, and for each of the three years in the period ended December 31, 2008, incorporated in this prospectus supplement by reference, and the effectiveness of BioSante Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2008, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference (which reports (1) express an unqualified opinion on the financial statements and include an explanatory paragraph expressing substantial doubt about the ability of BioSante Pharmaceuticals, Inc. to continue as a going concern, and (2) express an unqualified opinion on the effectiveness of internal control over financial reporting). 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>.



## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

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>.

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

In addition, we maintain a web site that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our web site is [www.biosantepharma.com](http://www.biosantepharma.com). Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not

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constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

This prospectus supplement and the accompanying prospectus are part of a registration statement on Form S-3 that we filed with the SEC registering the securities that may be offered and sold hereunder. The registration statement, including exhibits thereto, contains additional relevant information about us and these securities that, as permitted by the rules and regulations of the SEC, we have not included in this prospectus supplement or the accompanying prospectus. A copy of the registration statement can be obtained at the address set forth above. You should read the registration statement for further information about us and these securities.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference into this prospectus supplement 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 supplement, 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 supplement:

- our annual report on Form 10-K for the year ended December 31, 2008 (including information specifically incorporated by reference into our Form 10-K from our proxy statement for our 2009 Annual Meeting of Stockholders);
- our quarterly reports on Form 10-Q for the quarters ended March 31, 2009, June 30, 2009 and September 30, 2009;
- our current reports on Form 8-K as filed with the SEC on June 30, 2009, August 7, 2009, August 14, 2009, September 21, 2009 and October 14, 2009; 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 also are 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 supplement and prior to the sale of all securities registered hereunder or termination of the registration statement. 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 supplement.

## Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

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. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

You may request a copy of these filings, including exhibits to such documents that are specifically incorporated by reference, 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](mailto:pdonenberg@biosantepharma.com).

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Any statement contained in a document incorporated by reference into this prospectus supplement will be deemed modified or superseded to the extent that a statement contained in this prospectus supplement or in any other subsequently filed document which also is incorporated by reference into this prospectus supplement modifies or supersedes such statement. Statements contained in this prospectus supplement as to the contents of any contract or other documents are not necessarily complete, and in each instance investors are referred to the copy of the contract or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference and the exhibits and schedules thereto.

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**PROSPECTUS**

**\$75,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

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We may offer and sell from time to time up to \$75,000,000 in total of any combination of the securities described in this prospectus, either individually or in units. We also may offer common stock upon conversion of preferred stock or common stock or preferred stock upon the exercise of warrants. This prospectus provides a general description of the securities we may offer. Each time we offer securities, we will provide a prospectus supplement containing more information about the particular offering together with this prospectus. The prospectus supplement also may add, update or change information contained in this prospectus. This prospectus may not be used to offer and sell securities without a prospectus supplement.

The securities may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled "Plan of Distribution" in this prospectus. If any agents or underwriters are involved in the sale of any securities, the names of such agents or underwriters and any applicable fees, commissions, discounts and over-allotment options will be set forth in the applicable prospectus supplement.

Our common stock is listed on the NASDAQ Global Market under the symbol "BPAX". On May 28, 2009, the reported closing price of our common stock was \$2.00 per share. As of April 28, 2009, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$52,510,820, based on 27,042,764 shares of outstanding common stock, of which 24,423,637 shares were held by non-affiliates, and a per share price of \$2.15 based on the closing sale price of our common stock as reported by the Nasdaq Global Market on such date. As of the date of this prospectus, we have not offered any securities pursuant to General Instruction I.B.6. of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus.

