BIOSANTE PHARMACEUTICALS INC
Form 424B5
March 04, 2011
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PROSPECTUS SUPPLEMENT
(To the prospectuses dated June 9, 2009 and June 10, 2010)

Filed Pursuant to Rule 424(b)(5)
Registration Nos. 333-159606 and 333-166859

12,199,482 Units

Units Consisting of

One Share of Common Stock and

a Warrant to Purchase 0.33 of a Share of Common Stock

We are offering 12,199,482 units, with each unit consisting of one share of our common stock and a warrant to purchase 0.33 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 institutional investors pursuant to this prospectus supplement and the accompanying prospectuses. Each unit will be sold at a negotiated price of $2.0613. Each warrant has an exercise price of $2.25 per share, and is exercisable immediately for a period of three years. 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 2, 2011, the last reported sale price of our common stock on the NASDAQ Global Market was $2.03 per share. As of March 2, 2011, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $159.6 million based on 81,391,130 shares of outstanding common stock, of which 78,637,178 shares were held by non-affiliates, and a price of $2.03 per share, which was the last reported sale price of our common stock as quoted on the NASDAQ Global Market on March 2, 2011.

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

Rodman & Renshaw, LLC acted as the placement agent on this transaction. The placement agent is not required to sell any specific number or dollar amount of securities. The placement agent 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.

	Per Unit	Total
Public offering price	$ 2.0613	$ 25,146,792
Placement agent fees(1)	$ 0.1031	$ 1,257,767
Proceeds, before expenses, to BioSante Pharmaceuticals, Inc.(2)	$ 1.9582	$ 23,889,025

(1) In addition, we have agreed to issue the placement agent warrants to purchase up to 243,990 shares of our common stock at an exercise price of $2.58 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, 2011, 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 3, 2011

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You should rely only on information contained in this prospectus supplement, the accompanying prospectuses and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectuses. 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 prospectuses is accurate as of any date other than the date on the front of this prospectus supplement or the accompanying prospectuses or that any document that we incorporated by reference in this prospectus supplement or the accompanying prospectuses is accurate as of any date other than its filing date. You should not consider this prospectus supplement or the accompanying prospectuses 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 prospectuses 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 consists of the base prospectus dated June 9, 2009, included in the registration statement on Form S-3 (No. 333-159606), and the base prospectus dated June 10, 2010, included in the registration statement on Form S-3 (No. 333-166859), both of which we are supplementing with the information contained in this supplement. Generally, when we refer to this prospectus, we are referring to both parts combined. Some of the information in the base prospectuses may not apply to this offering.

This prospectus supplement is being filed under each of (1) our shelf registration statement on Form S-3 (File No. 333-159606), which became effective on June 9, 2009, with respect to the initial $28,179,186 of securities offered hereby (including the public offering price per unit and the exercise price to be paid in connection with the warrants) and (2) our shelf registration statement on Form S-3 (File No. 333-166859), which became effective on June 10, 2010, with respect to any securities sold in excess of such amount.

You also should read and consider the information in the documents that we have referred you to in Where You Can Find More Information on page S-36 of this prospectus supplement and the information described under Incorporation of Certain Documents by Reference on page S-37 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 prospectuses, 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 prospectuses. 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 prospectuses is accurate only as of the date of such information, regardless of the time of delivery of this prospectus supplement and the accompanying prospectuses 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 and BioLook . 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 prospectuses 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 prospectuses carefully, including the information referred to under the heading Risk Factors in this prospectus supplement beginning on page S-5, and the financial statements and other information incorporated by reference in this prospectus supplement and the accompanying prospectuses 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 and oncology.

Our products, either approved or in human clinical development, include:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (SPA) for the treatment of female sexual dysfunction (FSD).

- Elestrin once daily transdermal estradiol (estrogen) gel approved by the U.S. Food and Drug Administration (FDA) indicated for the treatment of moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause and marketed in the U.S.

- The Pill-Plus (triple component contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in Phase II 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.

- Cancer vaccines a portfolio of cancer vaccines in Phase II clinical development for the treatment of various cancers.

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway: two LibiGel Phase III safety and efficacy clinical trials under an FDA agreed SPA and one Phase III cardiovascular and breast cancer safety study. One of the efficacy trials has completed enrollment and the other efficacy trial is currently enrolling women. The Phase III safety study also is currently enrolling women. In February 2011, we announced that based upon the fifth review of study conduct and unblinded safety data from the safety study by the study s independent data monitoring committee (DMC), the DMC unanimously recommended continuing the safety study as described in the FDA-agreed study protocol, with no modifications. If enrollment is not completed

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sooner, enrollment will continue until the safety study reaches its predetermined maximum of 4,000 women. Upon completion of the statistical analyses of the safety study and efficacy trials, we intend to submit an NDA to the FDA, requesting approval to market LibiGel for the treatment of HSDD in menopausal women.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), BioSante s licensee, is marketing Elestrin in the U.S. using Azur s women s health sales force which targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur s sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year, although based on current sales levels we deem receipt of such payments unlikely in the near term if at all.

