

BIOSANTE PHARMACEUTICALS INC  
Form 424B5  
July 27, 2011

Table of Contents

The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and are they not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JULY 27, 2011

**Prospectus Supplement**  
(To prospectus dated June 17, 2011)

**Filed Pursuant to Rule 424(b)(5)**  
**Registration No. 333-174597**

**Shares**

**Common Stock**

We are offering \_\_\_\_\_ shares of our common stock. Our common stock is listed on The NASDAQ Global Market under the symbol "BPAX." On July 26, 2011, the last reported sale price of our common stock on The NASDAQ Global Market was \$3.26 per share.

**Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page S-7 of this prospectus supplement.**

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

---

	<b>PER SHARE</b>	<b>TOTAL</b>
Public Offering Price	\$	\$
Underwriting Discounts and Commissions	\$	\$
Proceeds to BioSante (before expenses)	\$	\$

---

Delivery of the shares of our common stock is expected to be made on or about August \_\_\_\_\_, 2011. We have granted the underwriters an option for a period of 30 days to purchase an additional \_\_\_\_\_ shares of our common stock solely to cover over-allotments. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ \_\_\_\_\_ and the total proceeds to us, before expenses, will be \$ \_\_\_\_\_.

*Sole Book-Running Manager*

**Jefferies**

Prospectus Supplement dated \_\_\_\_\_, 2011

Table of Contents**Table of Contents**

	<b>Page</b>
<b>Prospectus Supplement</b>	
<u>About this Prospectus Supplement</u>	<u>S-1</u>
<u>Prospectus Supplement Summary</u>	<u>S-2</u>
<u>Risk Factors</u>	<u>S-7</u>
<u>Cautionary Statement Regarding Forward-Looking Statements</u>	<u>S-29</u>
<u>Use of Proceeds</u>	<u>S-30</u>
<u>Dividend Policy</u>	<u>S-30</u>
<u>Dilution</u>	<u>S-31</u>
<u>Underwriting</u>	<u>S-32</u>
<u>Notice to Investors</u>	<u>S-36</u>
<u>Legal Matters</u>	<u>S-39</u>
<u>Experts</u>	<u>S-39</u>
<u>Where You Can Find More Information</u>	<u>S-39</u>
<u>Incorporation of Certain Documents by Reference</u>	<u>S-40</u>
<b>Prospectus</b>	
<u>About This Prospectus</u>	<u>1</u>
<u>About Our Company</u>	<u>1</u>
<u>Risk Factors</u>	<u>3</u>
<u>Cautionary Statement Regarding Forward-Looking Statements</u>	<u>3</u>
<u>Use of Proceeds</u>	<u>4</u>
<u>Dilution</u>	<u>4</u>
<u>Description of Common Stock</u>	<u>5</u>
<u>Description of Preferred Stock</u>	<u>6</u>
<u>Description of Warrants</u>	<u>8</u>
<u>Description of Units</u>	<u>11</u>
<u>Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law</u>	<u>12</u>
<u>Plan of Distribution</u>	<u>14</u>
<u>Legal Matters</u>	<u>18</u>
<u>Experts</u>	<u>18</u>
<u>Where You Can Find More Information</u>	<u>18</u>
<u>Incorporation of Certain Documents by Reference</u>	<u>19</u>

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

Table of Contents

**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 17, 2011, including the documents incorporated by reference therein, 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. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying base prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

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-39 of this prospectus supplement and the information described under "Incorporation of Certain Documents by Reference" on page S-40 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 SEC will automatically update and supersede this information.

You should rely only on the information that we have provided or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making offers to sell or solicitations to buy our common stock in any jurisdiction in which an offer or solicitation is not authorized or in which the person making that offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make an offer or solicitation. You should assume that the information in this prospectus supplement and the accompanying prospectus or any related free writing prospectus is accurate only as of the date on the front of the document and that any information that we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus or any related free writing prospectus, or any sale of a security.

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®, Elestrin®, LibiGel®, Bio-T-Gel® and The Pill Plus®. All other trademarks, trade names or service marks that are used in this prospectus are the property of their respective owners.

Table of Contents

**Prospectus Supplement Summary**

*This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, you should read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, and the information included in any free writing prospectus prepared by or on behalf of us or to which we have referred you. If you invest in our common stock, you are assuming a high degree of risk. See "Risk Factors" beginning on page S-7 and in other periodic reports incorporated by reference.*

**Our Business**

We are a specialty pharmaceutical company focused on developing products for female sexual health and oncology.

Our products, either approved, awaiting approval 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), specifically hypoactive sexual desire disorder (HSDD).

*/\*/*

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. Elestrin is marketed in the U.S. by Azur Pharma International II Limited (Azur).

*/\*/*

Bio-T-Gel once daily transdermal testosterone gel for the treatment of hypogonadism, or testosterone deficiency in men, for which a New Drug Application (NDA) is pending with a Prescription Drug User Fee Act (PDUFA) date of November 14, 2011 and which is licensed to Teva Pharmaceuticals USA, Inc.

*/\*/*

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 contraception.