**Investing in our securities involves a high degree of risk. We refer you to the section entitled Risk Factors of this prospectus on page 3 and in the applicable prospectus supplement and under similar sections in the documents we incorporate by reference into this prospectus.**

**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.**

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The date of this prospectus is June 9, 2009

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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 that are used in this prospectus, including BioSante®, Elestrin®, LibiGel®, Bio-T-Gel®, The Pill Plus®, BioVant®, BioLook®, CAP-Oral® and BioAir®.*

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You should rely only on the information contained in this prospectus, including information incorporated by reference as described above, or any prospectus supplement that we have specifically referred you to. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of those documents or that any document incorporated by reference is accurate as of any date other than its filing date. You should not consider this prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

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### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. Under this shelf registration process, we may offer to sell any one or more or a combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$75,000,000 (or its equivalent based on the applicable exchange rate at the time of the sale in one or more foreign currencies, currency units or composite currencies that we may designate). We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We also may add, update or change in the prospectus supplement any of the information contained in this prospectus. If there is an inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in the prospectus supplement. You should read carefully both this prospectus and the applicable prospectus supplement together with the documents we incorporate by reference into this prospectus as described under the heading **Incorporation of Certain Documents By Reference** before making an investment decision. This prospectus may not be used to offer and sell securities without a prospectus supplement.

The registration statement that contains this prospectus, including the exhibits to the registration statement and the information incorporated by reference, provides additional information about the securities offered under this prospectus. That registration statement can be read at the SEC web site or at the SEC public reference room as discussed under the heading **Where You Can Find More Information**.

You should rely only on the information provided in the registration statement, this prospectus and in any prospectus supplement, including the information incorporated by reference. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or any supplement to this prospectus is accurate at any date other than the date indicated on the cover page of these documents. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

### **ABOUT OUR COMPANY**

BioSante Pharmaceuticals, Inc. is 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. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

The following is a list of our key products:

- **LibiGel** – once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment, or SPA, for the treatment of female sexual dysfunction, or FSD.
- **Elestrin** – once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration, or FDA, indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.



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

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- 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.

In order to market our products in the United States, we are required to obtain approval of a new drug application, or NDA, or an abbreviated NDA, or ANDA, for each such product from the FDA. With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006. In addition, we received three years of marketing exclusivity for Elestrin. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited for the marketing of Elestrin and the sale of certain assets related to Elestrin. Azur has agreed to promote Elestrin using its women's health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement.

Prior to submitting an NDA or ANDA for our other products, the products must undergo human clinical trials. With respect to LibiGel, we believe, based on agreements with the FDA, including an 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, or HSDD, in menopausal women. 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 indicates that these agreed measures will serve as the basis for regulatory review and any decision by the FDA to approve an NDA for LibiGel. The LibiGel 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 and breast cancer 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 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 the safety study for an additional four years. 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. Alternatively, we may choose to sublicense LibiGel, Elestrin (outside the territories already sublicensed) 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 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 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

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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.

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.biosantepharm.com](http://www.biosantepharm.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. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

**RISK FACTORS**

An investment in our securities involves a high degree of risk. You should carefully consider the specific risks set forth under the section entitled Risk Factors in the applicable prospectus supplement and under similar sections in the documents we incorporate by reference into this prospectus before making an investment decision. The risks and uncertainties described in the prospectus supplement and the documents we incorporate by reference into this prospectus are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we believe are not material at the time could also materially adversely affect our business, financial condition or results of operations. In any case, the value of our securities could decline, and you could lose all or part of your investment. See also the information contained under the heading

Special Note Regarding Forward-Looking Statements immediately below.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and any accompanying prospectus supplement, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts included in or

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incorporated by reference into this prospectus and any accompanying prospectus supplement that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Our forward-looking statements generally include statements about our plans, objectives, strategies and prospects regarding, among other things, our business, results of operations, liquidity and financial condition. In some cases, we have identified these forward-looking statements with words like believe, may, could, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate, approximate, con negative of these words or other words and terms of similar meaning.