Our portfolio of cancer vaccines is designed to stimulate the patient s immune system to fight effectively the patient s own cancer. Multiple Phase II trials of these vaccines are ongoing at minimal cost to us at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center in various cancer types, including pancreatic cancer, leukemia and breast cancer. We anticipate Phase II trials for prostate cancer to begin in the first half of 2011. Four of these vaccines have been granted FDA orphan drug designation.

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. CaP currently is in development as a facial line filler (BioLook) in the area of aesthetic medicine.

One of our strategic goals is to continue to seek and implement strategic alternatives with respect to our products and our company, including licenses, business collaborations and other business combinations or transactions with other pharmaceutical and biotechnology companies. Therefore, as a matter of course, we may engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger or sale of our company.

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.biosantepharma.com. We make available on our website free of charge a link to our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the Securities and Exchange Commission, or SEC. 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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The Offering

Common stock offered by us	12,199,482 shares
Common stock to be outstanding after this offering	93,590,612 shares
Warrants offered by us	Warrants to purchase up to 4,025,827 shares of our common stock (excluding warrants to purchase up to 243,990 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 $2.25 per share and is exercisable immediately for a period of three years. 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.
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-10 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-5 of this prospectus supplement.

The number of shares of our common stock to be outstanding immediately after this offering is based on 81,391,130 shares of our common stock outstanding as of March 2, 2011. Unless we specifically state otherwise, the share information in this prospectus supplement does not include:

- 4,025,827 shares of our common stock issuable upon the exercise of warrants to be issued to purchasers in this offering and an additional 243,990 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in this offering;

- 5,611,348 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;

- 19,418,590 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of $3.01 per share;

- 5,260,186 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of $3.10 per share;

- 795,000 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. Amended and Restated 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, 2009, 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 likely would 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

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 will 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 the shares of common stock offered in this offering.

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.

Risks Related to the Warrants

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

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.

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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.

Risks Related to Our Common Stock

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 2, 2011, there were approximately 81.4 million shares of our common stock outstanding, and in addition, security holders held options, warrants, convertible notes or other convertible securities, which, if vested, exercised or converted, would obligate us to issue up to approximately 30.7 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 shelf registration statements, which subject to certain limitations, permits us to sell additional 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 per share to a high of $2.59 per share. 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;

- 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;

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- 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 licenses 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;
- 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 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 may negatively impact the trading volume for our stock. In addition, the occurrence of any of the risks described

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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.

Shares of our common stock represent equity interests in our company and are subordinate to all of our existing and future indebtedness.

Shares of our common stock represent equity interests in our company and, as such, rank junior to any indebtedness of our company now existing or created in the future, as well as to the rights of any preferred shares that may be issued in the future. There is no limitation on the amount of indebtedness we may incur in the future. Accordingly, we may incur substantial amounts of debt and other obligations that will rank senior to our common stock or to which our common stock will be structurally subordinated.

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

- 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.

Risks Related to Our Financial Condition and Future Capital Requirements

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

We are not profitable. Substantially all of our revenue to date has been derived from upfront and milestone payments earned on licensing transactions, revenue earned from subcontracts and royalty revenue. We expect to continue to incur substantial and continuing losses over the next 18 to 24 months 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. In order to generate new and significant revenues, we must develop and commercialize successfully our own products or enter into strategic partnering agreements with others who can develop and commercialize them successfully. Because of the numerous risks and uncertainties associated with our and our strategic partners product development programs, we are unable to predict when we may become profitable, if at all. Even if our products are introduced commercially, they may never achieve market acceptance and we may never generate sufficient revenues or receive sufficient license fees or royalties on our licensed products and technology in order to achieve or sustain future profitability.

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Because we have no source of significant recurring revenue, we must depend on financing or partnering to sustain our operations. We may need to continue to raise substantial additional capital or enter into strategic partnering agreements to fund our operations and we may be unable to raise such funds or enter into strategic partnering agreements when needed and on acceptable terms.

Developing products requires substantial amounts of capital. In particular, we expect the Phase III clinical study program of LibiGel to continue to require significant resources. We currently do not have sufficient cash resources to obtain regulatory approval of LibiGel or any of our other products in development. Our future capital requirements will depend upon numerous factors, including:

- the progress, timing, cost and results of our clinical development programs, including in particular our Phase III clinical study program for LibiGel, and our other product development efforts;

- subject recruitment and enrollment in our current and future clinical studies, including in particular our LibiGel Phase III safety study;

- our ability to license LibiGel or our other products in development;

- the success, progress, timing and costs of our business development efforts to seek strategic partners and implement business collaborations, licenses and other business combinations or transactions, including our efforts to continue to seek a strategic partner for LibiGel and evaluate various strategic alternatives available with respect to our cancer vaccines and other technologies that we acquired as a result of our merger with Cell Genesys, our products and our company;

- the cost, timing and outcome of regulatory reviews of our products in development;

- the rate of technological advances;

- the commercial success of our products;

- our general and administrative expenses;

- the timing and cost of obtaining third party reimbursement for our products; and

- the activities of our competitors.