*/\*/*

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

***LibiGel***

We believe LibiGel remains the most clinically advanced pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder 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 discussions with the FDA, including an SPA relating to the design of certain of our Phase III trials, that our 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 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. Currently, these three LibiGel Phase III studies are underway. We completed enrollment in the two LibiGel safety and efficacy trials in the first quarter 2011, and in May 2011 we announced the completion of enrollment in the LibiGel Phase III cardiovascular and breast cancer safety study. According to the protocol, the cardiovascular and breast cancer safety study will continue for 12 months of therapy from the last subject enrolled before the primary analysis will be conducted, which will provide data for our NDA submission. The study will continue for five years. 3,656 subjects were enrolled in the safety study resulting in over 4,000 subject-years of exposure as of June 30, 2011. We currently anticipate submitting our NDA for this product by the end of 2012.

Table of Contents

***Elestrin***

Elestrin is our first FDA approved product. Azur, our licensee, is marketing Elestrin in the U.S. In December 2009, we entered into an amendment to our original licensing agreement with Azur pursuant to which we received \$3.15 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 believe our receipt of such payments unlikely in the near term, if at all.

***Bio-T-Gel***

Bio-T-Gel was developed initially by BioSante, and then it was licensed to Teva for late stage clinical development. The financial terms of the development and license agreement included an upfront payment by Teva, certain milestones and royalties on sales of the product, if and when approved and marketed, in exchange for rights to develop and market the product. Teva also is responsible under the terms of the agreement for continued development, regulatory filings and all manufacturing and marketing associated with the product. Teva has filed the Bio-T-Gel NDA and the PDUFA date is November 14, 2011. In April 2011, Abbott Laboratories, a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement with respect to Bio-T-Gel. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent listed in the FDA Orange Book related to Abbott's testosterone gel for men. Although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

***The Pill Plus***

We have an exclusive license from Wake Forest University Health Sciences (formerly known as Wake Forest University) and Cedars-Sinai Medical Center for three issued U.S. patents relating to triple component contraception. We have licensed the rights to develop and market oral formulations of this technology to Pantarhei Bioscience B.V. (Pantarhei), a Netherlands-based pharmaceutical company, which is responsible for all expenses to develop and market the product. We may receive certain development and regulatory milestones, royalty payments on any sales of the product in the U.S., if and when approved and marketed, and a percentage of payments received by Pantarhei for any sublicense from a third party. In June 2010, we announced positive results in a Phase II study of the Pill-Plus "triple component" oral contraceptive, which study compared use of an oral contraceptive alone to the same oral contraceptive with the addition of an oral androgen. We are not currently developing non-oral formulations of this technology.

***Cancer Vaccines***

Our cancer vaccine technology is designed to stimulate the patient's immune system to fight effectively the patient's own cancer. Multiple Phase II trials of our 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. Four of these vaccines to treat pancreatic cancer, acute myeloid leukemia, chronic myeloid leukemia and melanoma have been granted FDA orphan drug designation. We license our cancer vaccine technology from Johns Hopkins University and The Whitehead Institute for Biomedical Research. Under various agreements, we are required to pay Johns Hopkins University certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the in-licensed technology.

In March 2011, we licensed our Pancreas Cancer Vaccine and Prostate Cancer Vaccine to Aduro BioTech, a clinical-stage immunotherapy company, solely for use in combination with Aduro's proprietary vaccine platform based on *Listeria monocytogenes* (Lm). Under the agreement, we are entitled to receive milestone and royalty payments upon the commercialization of combination cancer vaccines using our cancer vaccine

Table of Contents

technology. In June 2011, we announced that the FDA's clinical hold on the GVAX Prostate Cancer Vaccine (GVAX Prostate) for the treatment of prostate cancer has been lifted by the FDA. Manufacturing of clinical quantities of the new GVAX Prostate is complete, and planning for a Phase II clinical trial funded by others at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center is underway. In July 2011, we announced an exclusive worldwide license of its Melanoma Vaccine to The John P. Hussman Foundation, in exchange for our receipt of an upfront license fee, milestone payments, royalties on any sales and a percentage of any sublicense fees. Additionally, the Hussman Foundation has committed up to approximately \$11 million in Melanoma Vaccine clinical development funding.

*Product Portfolio*

**BioSante's Primary Product Portfolio**

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.

**Financial Update**

On July 25, 2011, we announced our results for our second quarter 2011. Our cash and cash equivalents as of June 30, 2011 were approximately \$37.1 million. We incurred a net loss of approximately \$15.0 million or (\$0.16) per share for the quarter ended June 30, 2011, compared to a net loss of \$10.8 million or (\$0.17) per share for the same period in 2010. This increase in net loss was due primarily to the conduct of the three ongoing LibiGel Phase III clinical studies. Research and development expenses increased to approximately \$11.1 million and \$26.0 million for the three and six month periods ended June 30, 2011 from \$8.7 million and \$18.1 million for the three and six month periods ended June 30, 2010.

Table of Contents

**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](http://www.biosantepharma.com). We make available on our web site 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 web site or that can be accessed through our web site does not constitute a part of this prospectus. We have included our web site address only as an inactive textual reference and do not intend it to be an active link to our web site.

Table of Contents

**The Offering**

<b>Common stock offered by us</b>	<b>shares</b>
<b>Common stock to be outstanding immediately after this offering</b>	<b>shares</b>
<b>Over-Allotment Option</b>	

We have granted the underwriters an option to purchase up to \_\_\_\_\_ additional shares of our common stock solely to cover over-allotments, if any. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.