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 include: our ability to 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; our ability to obtain additional capital when needed or on acceptable terms; the effects of the current global economic crisis and our ability to seek strategic alternatives or raise additional capital or otherwise conduct our business in light thereof; the level of market acceptance of Elestrin, and our other products if and when they are commercialized; our dependence upon our licensees for the development, marketing and sale of certain of our products, including in particular Azur to sell Elestrin; our dependence upon the maintenance of our licenses with Antares Pharma IPL AG, Wake Forest University Health Sciences and Cedars-Sinai Medical Center and the University of California Los Angeles; subject recruitment and enrollment in our current and future clinical trials, including in particular our Phase III clinical trial program for LibiGel; uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy; the failure of certain of our products to be commercially introduced for several years or at all; our failure to obtain and maintain required regulatory approvals on a timely basis or at all; our ability to compete in a competitive industry; our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties; our dependence upon key employees; our ability to maintain effective internal controls over financial reporting; adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations; changes in generally accepted accounting principles; or conditions and changes in the biopharmaceutical industry or in general economic or business conditions. We refer you to the section entitled Risk Factors included elsewhere in this prospectus and in the accompanying prospectus supplement and under similar sections in the documents we incorporate by reference into 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 above and under the section entitled Risk Factors included elsewhere in this prospectus and in the accompanying prospectus supplement and under similar sections in the documents we incorporate by reference into 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. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements, except if we otherwise are required by law. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the Securities and Exchange Commission.

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**USE OF PROCEEDS**

Unless we otherwise indicate in the applicable prospectus supplement, we currently intend to use the net proceeds from the sale of our securities, if such sale occurs, to finance our Phase III clinical trials for LibiGel and for working capital and other general corporate purposes. We also may 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 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 deposit the proceeds temporarily in our non-interest bearing 100% FDIC-insured checking account or to invest them temporarily in short-term or marketable securities until we use them for their stated purpose. We also may set forth additional information on the use of net proceeds from the sale of the securities we offer under this prospectus in a prospectus supplement relating to the specific offering.

**DESCRIPTION OF COMMON STOCK**

The following description of our common stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of our common stock that we may offer under this prospectus. For the complete terms of our common stock, please refer to our certificate of incorporation and bylaws, which are incorporated by reference into the registration statement which includes this prospectus. Copies of our certificate of incorporation and bylaws are on file with the SEC as exhibits to registration statements previously filed by us. See [Where You Can Find More Information](#). The terms of our common stock also may be affected by Delaware law.

**Authorized and Outstanding Capital Stock**

We are authorized to issue 100,000,000 shares of common stock, \$0.0001 par value per share, 4,687,684 shares of class C special stock, \$0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.0001 par value per share.

As of May 26, 2009, we had 27,042,764 shares of common stock outstanding. As of May 26, 2009, we had an aggregate of 2,736,691 shares of common stock reserved for issuance upon the exercise of outstanding stock options granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan and the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan and an additional 1,098,500 shares of common stock reserved for issuance pursuant to future grants under the BioSante Pharmaceuticals, Inc. 2008 Stock Incentive Plan. As of May 26, 2009, we had an aggregate of 2,698,705 shares of common stock reserved for issuance upon the exercise of outstanding warrants.

As of May 26, 2009, we had 391,286 shares of class C special stock outstanding. Each share of class C special stock entitles its holder to one vote per share. Each share of our class C special stock is exchangeable, at the option of the holder, for one share of common stock, at an exchange price of \$2.50 per share, subject to adjustment upon certain capitalization events. Holders of our class C special stock are not entitled to receive dividends. Holders of our class C special stock are not entitled to participate in the distribution of our assets upon any liquidation, dissolution or winding-up of our company. The holders of our class C special stock have no cumulative voting, preemptive, subscription,

redemption or sinking fund rights.

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As of the date of this prospectus, we do not have any shares of preferred stock outstanding.

**Voting Rights**

For all matters submitted to a vote of stockholders, each holder of common stock is entitled to one vote for each share registered in the holder's name on our books. Our common stock does not have cumulative voting rights. The holders of a majority of the shares of our common stock and class C special stock entitled to vote in any election of directors, voting together as a single class, can elect all of the directors standing for election, if they so choose.