Therefore, we may need to continue to raise substantial additional capital to fund our operations. Although we believe that our cash and cash equivalents, together with the net proceeds of this offering, will be sufficient to meet our liquidity requirements through at least the next 12 months, this estimate may prove incorrect since it is based on our currently projected expenditures for the remainder of 2011 and 2012. Our projected expenditures are based upon numerous other assumptions and subject to many uncertainties, and actual expenditures may differ significantly from our projections. Alternatively, we may decide to raise additional financing earlier in order to create a cash cushion and take advantage of favorable financing conditions.

To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. We currently have on file two effective shelf registration statements, each of which allows us to raise up to $75.0 million from the sale of common stock, preferred stock, warrants or units comprised of the foregoing. As of March 2, 2011, we had used approximately $46.8 million of this amount under one registration statement and $52.3 million of this amount under the other registration statement. We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, or at

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all. This is particularly true if economic and market conditions deteriorate, our Phase III clinical study program for LibiGel is unsuccessful or takes longer than we anticipate to complete or the FDA decides not to approve LibiGel during the time frame within which we anticipate 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 our Phase III clinical study program for LibiGel or otherwise make changes to our operations to cut costs. As an alternative to raising additional financing, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product, e.g., our cancer vaccines, 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.

Raising additional funds by issuing additional equity securities may cause dilution to our existing stockholders, raising additional funds by issuing additional debt financing may restrict our operations and raising additional funds through licensing arrangements may require us to relinquish proprietary rights.

If we raise additional funds through the issuance of additional equity or convertible debt securities, the percentage ownership of our stockholders could be diluted significantly, and these newly issued securities may have rights, preferences or privileges senior to those of our existing stockholders. If we incur additional debt financing, the payment of principal and interest on such indebtedness may limit 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 additional equity or debt securities, we may choose to license LibiGel, Elestrin (outside the territories already licensed) or another product to a third party, e.g., our cancer vaccines, 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.

Our committed equity financing facility with Kingsbridge Capital Limited may not be available to us if we elect to make a draw down.

We have a committed equity financing facility with Kingsbridge that expires in December 2011. The committed equity financing facility entitles us to sell and obligates Kingsbridge to purchase, from time to time through the expiration date, 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 facility 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 facility if Kingsbridge 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 committed equity financing facility, or if the facility 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 had not sold any shares to Kingsbridge under the committed equity financing facility.

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As a result of our merger with Cell Genesys, we have substantial indebtedness, which we may not be able to pay when it becomes due and payable.

As a result of our merger with Cell Genesys, we assumed $22.0 million in aggregate principal amount of outstanding convertible senior 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 approximately $0.7 million. We do not have any significant source of revenues and thus 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 on our convertible senior notes when it becomes due, especially if an event of default were to occur under the indentures governing the notes.

The indentures governing our convertible senior 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 senior 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 indentures, 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. 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 also is 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 known and unknown 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 its cancer vaccines 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 our merger with Cell Genesys, 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 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.

Risks Related to Our Business

Most of our products are in the human clinical development stages and, depending on the product, likely will not be introduced commercially for at least one year and likely more, if at all.

Most of our products are in the human clinical 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 has been introduced commercially and most are not expected to be for at least one year and likely more, if at all. Some of our products are not in active development. We cannot assure you that any of our products in human clinical development will:

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- 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 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 and we may be restricted or prohibited from marketing or manufacturing a product if previously unknown problems with the product or our manufacture of the product 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 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. We expect the number of 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,

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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.

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.

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 and product launch, 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 in naturally menopausal women. We have an additional SPA agreement which covers the LibiGel stability, or shelf life

studies for the intended commercialization of LibiGel product. 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.

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Delays in the completion of our Phase III clinical study program for LibiGel, which can result from unforeseen issues, FDA interventions, problems with enrolling subjects and other reasons, could delay significantly FDA approval and commercial launch of LibiGel and adversely affect our product development cost estimates. 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.

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

The FDA conducts in-depth reviews of NDAs to determine whether to approve products for commercial marketing for the indications proposed. If the FDA is not satisfied with the information provided, the FDA may refuse to approve an NDA or may require a company to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve an NDA for many reasons, including:

- the information submitted may be insufficient to demonstrate that a product is safe and effective;

- the FDA might not approve the processes or facilities of a company, or those of its vendors, that will be used for the commercial manufacture of a product; or

- the FDA s interpretation of the nonclinical, clinical or manufacturing data provided in an NDA may differ from a company s interpretation of such data.