**Use of Proceeds**

We intend to use the net proceeds from this offering for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital. We also may use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions. Please see the section entitled "Use of Proceeds" on page S-30 of this prospectus supplement.

**NASDAQ Global Market Symbol**

Our common stock is listed on The NASDAQ Global Market under the symbol "BPAX."

**Risk Factors**

An investment in our common stock involves a high degree of risk. Please see the section entitled "Risk Factors" beginning on page S-7 of this prospectus supplement.

**Outstanding Shares**

The number of shares of our common stock to be outstanding immediately after this offering is based on 93,590,612 shares of our common stock outstanding as of March 31, 2011 and excludes as of that date:

- /\*/  
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;
- /\*/  
23,688,407 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$2.88 per share;
- /\*/  
5,420,186 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$3.06 per share;
- /\*/  
635,000 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan;
- /\*/  
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; and
- /\*/  
shares of our common stock that may be issuable to Paladin Labs Inc. upon our achievement of certain regulatory milestones at a purchase price to be paid by Paladin equal to a 10 percent premium to the market price of our common stock on the date of issuance.



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

On May 26, 2011, our stockholders approved the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan, under which the number of shares of our common stock reserved for issuance under the plan was increased by 2,000,000 shares.

Except as otherwise indicated, all information in the prospectus supplement assumes no exercise by the underwriters of their over-allotment option.

S-6

---

Table of Contents

**Risk Factors**

*An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus, the information and documents incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.*

**Risks Related to this Offering and Our Common Stock**

**The price of our common stock has been volatile, and your investment in our common stock could decline in value.**

The price of our common stock has fluctuated in the past and 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. If the market price of our common stock declines, the per share value of the common stock you purchase will decline. 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 needed financing;
- /\*/  
equity sales by us to fund our operations;
- /\*/  
actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to our products in development or our competitors' products;
- /\*/  
actual or anticipated results of our clinical studies or those of our competitors;
- /\*/  
changes in laws or regulations applicable to our products;
- /\*/  
changes in anticipated or actual timing of our development programs, including delays or cancellations of clinical studies for our products;
- /\*/  
announcements of technological innovations or new products by us or our competitors;
- /\*/  
announcements by licensors or licensees of our technology;
- /\*/  
entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- /\*/

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

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

/\*/

developments or disputes concerning patents or other proprietary rights;

/\*/

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

/\*/

loss of key management;

/\*/

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

/\*/

reports issued by securities analysts regarding our common stock and articles published regarding our business and/or products;

/\*/

changes in the market valuations of other life science or biotechnology companies; and

/\*/

other financial announcements, including delisting of our common stock from The NASDAQ Global Market, review of any of our filings by the SEC, changes in accounting treatment or restatement of

S-7

---

Table of Contents

previously reported financial results, delays in our filings with the SEC or our failure to maintain effective internal control over financial reporting.

In addition, the occurrence of any of the risks described in this prospectus supplement 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.

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

Since the price per share of our common stock being offered will be substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Our net tangible book value as of March 31, 2011 was approximately \$26.14 million, or \$0.28 per share. Based on the public offering price of \$        per share and our net tangible book value as of March 31, 2011, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$        per share with respect to the net tangible book value of the common stock. See the section entitled "Dilution" below for a more detailed discussion of the dilution you would incur if you purchase common stock in this offering.

In addition, we have a significant number of stock options and warrants outstanding. To the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution. Further, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to investors purchasing our common stock in this offering or result in downward pressure on the price of our common stock.

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

We intend to use the net proceeds from this offering for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital. We also may use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions. 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.

Table of Contents

**Future exercises by holders of warrants and options and conversions by holders of our convertible senior notes and other issuances of additional securities could substantially dilute our common stock.**

As of March 31, 2011, we had warrants to purchase an aggregate of 23.7 million shares of our common stock outstanding that are exercisable at prices ranging from \$2.00 per share to \$39.27 per share and options to purchase an aggregate of 5.4 million shares of our common stock outstanding that are exercisable at prices ranging from \$1.41 per share to \$36.82 per share. In addition, as of March 31, 2011, we had \$1.2 million in principal amount of convertible senior notes that are convertible into an aggregate of 24,789 shares of our common stock at a conversion price of \$49.78 per share and an additional \$20.8 million in principal amount of convertible senior notes that are convertible into an aggregate of 5,586,559 shares of our common stock at a conversion price of \$3.72 per share. Our stockholders, therefore, could experience substantial dilution of their investment upon exercise of these warrants and options and conversion of these notes. A substantial majority of these shares of common stock issuable upon exercise of the warrants and options and conversion of the notes currently are registered and thus once issued will be available for immediate resale in the public market. In addition, we have the ability to offer and sell common stock, preferred stock and warrants under currently effective universal shelf registration statements. Any issuance of additional equity securities would dilute your share ownership. In addition, these sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

**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 stockholders to elect director candidates; and

/\*/  
advance notice provisions in connection with stockholder proposals and director nominations 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.

**We do not intend to pay any cash dividends in the foreseeable future and, therefore, any return on an 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 an investment in our common stock must come from increases in the fair market value and trading price of our common stock.

**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. We incurred a net loss of \$46.2 million for the year ended December 31, 2010 and as of December 31, 2010, our accumulated deficit was \$165.6 million. For the three months ended March 31, 2011, we incurred a net loss of \$17.3 million and as of March 31, 2011, our accumulated deficit was \$182.9 million. 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

Table of Contents

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.