**Dividends**

Subject to limitations under Delaware law and preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by our board of directors out of legally available funds.

**Liquidation**

Upon our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities of our company, subject to the prior rights of any preferred stock then outstanding.

**Fully Paid and Nonassessable**

All shares of our outstanding common stock are fully paid and nonassessable and any additional shares of common stock that we issue will be fully paid and nonassessable.

**Other Rights and Restrictions**

Holders of our common stock do not have preemptive or subscription rights, and they have no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of preferred stock which we may designate in the future. Our certificate of incorporation and bylaws do not restrict the ability of a holder of common stock to transfer the holder's shares of common stock.



**Listing**

Our common stock is listed on the Nasdaq Global Market under the symbol BPAX.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Investor Services, LLC.

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**DESCRIPTION OF PREFERRED STOCK**

The following description of our preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of our preferred stock that we may offer under this prospectus. For the complete terms of our preferred stock, please refer to our certificate of incorporation and bylaws, which are incorporated by reference into the registration statement which includes this prospectus. Copies of our certificate of incorporation and bylaws are on file with the SEC as exhibits to registration statements previously filed by us. See [Where You Can Find More Information](#). The terms of our preferred stock also may be affected by Delaware law. If we offer a specific class or series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC.

**Authorized and Outstanding Shares**

We currently have authorized 10,000,000 shares of preferred stock, \$0.0001 par value per share. As of the date of this prospectus, we did not have any shares of preferred stock outstanding.

**Designations, Powers, Preferences, Rights, Qualifications, Limitations and Restrictions**

Prior to issuance of shares of each series of our undesignated preferred stock, our board of directors is required by the Delaware General Corporate Law, or DGCL, and our certificate of incorporation to adopt resolutions and file a Certificate of Designations with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series.

Our board of directors could authorize the issuance of shares of preferred stock with terms and conditions more favorable than our common stock or class C special stock and with rights that could adversely affect the voting power or other rights of holders of our common stock or class C special stock. In addition, our board of directors could authorize the issuance of shares of preferred stock with terms and conditions which could have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of such shares might believe to be in their best interests or in which holders of some, or a majority, of such shares might receive a premium for their shares over the then-market price of such shares.

Subject to limitations prescribed by the DGCL, our certificate of incorporation and our bylaws, our board of directors is authorized to fix the number of shares constituting each series of preferred stock and the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series, including such provisions as may be desired concerning voting, redemption, dividends, dissolution or the distribution of assets, conversion or exchange, and such other subjects or matters as may be fixed by resolution of the board of directors. Each series of preferred stock that we offer under this prospectus will, when issued, be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

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The applicable prospectus supplement(s) will describe the following terms of the series of preferred stock in respect of which this prospectus is being delivered:

- the title and stated value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the purchase price of the preferred stock;

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- the dividend rate(s), period(s) and/or payment date(s) or the method(s) of calculation for dividends;
  
- whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
  
- the procedures for any auction and remarketing, if any, for the preferred stock;
  
- the provisions for a sinking fund, if any, for the preferred stock;
  
- the provisions for redemption, if applicable, of the preferred stock;
  
- any listing of the preferred stock on any securities exchange or market;
  
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price (or its manner of calculation) and conversion period;
  
- voting rights, if any, of the preferred stock;
  
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
  
- whether interests in the preferred stock will be represented by depositary shares;
  
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs;
  
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and

- any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our preferred stock will be set forth in the applicable prospectus supplement.