If the FDA determines that the clinical studies submitted for a product candidate in support of an NDA are not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the FDA does not agree with a company s interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical studies required to support an NDA could negatively affect a company s ability to obtain marketing authorization for a product and would have a material adverse effect on a company s business and financial condition. In addition, an NDA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period.

We cannot ensure that even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

We may not achieve projected goals and objectives in the time periods that we anticipate or announce publicly, which could have an adverse effect on our business and could cause our stock price to decline.

We set goals and objectives for, and make public statements regarding, the timing of certain developments and milestones regarding our business, such as the initiation and completion of clinical studies, the completion of enrollment for clinical studies, the filing of applications for regulatory approvals, the receipt of regulatory approvals and other developments and milestones. The actual timing of these events can vary dramatically due to a number of factors including without limitation delays or failures in our current clinical studies, the amount of time, effort and resources committed to our programs by us and our current and potential future strategic partners and the uncertainties inherent in the clinical studies and regulatory approval process. As a result, there can be no assurance that clinical studies involving our products in development will advance or be completed in the time periods that we or our strategic partners announce or expect, that we or our current and potential future strategic partners will make regulatory submissions or receive regulatory approvals as planned or that we or our current and potential future strategic partners will be able to adhere to our current schedule for the achievement of key milestones under any of our

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development programs. If we or any of our strategic partners fail to achieve one or more of these milestones as planned, our business could be materially adversely affected and the price of our common stock could decline.

We also disclose from time to time projected financial information, including our anticipated burn rate and other expenditures, for future periods. These financial projections are based on management s current expectations and do not contain any margin of error or cushion for any specific uncertainties, or for the uncertainties inherent in all financial forecasting.

If the market opportunities for LibiGel and our other products in development are smaller than we anticipate, then our future revenues and business may be adversely affected.

We believe there is significant market opportunity for LibiGel. Our belief is based on certain market data information, off-label use of products for HSDD, numerous publications reporting on the incidence of HSDD, the urgency placed on the condition by various medical societies and a recent survey of over 100 obstetrician/gynecologists and primary care physicians regarding the need for an FDA-approved drug to treat FSD and specifically HSDD conducted independently for us by Campbell Alliance Group, Inc. Our projection of the market opportunity for LibiGel is based on certain market data information, including this survey and thus estimates of the number of physicians that believe that FSD is an important and legitimate disorder requiring treatment and the number of physicians that would prescribe LibiGel to treat FSD. If these estimates prove to be incorrect, the market opportunity for LibiGel may be smaller than we anticipate. If the market opportunity for LibiGel is smaller than we anticipate, then it may be difficult for us to find a strategic partner to assist us in the development and commercialization of LibiGel and our prospects for generating LibiGel revenue and business may be adversely affected. This is also true with respect to our other products in development, although to a lesser extent, since LibiGel is our lead product in development.

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 our 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 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.

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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 studies for our products are prolonged or delayed, it may be difficult for us to find a strategic partner to assist us in the development and commercialization of our non-partnered products or commercialize such 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 studies for our products that may cause us or the FDA to delay or suspend those studies 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 studies for our products in development and negatively impact our ability to obtain regulatory approval or enter into strategic partnerships 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 studies;

- 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 studies;

- negative or inconclusive results from clinical studies, 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 our clinical studies; or

- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Regulatory authorities, clinical investigators, institutional review boards, data safety monitoring boards and the sites at which our clinical studies are conducted all have the power to stop our clinical studies prior to completion. Our clinical studies for our products in development may not begin as planned, may need to be amended, 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 development program.

We rely on a few third parties to assist us in certain aspects of our clinical studies. If these third parties do not perform as contractually required or expected, our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.

We rely on a few third parties, such as medical institutions, academic institutions, clinical investigators and contract laboratories, to assist us in certain aspect of our clinical studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on

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these few third parties does not relieve us of these responsibilities. If the third parties assisting us with certain aspects of our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA s good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, our ability to collect damages may be limited contractually.

Our products will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals, and the sale of any future products could be suspended.

Even if we receive regulatory approval to market a particular product in development, the FDA or a foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of our approved labeling or could impose burdensome post-approval obligations under a Risk Evaluation and Mitigation Strategy, or REMS. If required, a REMS may include various elements, such as publication of a medication guide, a patient package insert, a communication plan to educate healthcare providers of the drug s risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. Moreover, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market, cause the FDA to impose additional REMS obligations or impede or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to FDA review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product.

If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities or previously unknown problems with any future products, suppliers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, suppliers or manufacturing processes;
- warning letters or untitled letters;
- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;

- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

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We intend to enter into additional strategic relationships with third parties to develop and commercialize our products in development, including in particular LibiGel. If we do not enter into such relationships, we will need to undertake development and commercialization efforts on our own, which would be costly and could delay our ability to commercialize our future products.