**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. 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;
- /\*/  
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.

We may need to continue to raise substantial additional capital to fund our operations. Although we believe that our cash and cash equivalents of \$51.3 million at March 31, 2011 and the additional net proceeds we expect to receive from this offering will be sufficient to meet our liquidity requirements through at least the next [ ] 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.

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

To date, we have relied primarily upon proceeds from sales of our equity securities to finance our business and operations. We can provide no assurance that additional financing, if needed, will be available on terms favorable to us, or at 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

S-10

---

Table of Contents

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.



Table of Contents

**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 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 notes when it becomes due, especially if an event of default were to occur under the indentures governing the convertible 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**

**Several 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.**

Several 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:

/\*/

be developed successfully;

/\*/

prove to be safe and effective in clinical studies;

Table of Contents

/\*/

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, 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;

S-13

---

Table of Contents

/\*/

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 have reached agreement with the FDA under the Special Protocol Assessment process for our Phase III safety and efficacy clinical trial protocols 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 relating to the protocols for our Phase III safety and efficacy trials, 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. Pursuant to the SPA process the FDA has agreed 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 the FDA will not later alter its perspective on issues of design execution or analysis, with certain exceptions that are discussed below. These SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the protocols for our 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.

Delays in the completion of our Phase III clinical study program for LibiGel, which can result from unforeseen issues, FDA interventions and other potential 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. Although it is our objective to submit an NDA for LibiGel to the FDA in 2012, we cannot ensure that we will meet this objective or that even after extensive clinical trials, regulatory approval will ever be obtained for LibiGel.

Table of Contents

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

Our objective is to submit an NDA for LibiGel to the FDA in 2012. We cannot ensure that we will meet this objective, however, or that even after extensive clinical studies, regulatory approval ever will be obtained for LibiGel.

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 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 accomplishments 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 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.

Table of Contents

**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.

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

Table of Contents

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 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 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.

Table of Contents

**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.

**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 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.



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

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

S-18

---

Table of Contents

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;

/\*/

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 with respect to Bio-T-Gel and with Pantarhei Science with respect to The Pill Plus and certain other companies with respect to our cancer vaccines. We currently do not have a strategic partner for LibiGel.

Table of Contents

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;

/\*/

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.

**Although we maintain the right to receive sales-based milestones of up to \$140 million, our ability to receive these milestones is dependent upon Azur's ability to market and sell Elestrin, and based on Elestrin sales during 2010, we believe it is unlikely that we will receive any sales-based milestone payments from Azur in the foreseeable future or at all.**

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 \$3.15 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 continue to recognize certain royalty revenue from Azur's sales of Elestrin; however, such revenue is offset by our corresponding obligation to pay royalties to Antares, from whom we licensed the technology underlying our Elestrin product. 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 relatively 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.

S-20

---

Table of Contents

**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;
- /\*/  
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 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

S-21

---

Table of Contents

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 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 than 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.

Table of Contents

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 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



Table of Contents

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 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.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to assess the effectiveness of our internal control over financial reporting and to provide a report by our registered independent public accounting firm addressing the effectiveness of our internal control over financial reporting. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) provides a framework for companies to assess and improve their internal control systems. If we are unable to assert that our internal control over financial reporting is effective (or if our registered independent public accounting firm is unable to express an opinion on the effectiveness of the internal controls or they issue an adverse opinion on our internal control over financial reporting), we could lose investor confidence in the accuracy and completeness of our financial reports, which in turn could have an adverse effect on our stock price. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain effective internal control over financial reporting could have an adverse effect on our common stock price.

**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 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.

Table of Contents

**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, cash flow 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 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

Table of Contents

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, and The Pill Plus from Wake Forest University Health Sciences. 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.

**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 some of our gel products to third parties, including Azur, Teva Pharmaceuticals USA, Inc., Pantarhei Bioscience B.V. and PharmaSwiss SA (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. Any 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

Table of Contents

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.

/\*/

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.

Table of Contents

**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 Hatch-Waxman Act and an additional six months of pediatric exclusivity. Depending upon if and when we receive regulatory approval for 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 operating results and 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. With respect to products which we have licensed to others, our licensees may be responsible for the defense of any patent infringement claims, which would result in our dependence upon them to defend our intellectual property rights. With respect to Bio-T-Gel, which was developed initially by BioSante and then was licensed to Teva for late stage clinical development, Abbott Laboratories, a marketer of a testosterone gel, in April 2011 filed a complaint against Teva alleging patent infringement. Under our agreement with Teva, Teva must assume the direction, control and disposition of the defense of such claims. There can be no assurance that Teva will be successful in the infringement claim. In its NDA filing, Teva has asserted that Bio-T-Gel does not infringe any patent owned by Abbott related to testosterone gels for men. In addition, although the outcome of the litigation is uncertain, it could delay the FDA approval and commercial launch of Bio-T-Gel and therefore potentially affect our receipt of royalties based on sales of Bio-T-Gel by Teva.