#### **DESCRIPTION OF WARRANTS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement, including a form of warrant certificate, that describes the terms of the series of warrants we are offering, and any

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supplemental agreements, before the issuance of the related series of warrants. The following summaries of material terms and provisions of the warrant agreements and warrant certificate are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we may offer under this prospectus and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

**Outstanding Warrants**

As of May 26, 2009, the following warrants were outstanding:

- Warrants to purchase an aggregate of 534,996 shares of our common stock at an exercise price of \$7.00 per share issued to various institutional and accredited investors in connection with our private placement completed on May 14, 2004;
- Warrants to purchase an aggregate of 853,292 shares of our common stock at an exercise price of \$2.75 per share issued to various institutional and accredited investors in connection with our private placement completed on July 21, 2006;
- Warrants to purchase an aggregate of 763,750 shares of our common stock at an exercise price of \$8.00 per share issued to various institutional and accredited investors in connection with our private placement completed on June 13, 2007;
- A warrant to purchase up to 300,000 shares of our common stock at an exercise price of \$4.00 per share issued to Kingsbridge Capital Limited on December 15, 2008 connection with our committed equity financing facility; and
- Warrants to purchase an aggregate of 246,667 shares of our common stock at exercise prices ranging from \$4.78 to \$8.00 issued to investor and public relations vendors in 2007 and 2008.

**General**

We may issue warrants for the purchase of common stock or preferred stock in one or more series. We may issue warrants independently or together with common stock or preferred stock, and the warrants may be attached to or separate from these securities.

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We will evidence each series of warrants by warrant certificates that we will issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. If we elect to do so, the warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation or relationship of agency or trust for or with any registered holders of warrants or beneficial owners of warrants. We will indicate the name and address and other information regarding the warrant agent in the applicable prospectus supplement relating to a particular series of warrants if we elect to use a warrant agent.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;

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- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
  
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
  
- the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
  
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
  
- the terms of any rights to redeem or call the warrants;
  
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
  
- the dates on which the right to exercise the warrants will commence and expire;
  
- the manner in which the warrant agreement and warrants may be modified;
  
- material U.S. federal income tax consequences of holding or exercising the warrants;
  
- the terms of the securities issuable upon exercise of the warrants;
  
- the identify of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
  
- the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;



- the anti-dilution provisions of the warrants, if any;
- any redemption or call provisions; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

#### **Exercise of Warrants**

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to 5:00 p.m., New York City time, on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

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Holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

**Enforceability of Rights by Holders of Warrants**

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

**DESCRIPTION OF UNITS**

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the units that we may offer under this prospectus and any related unit agreements and unit certificates. While the terms summarized below will apply generally to any units that we may offer, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any units offered under that prospectus supplement may differ from the terms described below.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, any form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of such unit agreements and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we may offer under this prospectus and the complete unit agreement and any supplemental agreements that contain the terms of the units.

**General**

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We may issue, in one more series, units comprised of shares of our common stock or preferred stock and warrants to purchase common stock or preferred or any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under

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which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We may evidence units by unit certificates that we issue under a separate agreement. We may issue the units under a unit agreement between us and one or more unit agents. If we elect to enter into a unit agreement with a unit agent, the unit agent will act solely as our agent in connection with the units and will not assume any obligation or relationship of agency or trust for or with any registered holders of units or beneficial owners of units. We will indicate the name and address and other information regarding the unit agent in the applicable prospectus supplement relating to a particular series of units if we elect to use a unit agent.

We will describe in the applicable prospectus supplement the terms of the series of units being offered, including:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The other provisions regarding our common stock, preferred stock and warrants as described in this section will apply to each unit to the extent such unit consists of shares of our common stock and preferred stock and warrants to purchase our common stock.

**Enforceability of Rights by Holders of Units**

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

**ANTI-TAKEOVER EFFECTS OF PROVISIONS OF OUR CERTIFICATE OF INCORPORATION, OUR BYLAWS AND DELAWARE LAW**

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Some provisions of our certificate of incorporation and bylaws and Delaware law contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions also are designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal

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to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

**Authorized But Unissued Capital Stock**

We have shares of common stock, class C special stock and undesignated preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of the Nasdaq Global Market. We may use these additional shares for a variety of corporate purposes, including for future public offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved capital stock may enable our board of directors to issue shares to persons friendly to current management that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

**Stockholder Meetings**

Our bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, president and chief executive officer, or by our board of directors.