A key element of our business strategy is our intent to partner selectively with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have entered into a strategic relationship with Azur with respect to Elestrin, with Teva USA with respect to Bio-T-Gel and with Pantarhei Science with respect to The Pill Plus. We currently do not have a strategic partner for LibiGel.

We intend to enter into additional strategic relationships with third parties to develop, and if regulatory approval is obtained commercialize, our products in development, including in particular LibiGel. We face significant competition in seeking appropriate strategic partners, and these strategic relationships can be intricate and time consuming to negotiate and document. We may not be able to negotiate additional strategic relationships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic relationships because of the numerous risks and uncertainties associated with establishing such relationships. If we are unable to negotiate additional strategic relationships for our products, such as LibiGel, we may be forced to curtail the development of a particular product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of anticipated sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development and commercialization of that product. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our products in development if they receive regulatory approvals to market and generate product revenue.

If we are unable to partner with a third party and obtain assistance for the potential commercialization of our products, including in particular LibiGel, if approved for commercial sale, we would need to establish our own sales and marketing capabilities, which involves risk.

We do not have an internal sales and marketing organization and we have limited experience in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, revenues from sales of the product or the profitability of these product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

Although our preferred alternative would be to engage a pharmaceutical or other healthcare company with an existing sales and marketing organization and distribution systems to sell, market and distribute our products, if approved for commercial sale, if we are unable to engage such a sales and marketing partner, we may need to establish our own specialty sales force. Factors that may inhibit our efforts to commercialize any future products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

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- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales and marketing capabilities depends on the progress towards commercialization of our products and because of the numerous risks and uncertainties involved with establishing our own sales and marketing capabilities, we are unable to predict when, if ever, we will establish our own sales and marketing capabilities. If we are not able to partner with additional third parties and are unsuccessful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our products, which would adversely affect our business and financial condition.

Our current strategic relationships and any future additional strategic relationships we may enter into involve risks with respect to the development and commercialization of our products.

A key element of our business strategy is to selectively partner with pharmaceutical, biotechnology and other companies to obtain assistance for commercialization and, in some cases, development of our products. For example, we have entered into a strategic relationship with Azur with respect to Elestrin, with Teva USA with respect to Bio-T-Gel and with Pantarhei Science with respect to The Pill Plus. We currently do not have a strategic partner for LibiGel.

Our current strategic relationships and any future additional strategic relationships we may enter into involve a number of risks, including:

- business combinations or significant changes in a strategic partner s business strategy may adversely affect a strategic partner s willingness or ability to complete its obligations under any arrangement;

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our partnered products;

- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a partnered product, repeat or conduct new clinical trials or require a new version of a product for clinical testing;

- strategic partners may not pursue further development and commercialization of partnered products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;

- strategic partners may not commit adequate resources to the marketing and distribution of our partnered products, limiting our potential revenues from these products;

- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our partnered products or that result in costly litigation or arbitration that diverts management s attention and consumes resources;

- strategic partners may experience financial difficulties;

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- strategic partners may not maintain properly or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- strategic partners independently could move forward with competing products developed either independently or in collaboration with others, including our competitors; and

- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing or commercializing our products.

We entered into an exclusive license agreement with Azur Pharma International II, Limited for the marketing of Elestrin in the United States. Our ability to obtain sales-based milestones of up to $140 million from Azur is dependent upon Azur s ability to market and sell Elestrin.

Elestrin is our first FDA approved product. Azur Pharma International II Limited 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 amendment to our original licensing agreement with Azur pursuant to which we received $3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments and certain milestone payments that could have been paid to us related to Azur s sales of Elestrin. We maintain the right to receive up to $140 million in sales-based milestone payments from Azur if Elestrin reaches certain predefined sales per calendar year. We cannot assure you that Azur will be successful in marketing Elestrin, Elestrin will be widely accepted in the marketplace or that Azur will remain focused on the commercialization of Elestrin, especially if Azur does not experience significant Elestrin sales. Market penetration of Elestrin during 2010 was low. Based on such low sales of Elestrin, we believe it is unlikely that we will receive any sales-based milestone payments from Azur in the foreseeable future or at all.

If our products in development receive FDA approval and are introduced commercially, they may not achieve expected levels of market acceptance, which could harm 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 in development, if they receive the required FDA or other regulatory approvals, is dependent upon acceptance by physicians, patients, third-party payors and the medical community. Levels of market acceptance for such products, if approved for commercial sale, could be affected by several factors, including:

- demonstration of efficacy and safety in clinical trials;

- the existence, prevalence and severity of any side effects;

- the availability of alternative treatments and potential or perceived advantages or disadvantages compared to alternative treatments;

- perceptions about the relationship or similarity between our products and the parent drug compound upon which the product is based;

- the timing of market entry relative to competitive treatments;

- the ability to offer our products for sale at competitive prices;

- relative convenience, product dependability and ease of administration;

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- the strength of marketing and distribution support;

- the sufficiency of coverage and reimbursement of our products by third-party payors and governmental and other payors; and

- the product labeling or product insert required by the FDA or regulatory authorities in other countries.