Table of Contents

**Cautionary Statement Regarding Forward-Looking Statements**

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

- /\*/  
the timing of the commencement, enrollment and successful completion of our clinical studies, the submission of new drug applications and other regulatory status of our products in development;
- /\*/  
approval by the U.S. Food and Drug Administration of our products that are currently in clinical development;
- /\*/  
our spending capital on research and development programs, pre-clinical studies and clinical studies, regulatory processes, establishment of sales and marketing capabilities and licensure or acquisition of new products;
- /\*/  
our efforts to continue to evaluate various strategic alternatives with respect to our products and our company;
- /\*/  
the future market size and market acceptance of our products;
- /\*/  
the effect of new accounting pronouncements and future health care, tax and other legislation;
- /\*/  
whether and how long our existing cash will be sufficient to fund our operations;
- /\*/  
our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- /\*/  
our substantial and continuing losses.

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

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the section entitled "Risk Factors" included elsewhere in this prospectus supplement and in the accompanying prospectus and under similar sections in the documents we incorporate by reference into this prospectus. We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the section entitled "Risk Factors" included elsewhere in this prospectus supplement and in the accompanying prospectus and under similar sections in the documents we incorporate by reference into this prospectus, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

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.

S-29

---

Table of Contents

**Use of Proceeds**

We estimate the net proceeds from this offering to be up to approximately \$            million after deducting the underwriting discounts and commissions, 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, or approximately \$            million, if the underwriters exercise their over-allotment option in full. We currently expect to use the net proceeds from this offering for general corporate purposes, including, without limitation, to fund our Phase III clinical study program for LibiGel, and for working capital. We also may use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions.

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.

**Dividend Policy**

To date, we have paid no cash dividends to our stockholders, and we do not intend to pay cash dividends in the foreseeable future.



Table of Contents**Dilution**

Our net tangible book value as of March 31, 2011 was approximately \$26.14 million, or approximately \$0.28 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 March 31, 2011, other than to give effect to our receipt of the estimated net proceeds from the sale of \_\_\_\_\_ shares of common stock at a public offering price of \$ \_\_\_\_\_ per share, less the underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of March 31, 2011, after giving effect to the items above, would have been approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in net tangible book value of \$ \_\_\_\_\_ per share of common stock to our existing stockholders and an immediate dilution in net tangible book value of \$ \_\_\_\_\_ per share of common stock to investors purchasing our common stock in this offering. The following table illustrates this per share dilution:

---

Public offering price per share	\$
Net tangible book value per share as of March 31, 2011	\$0.28
Increase in net tangible book value per share attributable to this offering	

Pro forma net tangible book value per share as of March 31, 2011, after giving effect to this offering

Dilution in net tangible book value per share to investors in this offering	\$
---	----

---

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, our pro forma net tangible book value per share at March 31, 2011 after giving effect to this offering would have been \$ \_\_\_\_\_ per share, and the dilution in pro forma net tangible book value per share to investors in this offering would have been \$ \_\_\_\_\_ per share. The above table is based on 93,590,612 shares of our common stock outstanding as of March 31, 2011 and excludes, as of such date:

/\*/

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;

/\*/

23,688,407 shares of our common stock issuable upon the exercise of warrants outstanding at a weighted average exercise price of \$2.88 per share;

/\*/

5,420,186 shares of our common stock issuable upon the exercise of options outstanding at a weighted average exercise price of \$3.06 per share;

/\*/

635,000 shares of our common stock available for future issuance under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan;

/\*/

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; and

/\*/

an undetermined number of shares of our common stock that may be issuable to Paladin Labs Inc. upon the achievement of certain milestones at a purchase price equal to a 10 percent premium to the then current market price of our common stock on the date of issuance.

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

On May 26, 2011, our stockholders approved the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan, under which the number of shares of our common stock reserved for issuance under the plan was increased by 2,000,000 shares.

To the extent that outstanding options or warrants are exercised or new stock options or other stock-based incentive awards are issued under our equity compensation plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

S-31

---

Table of Contents

**Underwriting**

Subject to the terms and conditions set forth in the underwriting agreement to be dated on or about July , 2011, between us and Jefferies & Company, Inc., as underwriters, we have agreed to sell to the underwriters and the underwriters have severally agreed to purchase from us, the number of common shares indicated in the table below:

---

<b>Underwriters</b>	<b>Number of Common Shares</b>
Jefferies & Company, Inc.	
Total	

---

Jefferies & Company, Inc. is acting as sole book-running manager of this offering and as representative of the underwriters named above.

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that they currently intend to make a market in the common shares. However, the underwriters are not obligated to do so and may discontinue any market-making activities at any time without notice. No assurance can be given as to the liquidity of the trading market for the common shares.

The underwriters are offering the common shares subject to their acceptance of the shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

**Commissions and Expenses**

The underwriters have advised us that they propose to offer the common shares to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per common share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ per common share to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such

Table of Contents

amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$ .

**Listing**

Our common shares are listed on The Nasdaq Global Market under the trading symbol "BPAX".

**Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of additional common shares at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

**Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and liabilities arising from certain breaches by us of the underwriting agreement. We have also agreed to contribute to payments that the underwriters may be required to make in respect of those liabilities.

**No Sales of Similar Securities**

We, our officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

/\*/  
sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or

/\*/  
otherwise dispose of any common shares, options or warrants to acquire common shares, or securities exchangeable or exercisable for or convertible into common shares currently or hereafter owned either of record or beneficially, or

/\*/  
publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies & Company, Inc.