**Requirements for Advance Notification of Stockholder Nominations and Proposals**

Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

**No Cumulative Voting Rights**

Our certificate of incorporation and bylaws do not provide for cumulative voting rights. The holders of a majority of the shares of our common stock and class C special stock entitled to vote in any election of directors, voting together as a single class, can elect all of the directors standing for election, if they so choose.

**Delaware Anti-Takeover Statute**

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We are subject to Section 203 of the Delaware General Corporation Law. This law prohibits a publicly-held Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are

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directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of our assets involving the interested stockholder;
- in general, any transaction that results in the issuance or transfer by us of any of our stock to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

**PLAN OF DISTRIBUTION**

We may sell the securities offered by this prospectus in one or more of the following ways from time to time:

- to or through underwriters or dealers; or
- directly to purchasers, including our affiliates, or to a single purchaser.
- through one or more agents;



- through a block trade in which the broker or dealer engaged to handle the block will attempt to sell the securities as agent, but may position and resell a portion of the block as principal to facilitate the transaction; or
- through a combination of any of these methods of sale.

In addition, we may issue the securities being offered by this prospectus as a dividend or distribution.

We may effect the distribution of the securities from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices.

We will set forth in a prospectus supplement the terms of the offering of our securities, including:

- the type and amount of securities we are offering;
- the purchase price of our securities being offered and the net proceeds we will receive from the sale;

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- the method of distribution of the securities we are offering;
- the name or names of any agents, underwriters or dealers;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any underwriting discounts and commissions or agency fees and commissions and other items constituting underwriters' or agents' compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchanges on which such securities may be listed.

**Sale Through Underwriters or Dealers**

If we use an underwriter or underwriters in the sale of securities offered by this prospectus, the underwriters will acquire the securities for their own account, including through underwriting, purchase, security lending or repurchase agreements with us. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions. Underwriters may sell the securities in order to facilitate transactions in any of our other securities (described in this prospectus or otherwise), including other public or private transactions and short sales. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless otherwise indicated in the prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. The underwriters may change from time to time any public offering price and any discounts or concessions allowed or reallocated or paid to dealers.

If we use an underwriter or underwriters in the sale of securities, we will execute an underwriting agreement with the underwriter or underwriters at the time we reach an agreement for sale. We will set forth in the applicable prospectus supplement the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transactions, including compensation of the underwriters and dealers. This compensation may be in the form of discounts, concessions or commissions.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions. If we grant any over-allotment option, the terms of any over-allotment option will be set forth in the prospectus supplement relating to those securities.

**Sale Through Dealers**

If we use dealers in the sale of the securities offered by this prospectus, we or an underwriter will sell the securities to them as principals. The dealers may then resell those securities to the public at varying prices to be determined by the dealers at the time of resale. The applicable prospectus supplement will set forth the names of the dealers and the terms of the transactions.

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**Direct Sales**

We may directly solicit offers to purchase the securities offered by this prospectus. In this case, no underwriters or agents would be involved. We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

**Sales Through Agents**

Securities also may be offered and sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and will describe any commissions payable to the agent. Unless otherwise indicated in the applicable prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment. Any agent may be deemed to be an underwriter within the meaning of the Securities Act with respect to any sale of those securities.

**Delayed Delivery Contracts**

If the applicable prospectus supplement indicates, we may authorize agents, underwriters or dealers to solicit offers from institutions to purchase securities at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. Institutions with which contracts of this type may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions, but in all cases those institutions must be approved by us. The obligations of any purchaser under any contract of this type will be subject to the condition that the purchase of the securities shall not at the time of delivery be prohibited under the laws of the jurisdiction to which the purchaser is subject. The applicable prospectus supplement will describe the commission payable for solicitation of those contracts.