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 the U.S. marketing rights to Elestrin to Azur, the U.S. development and marketing rights to Bio-T-Gel to Teva USA and the U.S. marketing rights to The Pill Plus to Pantarhei Science. 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 our industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the use, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and in the future may result, in the discontinuance of product marketing. These situations, should they occur, could harm our business, financial position and results of operations, and the market value of our common stock could decline.

Even if we or our strategic partners successfully develop and commercialize any of our products under development, we face uncertainty with respect to pricing, third-party reimbursement and healthcare reform, all of which could adversely affect the commercial success of our products.

Our ability to collect significant revenues from sales of our products, if approved and commercialized, may depend on our ability, and the ability of any current or potential future strategic partners or customers, to obtain adequate levels of coverage and reimbursement for such products from third-party payers such as:

- private health insurers;

- health maintenance organizations;

- pharmacy benefit management companies;

- government health administration authorities; and

- other healthcare-related organizations.

Third party payers increasingly are challenging the prices charged for medical products and services. For example, third-party payers may deny coverage or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or offer inadequate levels of reimbursement, we or any of our strategic partners may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced

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reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, which we refer to as the PPACA. This legislation may have far reaching consequences for life science companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, biopharmaceuticals and medical devices. If reimbursement for our products, if approved, is substantially less that we expect in the future, our business could be affected materially and adversely.

The cost-containment measures that healthcare providers are instituting and the results of healthcare reforms such as the PPACA may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results. In addition, to the extent that our approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise significantly harm our business, financial condition and operating results.

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

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

To the extent that we or our licensees enter into manufacturing arrangements with third parties, we and such licensees 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.

Our existing and future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. If a natural disaster, business failure, strike or other difficulty occurs, we may be unable to replace these contract manufacturers in a timely or cost-effective manner and the production of our products would be interrupted, resulting in delays and additional costs. Switching manufacturers or manufacturing sites would be difficult and time-consuming because the number of potential manufacturers is limited. In addition, before a product from any replacement manufacturer or manufacturing site can be commercialized, the FDA

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must approve that site. This approval would require regulatory testing and compliance inspections. A new manufacturer or manufacturing site also would have to be educated in, or develop substantially equivalent processes for, production of our products. It may be difficult or impossible to transfer certain elements of a manufacturing process to a new manufacturer or for us to find a replacement manufacturer on acceptable terms quickly, or at all, either of which would delay or prevent our ability to develop and commercialize our products.

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 strategic partners may be unable to initiate or continue clinical studies of our products that are under development;

- we and our strategic partners may be delayed in submitting applications for regulatory approvals for our products that are under development; and

- we and our strategic partners may be unable to meet commercial demands for any approved products.

In addition, if a third-party manufacturer fails to perform as agreed, our ability to collect damages may be contractually limited.

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 our executive officers, but none of these 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.

If plaintiffs bring product liability lawsuits against us, we may incur substantial liabilities and may be required to delay development or limit commercialization of any of our products approved for commercial sale.

We face an inherent risk of product liability as a result of the clinical testing of our products in development and the commercial sale of our products that have been or will be approved for commercial sale. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, liability claims may result in decreased demand for our products, injury to our reputation, withdrawal of clinical studies, costs to defend litigation, substantial monetary awards to clinical study participants or patients, loss of revenue and the inability to commercialize any products that we develop.

We currently maintain limited product liability insurance. We may not have sufficient resources to pay for any liabilities resulting from a personal injury or other claim excluded from, or beyond the limit of, our insurance coverage. Our insurance does not cover third parties negligence or malpractice, and our clinical investigators and sites may have inadequate insurance or none at all. In addition, in order to conduct our clinical studies or otherwise carry out our business, we may have to assume liabilities contractually for which we may not be insured. If we are unable to look to our own or a third party s insurance to pay claims

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against us, we may have to pay any arising costs and damages ourselves, which may be substantial. Even if we ultimately are successful in product liability litigation, the litigation likely would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which likely would impair our ability to generate sales of the affected product and our other products. Moreover, product recalls may be issued at our discretion or at the direction of the FDA, other governmental agencies or other companies having regulatory control for our product sales. Product recalls generally are expensive and often have an adverse effect on the reputation of the products being recalled and of the product s developer or manufacturer.

We may be required to indemnify third parties against damages and other liabilities arising out of our development, commercialization and other business activities, which could be costly and time-consuming and distract management. If third parties that have agreed to indemnify us against damages and other liabilities arising from their activities do not fulfill their obligations, then we may be held responsible for those damages and other liabilities.

Our business is subject to increasingly complex corporate governance, public disclosure and accounting requirements that could adversely affect our business and financial results.