Table of Contents

This restriction terminates after the close of trading of the common shares on and including the 90 days after the date of this prospectus. However, subject to certain exceptions, in the event that either:

/\*/

during the last 17 days of the 90-day restricted period, we issue an earnings release or material news or a material event relating to us occurs, or

/\*/

prior to the expiration of the 90-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day restricted period,

then in either case the expiration of the 90-day restricted period will be extended until the expiration of the 18-day period beginning on the date of the issuance of an earnings release or the occurrence of the material news or event, as applicable, unless Jefferies & Company, Inc. waives, in writing, such an extension.

Jefferies & Company, Inc. may, in its sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

**Price Stabilization**

The underwriter has advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in transactions, including overallotment, stabilizing bids, syndicate covering transactions or the imposition of penalty bids, which may have the effect of stabilizing or maintaining the market price of the common shares at a level above that which might otherwise prevail in the open market. Overallotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common shares or purchasing shares of our common shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of common shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the common shares. A syndicate covering transaction is the bid for or the purchase of common shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common shares originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Table of Contents

Neither we, nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common shares. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the NASDAQ Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

**Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of common shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

**Affiliations**

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer. The underwriter and certain of its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Table of Contents

**Notice To Investors**

**Australia**

This prospectus supplement is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus supplement in Australia:

You confirm and warrant that you are either:

/\*/

a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;

/\*/

a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;

/\*/

"professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus supplement is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus supplement for resale in Australia within 12 months of those shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

**European Economic Area**

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**"), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the "**Relevant Implementation Date**"), no offer of any securities which are the subject of the offering contemplated by this prospectus supplement has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

(a)

to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

(b)

to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

(c)

in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure

S-36

---



Table of Contents

implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

**Hong Kong**

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus supplement has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus supplement may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus supplement and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

**Japan**

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

**Singapore**

This prospectus supplement has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus supplement and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Table of Contents

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- (i) to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;
- (ii) where no consideration is given for the transfer; or
- (iii) where the transfer is by operation of law.

**Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("**SIX**") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus supplement has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus supplement nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus supplement nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus supplement will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA ("**FINMA**"), and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("**CISA**"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

**United Kingdom**

This prospectus supplement is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "**Order**") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "**relevant person**").

This prospectus supplement and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Table of Contents

**Legal Matters**

The validity of the issuance of the shares of common stock offered hereby will be passed upon for us by Oppenheimer Wolff & Donnelly LLP, Minneapolis, Minnesota. Dewey & LeBoeuf LLP, New York, New York is counsel for the underwriters in connection with this offering.

**Experts**

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

**Where You Can Find More Information**

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

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

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

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

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

Table of Contents

**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, 2010;
- /\*/  
our quarterly report on Form 10-Q for the quarter ended March 31, 2011;
- /\*/  
our current reports on Form 8-K as filed with the SEC on January 27, 2011, March 4, 2011 and May 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 web site or our web site 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 web site or that can be accessed through our web site does not constitute a part of this prospectus. We have included our web site address only as an inactive textual reference and do not intend it to be an active link to our web site.

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, Senior Vice President of Finance, Chief Financial Officer 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.

Table of Contents

**PROSPECTUS**

**\$150,000,000**

**Common Stock  
Preferred Stock  
Warrants  
Units**

---

We may offer and sell from time to time up to \$150,000,000 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 June 15, 2011, the reported closing price of our common stock was \$2.60 per share. Prospective purchasers of securities are urged to obtain current information as to the market prices of our common stock.

**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 17, 2011

---

Table of Contents

**TABLE OF CONTENTS**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	<u>1</u>
<u>ABOUT OUR COMPANY</u>	<u>1</u>
<u>RISK FACTORS</u>	<u>3</u>
<u>CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</u>	<u>3</u>
<u>USE OF PROCEEDS</u>	<u>4</u>
<u>DILUTION</u>	<u>4</u>
<u>DESCRIPTION OF COMMON STOCK</u>	<u>5</u>
<u>DESCRIPTION OF PREFERRED STOCK</u>	<u>6</u>
<u>DESCRIPTION OF WARRANTS</u>	<u>8</u>
<u>DESCRIPTION OF UNITS</u>	<u>11</u>
<u>ANTI-TAKEOVER EFFECTS OF PROVISIONS OF OUR CERTIFICATE OF INCORPORATION, OUR BYLAWS AND DELAWARE LAW</u>	<u>12</u>
<u>PLAN OF DISTRIBUTION</u>	<u>14</u>
<u>LEGAL MATTERS</u>	<u>18</u>
<u>EXPERTS</u>	<u>18</u>
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	<u>18</u>
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	<u>19</u>

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

*We own or have the rights to use various trademarks, trade names or service marks that are used in this prospectus, including BioSante®, Elestrin , LibiGel®, Bio-T-Gel and The Pill Plus .*

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

Table of Contents

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (SEC) using a "shelf" registration process. Under this shelf registration process, we may offer to sell any one or more or a combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$150,000,000 (or its equivalent based on the applicable exchange rate at the time of the sale in one or more foreign currencies, currency units or composite currencies that we may designate). We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. We also may add, update or change in the prospectus supplement any of the information contained in this prospectus. If there is an inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in the prospectus supplement. You should read carefully both this prospectus and the applicable prospectus supplement together with the documents we incorporate by reference into this prospectus as described under the heading "Incorporation of Certain Documents By Reference" before making an investment decision. This prospectus may not be used to offer and sell securities without a prospectus supplement.