**Market Making, Stabilization and Other Transactions**

Our common stock is listed on the Nasdaq Global Market. Any common stock sold pursuant to a prospectus supplement will be eligible for listing and trading on the Nasdaq Global Market, subject to official notice of issuance. Unless the applicable prospectus supplement states otherwise, each other class or series of securities issued will be a new issue and will have no established trading market. We may elect to list any other class or series of securities on an exchange, but we are not currently obligated to do so. Any underwriters that we use in the sale of offered securities may make a market in such securities, but may discontinue such market making at any time without notice. Therefore, we cannot assure you that the securities will have a liquid trading market.

Any underwriter may also engage in stabilizing transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended. Stabilizing transactions involve bids to purchase the underlying security in the open market for the purpose of pegging, fixing or maintaining the price of the securities. Syndicate covering transactions involve purchases of the securities in the open market after the distribution has been completed in order to cover syndicate short positions.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a syndicate covering transaction to cover syndicate short positions. Stabilizing transactions, syndicate covering transactions and penalty bids may cause the price of the securities to be higher than it would be in the absence of the transactions. The underwriters may, if they commence these transactions, discontinue them at any time.

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The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

**Derivative Transactions and Hedging**

We, the underwriters or other agents may engage in derivative transactions involving the securities. These derivatives may consist of short sale transactions and other hedging activities. The underwriters or agents may acquire a long or short position in the securities, hold or resell securities acquired and purchase options or futures on the securities and other derivative instruments with returns linked to or related to changes in the price of the securities. In order to facilitate these derivative transactions, we may enter into security lending or repurchase agreements with the underwriters or agents. The underwriters or agents may effect the derivative transactions through sales of the securities to the public, including short sales, or by lending the securities in order to facilitate short sale transactions by others. The underwriters or agents may also use the securities purchased or borrowed from us or others (or, in the case of derivatives, securities received from us in settlement of those derivatives) to directly or indirectly settle sales of the securities or close out any related open borrowings of the securities.

**Electronic Auctions**

We also may make sales through the Internet or through other electronic means. Since we may from time to time elect to offer securities directly to the public, with or without the involvement of agents, underwriters or dealers, utilizing the Internet or other forms of electronic bidding or ordering systems for the pricing and allocation of such securities, you will want to pay particular attention to the description of that system we will provide in a prospectus supplement.

Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering systems may present to each bidder, on a so-called "real-time" basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder's individual bids would be accepted, prorated or rejected. Of course, many pricing methods can and may also be used.

Upon completion of such an electronic auction process, securities will be allocated based on prices bid, terms of bid or other factors. The final offering price at which securities would be sold and the allocation of securities among bidders would be based in whole or in part on the results of the Internet or other electronic bidding process or auction.

**General Information**

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against specified liabilities, including liabilities under the Securities Act, or to contribution by us to payments they may be required to make in respect to such liabilities. The applicable prospectus supplement will describe the terms and conditions of indemnification or contribution. Some of our agents,

underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business. We will describe in the prospectus supplement the nature of any such relationship and the name of the parties involved. Any lockup arrangements will be set forth in the applicable prospectus supplement.

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**LEGAL MATTERS**

The validity of the securities offered hereby will be passed upon for us by Oppenheimer Wolff & Donnelly LLP.

**EXPERTS**

The financial statements incorporated in this prospectus by reference from the BioSante Pharmaceuticals, Inc.'s 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.

**LIMITATION ON LIABILITY AND DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the DGCL. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**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>.

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



In addition, we maintain a web site that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our web site is [www.biosantepharma.com](http://www.biosantepharma.com). Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

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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, 2008 (including information specifically incorporated by reference into our Form 10-K from our proxy statement for our 2009 Annual Meeting of Stockholders);
- our quarterly report on Form 10-Q for the quarter ended March 31, 2009; 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 also are 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 addition, we also are 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 the initial registration statement of which this prospectus is a part and prior to effectiveness of such registration statement. 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. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

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

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**\$75,000,000**

**Common Stock**

**Preferred Stock**

**Warrants**

**Units**

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**PROSPECTUS**

**June 9, 2009**

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