We are subject to changing rules and regulations of federal and state governments as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the SEC and the NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. In July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management s time from our other business activities.

Risks Related to Our Industry

Because our industry is very competitive, we may not succeed in bringing certain of our products to market and any products we introduce commercially may not be successful.

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 strategic partners, will not succeed in developing similar technologies and products more rapidly than we do, commercially introducing such technologies and products to the marketplace prior to us, or that these competing technologies and products will not be more effective or successful than any of those that we currently are developing or will develop.

Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply, we could experience material adverse effects on our business, financial position and results of operations, and the market value of our common stock could decline.

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the U.S. Drug Enforcement Administration (DEA), and state

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governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act (FDCA), the Controlled Substances Act of 1970 (CSA) and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals.

In addition to compliance with current good manufacturing practice regulations, commonly referred to as cGMP regulations and requirements, drug manufacturers must register each manufacturing facility with the FDA. Manufacturers and distributors of prescription drug products are also required to be registered in the states where they are located and in certain states that require registration by out-of-state manufacturers and distributors. Manufacturers also must be registered with the DEA and similar applicable state and local regulatory authorities if they handle controlled substances, and also must comply with other applicable DEA requirements.

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.

The trend towards consolidation in the pharmaceutical and biotechnology industries may affect us adversely.

There is a trend towards consolidation in the pharmaceutical and biotechnology industries. This consolidation trend may result in the remaining companies in these industries having greater financial resources and technological capabilities, thus intensifying competition in these industries. This trend also may result in fewer potential strategic partners or licensees for our products and technology. Also, if a consolidating company is already doing business with our competitors, we may lose existing licensees or strategic partners as a result of such consolidation. This trend may adversely affect our ability to enter into strategic arrangements for the development and commercialization of our products, and as a result may harm our business.

Risks Related to Our Intellectual Property

We license rights to the technology underlying LibiGel and many of our other products and technologies from third parties. The loss of these rights, including in particular, our rights underlying LibiGel, could have an adverse effect on our business and future prospects and could cause the market value of our common stock to decline.

We license rights to certain of the technology underlying our gel products, including LibiGel, from Antares Pharma, Inc., our cancer vaccines 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.

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We have licensed some of our products to third parties and any breach by these parties of their obligations under these license agreements or a termination of these license 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 Medical Aesthetics Technology Corporation and some of our gel products to third parties, including Azur, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA (to be acquired by Valeant Pharmaceuticals). All of these parties, except for Azur, have agreed to be responsible for continued development, regulatory filings and all have agreed to manufacturing and marketing associated with the products. In addition, in the future we 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 strategic 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, in 2005, we were notified that Teva USA had discontinued development of our male testosterone gel, Bio-T-Gel, product. 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, no assurance can be provided that Teva will continue such development. Any future breach of this agreement by Teva or any other breach by our strategic partners or any other third party of their obligations under these agreements or a termination of these agreements by these parties could harm development of the partnered 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 licensor s 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.

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- 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 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.

The patent protection for our products may expire before we are able to maximize their commercial value which may subject us to increased competition, inhibit our ability to find strategic partners and reduce or eliminate our opportunity to generate product revenue.

The patents for our commercialized products and products in development have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, the U.S. patents covering the formulations used in Elestrin and LibiGel which we license from Antares Pharma are scheduled to expire in June 2022. Although we have filed additional U.S. patent applications covering LibiGel, we can provide no assurance that such applications will be granted and that the patents will issue. In addition to patents, we may receive three years of marketing exclusivity for LibiGel under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. Depending upon if and when we receive regulatory approval for

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LibiGel and our other products in development and the then expiration dates of the patents underlying LibiGel and such other products, we may not have sufficient time to recover our development costs prior to the expiration of such patents and consequently it may be difficult to find a strategic partner for such products.

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
- 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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectuses 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 prospectuses 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;

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- 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.

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 prospectuses 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 prospectuses 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

We expect the net proceeds from this offering to be up to approximately $23.8 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.

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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 checking account or to invest them temporarily in U.S. treasury notes or short-term or marketable securities until we use them for their stated purpose.

DILUTION

Our net tangible book value on September 30, 2010 was approximately $15.3 million, or approximately $0.22 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, 2010 (including without limitation our receipt of the net proceeds from our December 2010 offering), other than to give effect to our receipt of the estimated net proceeds from the sale of 12,199,482 units at an offering price of $2.0613 per unit, less the placement agent fees and our estimated offering expenses, our net tangible book value as of September 30, 2010, after giving effect to the items above, would have been approximately $39.1 million, or $0.47 per share. This represents an immediate increase in net tangible book value of $0.25 per share of common stock to our existing stockholders and an immediate dilution in net tangible book value of $1.5913 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			$	2.0613
Net tangible book value per share as of September 30, 2010	$	0.22		
Increase in net tangible book value per share attributable to this offering		0.25		
Pro forma net tangible book value per share as of September 30, 2010, after giving effect to this offering				0.47
Dilution in net tangible book value per share to new investors in this offering			$	1.5913

The above table is based on 70,802,894 shares of our common stock outstanding as of September 30, 2010 and excludes, as of September 30, 2010:

- 4,025,827 shares of our common stock issuable upon the exercise of warrants to be issued to purchasers in this offering and an additional 243,990 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in this offering;

- 5,611,348 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;

- 14,390,575 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of $4.74 per share;

- 3,680,703 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of $3.73 per share;

- 2,387,583 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan; and

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- 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.