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

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

**ABOUT OUR COMPANY**

BioSante Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing products for female sexual health 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.

/\*/

Bio-T-Gel once daily transdermal testosterone gel for the treatment of hypogonadism, or testosterone deficiency in men, for which a New Drug Application (NDA) is pending with a Prescription Drug User Fee Act (PDUFA) date of November 14, 2011 and which is licensed to Teva Pharmaceuticals USA, Inc.

/\*/

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.

/\*/

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





Table of Contents

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 an 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. We have completed enrollment in the two efficacy trials and safety study. 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. It is our objective to submit the LibiGel NDA to the FDA in 2012.

Elestrin is our first FDA approved product. Azur Pharma International II Limited (Azur), our licensee, is marketing Elestrin in the U.S. 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 believe our 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. Four of these vaccines have been granted FDA orphan drug designation. We license our cancer vaccine technology from Johns Hopkins University and The Whitehead Institute for Biomedical Research. Under various agreements, we are required to pay Johns Hopkins University certain development and regulatory milestone payments and royalties based on net sales of any products we or our licensees sell incorporating the in-licensed technology.

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.

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, we acquired Cell Genesys, Inc. through a direct merger.

Our principal executive offices are located at 111 Barclay Boulevard, Lincolnshire, Illinois 60069. Our telephone number is (847) 478-0500 and our Internet web site address is [www.biosantepharm.com](http://www.biosantepharm.com). We make available on our website free of charge a link to our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the Securities and Exchange Commission, or SEC. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

Table of Contents

**RISK FACTORS**

An investment in our securities involves a high degree of risk. You should carefully consider the risk factors described in Part I, Item 1A, "Risk Factors" in our annual report on Form 10-K for the fiscal year ended December 31, 2010, Part II, Item 1A, "Risk Factors" in our quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2011 and our other reports filed from time to time with the SEC, which are incorporated by reference into this prospectus, as the same may be amended, supplemented or superseded from time to time by our filings under the Exchange Act, as well as any prospectus supplement relating to a specific security. Before making any investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus or in any applicable prospectus supplement. The risks and uncertainties described in the prospectus supplement and the documents we incorporate by reference into this prospectus are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we believe are not material at the time could also materially adversely affect our business, financial condition or results of operations. In any case, the value of our securities could decline, and you could lose all or part of your investment. See also the information contained under the heading "Cautionary Statement Regarding Forward-Looking Statements" immediately below.

**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and any accompanying prospectus supplement, including the documents that we incorporate by reference, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts included in or incorporated by reference into this prospectus and any accompanying prospectus supplement that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Our forward-looking statements generally include statements about our plans, objectives, strategies and prospects regarding, among other things, our business, results of operations, liquidity and financial condition. In some cases, we have identified these forward-looking statements with words like "believe," "may," "could," "might," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate," "contemplate" or "continue" or the negative of these words or other words and terms of similar meaning.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements include: our ability to obtain additional capital when needed or on acceptable terms; subject recruitment and enrollment in our current and future clinical studies, including in particular our Phase III clinical study program for LibiGel; our failure to obtain and maintain required regulatory approvals on a timely basis or at all; the failure of certain of our products to be commercially introduced for several years or at all; the level of market acceptance of our products if and when they are commercialized; uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy; our dependence upon the maintenance of certain of our licenses with; our dependence upon our licensees for the development, marketing and sale of certain of our products; our ability to compete in a competitive industry; our ability to protect our proprietary technology and to operate our business without infringing the proprietary rights of third parties; our dependence upon key employees; adverse changes in applicable laws or regulations and our failure to comply with applicable laws and regulations; changes in generally accepted accounting principles; or conditions and changes in the biopharmaceutical industry or in general economic or business conditions. We refer you to the section entitled "Risk Factors" included elsewhere in this prospectus and in the accompanying prospectus supplement and under similar sections in the documents we incorporate by reference into this prospectus.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results,

Table of Contents

which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described above and under the section entitled "Risk Factors" included elsewhere in this prospectus and in the accompanying prospectus supplement and under similar sections in the documents we incorporate by reference into this prospectus, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements, except if we otherwise are required by law. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the SEC.

**USE OF PROCEEDS**

Unless we otherwise indicate in the applicable prospectus supplement, we currently intend to use the net proceeds from the sale of our securities, if such sale occurs, for general corporate purposes, including working capital, to finance our Phase III clinical studies for LibiGel, capital expenditures and potentially the repayment, repurchase or redemption of our 3.125% convertible senior subordinated notes due November 2011 and May 2013. We also may use a portion of the proceeds to acquire or invest in complementary businesses or products or to obtain rights to additional product candidates and other technologies. We have no commitments with respect to any such acquisitions or investments. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress in, and costs of, our Phase III clinical 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. We therefore cannot estimate the amount of proceeds to be used for all of the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the proceeds. Pending the uses described above, we intend to deposit the proceeds in our non-interest bearing checking account, U.S. Treasury money market fund or invest them temporarily in short-term or marketable securities until we use them for their stated purpose. We also may set forth additional information on the use of net proceeds from the sale of the securities we offer under this prospectus in a prospectus supplement relating to the specific offering.