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. Amended and Restated 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.

Subsequent to September 30, 2010, in December 2010, we completed an offering of 10,588,236 shares of our common stock and warrants to purchase an aggregate of 5,294,118 shares of our common stock, resulting in net proceeds of approximately $16.9 million, after deducting placement agent fees and offering expenses.

DESCRIPTION OF SECURITIES WE ARE OFFERING

In this offering, we are offering a maximum of 12,199,482 units, consisting of 12,199,482 shares of common stock and warrants to purchase 4,025,827 shares of common stock. Each unit consists of one share of common stock and warrants to purchase 0.33 of a share of common stock at an exercise price of $2.25 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.

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.

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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.

Warrants

The material terms and provisions of the warrants being offered pursuant to this prospectus supplement and the accompanying prospectuses 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 4,025,827 shares of our common stock at an exercise price of $2.25 per share. Each warrant will be exercisable for a period of three years commencing three. 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 4.99% (or 9.99% in the case of certain holders) 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 from 4.99% to 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) 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.

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In addition, the warrant holders are entitled to a cashless exercise option if, at any time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance or resale of the shares of common stock underlying the warrants. 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.

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, or (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 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

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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;

- 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.

PLAN OF DISTRIBUTION

We have entered into a placement agency agreement, dated as of March 3, 2011, 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 Oppenheimer & Co. Inc., Roth Capital Partners, LLC, JMP Securities LLC and Trout Capital LLC as financial advisors in connection with the offering. The placement agent is not required to arrange the purchase or sale of any additional specific number or dollar amount of the securities.

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. We will enter into securities purchase agreements directly with the investors who purchase securities in this offering.

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, 2011. 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.

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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 prospectuses.

We will pay the placement agent an aggregate cash commission equal to 5.0% of the gross proceeds from the sale of the units in this offering. We have engaged the following four financial advisors in connection with the offering: Oppenheimer & Co. Inc., Roth Capital Partners, LLC, JMP Securities LLC and Trout Capital LLC. Each of the financial advisors will be paid $50,000 out of the placement agent s cash compensation, except for Trout Capital LLC who will receive $25,000: 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 $25,000. The placement agent also will receive warrants to purchase up to 243,990 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 $2.58 per share (125% of the public offering price) and an expiration date of June 9, 2015 (the five year anniversary of the effective date of our shelf registration statement on Form S-3 (File No. 333-159606), which became effective on June 9, 2009).

The estimated offering expenses payable by us, in addition to the aggregate fee of $1.26 million due to the placement agent, are approximately $0.1 million 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 $25.1 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 prospectuses, 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	$	0.1031
Maximum offering total	$	1,257,767

Because there is no minimum offering amount required as a condition to closing in this offering, the actual total offering fees, if any, are not presently determinable and may be substantially less than the maximum amount set forth above.

Rodman & Renshaw, LLC and any broker-dealer or agent acting on its behalf may be deemed to be underwriters and as such are required to comply with the requirements of the Securities Act and the Exchange Act, including without limitation, Rule 10b-5 and, to the extent applicable, Regulation M under the Exchange Act. Under these rules and regulations, Rodman & Renshaw, LLC and any broker-dealer or agent acting on its behalf:

- may not engage in any stabilization activity in connection with our securities;

- must furnish each broker which offers securities covered by this prospectus with the number of copies of this prospectus and any prospectus supplement that are required by each broker; and

- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

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

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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.

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 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 incorporated in this Prospectus by reference from the Company s Annual Report on Form 10-K have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

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

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.

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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. 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.

This prospectus supplement and the accompanying prospectuses 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 prospectuses. 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, 2009 (including information specifically incorporated by reference into our Form 10-K from our definitive proxy statement for our 2010 annual meeting of stockholders);

- our quarterly reports on Form 10-Q for the quarters ended March 31, 2010, June 30, 2010 and September 30, 2010;

- our current reports on Form 8-K as filed with the SEC on March 5, 2010, May 3, 2010 (and as amended on June 7, 2010), June 11, 2010, June 21, 2010, November 17, 2010, December 23, 2010, December 29, 2010 (Item 1.01 only), and January 27, 2011; 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.

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, 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.

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

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.

The date of this prospectus is June 9, 2009

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