**DILUTION**

We will set forth in a prospectus supplement the following information regarding any material dilution of the equity interests of investors purchasing securities in an offering under this prospectus:

/\*/

the net tangible book value per share of our equity securities before and after the offering;

/\*/

the amount of the increase in such net tangible book value per share attributable to the cash payments made by purchasers in the offering; and

/\*/

the amount of the immediate dilution from the public offering price which will be absorbed by such purchasers.

Table of Contents

**DESCRIPTION OF COMMON STOCK**

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

**Authorized and Outstanding Capital Stock**

We are authorized to issue 200,000,000 shares of common stock, \$0.0001 par value per share, 4,687,684 shares of class C special stock, \$0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, \$0.0001 par value per share.

As of June 15, 2011, we had 93,596,279 shares of common stock outstanding. As of June 15, 2011, we had an aggregate of 5,442,230 shares of common stock reserved for issuance upon the exercise of outstanding stock options granted under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan, the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan and certain assumed Cell Genesys stock plans and an additional 2,514,335 shares of common stock reserved for issuance pursuant to future grants under the BioSante Pharmaceuticals, Inc. Second Amended and Restated 2008 Stock Incentive Plan. As of June 15, 2011, we had an aggregate of 23,621,740 shares of common stock reserved for issuance upon the exercise of outstanding warrants.

As of June 15, 2011, we had 391,286 shares of class C special stock outstanding. Each share of class C special stock entitles its holder to one vote per share. Each share of our class C special stock is exchangeable, at the option of the holder, for one share of common stock, at an exchange price of \$2.50 per share, subject to adjustment upon certain capitalization events. Holders of our class C special stock are not entitled to receive dividends. Holders of our class C special stock are not entitled to participate in the distribution of our assets upon any liquidation, dissolution or winding-up of our company. The holders of our class C special stock have no cumulative voting, preemptive, subscription, redemption or sinking fund rights.

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

**Voting Rights**

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

Table of Contents

**Dividends**

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

**Liquidation**

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

**Fully Paid and Nonassessable**

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

**Other Rights and Restrictions**

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

**Listing**

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

**Transfer Agent and Registrar**

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

**DESCRIPTION OF PREFERRED STOCK**

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

Table of Contents

**Authorized and Outstanding Shares**

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

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

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

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

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

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

- /\*/  
the title and stated value of the preferred stock;
- /\*/  
the number of shares of the preferred stock offered, the liquidation preference per share and the purchase price of the preferred stock;
- /\*/  
the dividend rate(s), period(s) and/or payment date(s) or the method(s) of calculation for dividends;
- /\*/  
whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
- /\*/  
the procedures for any auction and remarketing, if any, for the preferred stock;
- /\*/  
the provisions for a sinking fund, if any, for the preferred stock;
- /\*/  
the provisions for redemption, if applicable, of the preferred stock;
- /\*/  
any listing of the preferred stock on any securities exchange or market;
- /\*/

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form 424B5

the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price (or its manner of calculation) and conversion period;

*/\*/*

voting rights, if any, of the preferred stock;

*/\*/*

a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;

*/\*/*

whether interests in the preferred stock will be represented by depositary shares;

*/\*/*

the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs;

Table of Contents

/\*/  
any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and

/\*/  
any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

**Transfer Agent and Registrar**

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

**DESCRIPTION OF WARRANTS**

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

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

**Outstanding Warrants**

As of June 15, 2011, the following warrants were outstanding:

/\*/  
Warrants to purchase an aggregate of 853,292 shares of our common stock at an exercise price of \$2.75 per share issued to various institutional and accredited investors in connection with our private placement completed on July 21, 2006;

/\*/  
A warrant to purchase up to 300,000 shares of our common stock at an exercise price of \$4.00 per share issued to Kingsbridge Capital Limited on December 15, 2008 in connection with our committed equity financing facility;

/\*/  
Warrants to purchase an aggregate of 395,246 shares of our common stock at an exercise price of \$39.27 per share, originally issued by Cell Genesys, Inc. to various institutional investors in connection with Cell Genesys's registered direct offering completed on April 11, 2007, which warrants were assumed by us and converted into warrants to purchase shares of our common stock in connection with our merger with Cell Genesys on October 14, 2009;

/\*/  
Warrants to purchase an aggregate of 2,640,000 shares of our common stock at an exercise price of \$2.50 per share issued to various institutional investors and our placement agent in connection with our registered direct offering completed on August 13, 2009;

/\*/  
Warrants to purchase an aggregate of 5,202,313 shares of our common stock at an exercise price of \$2.08 per share issued to various institutional investors in connection with our registered direct offering completed on March 8, 2010;





Table of Contents

/\*/  
Warrants to purchase an aggregate of 208,093 shares of our common stock at an exercise price of \$2.16 per share issued to our placement agent in connection with our registered direct offering completed on March 8, 2010;

/\*/  
Warrants to purchase an aggregate of 3,567,183 shares of our common stock at an exercise price of \$2.45 per share issued to various institutional investors in connection with our registered direct offering completed on June 23, 2010;

/\*/  
Warrants to purchase an aggregate of 214,031 shares of our common stock at an exercise price of \$2.63 per share issued to our placement agent in connection with our registered direct offering completed on June 23, 2010;

/\*/  
Warrants to purchase an aggregate of 5,294,118 shares of our common stock at an exercise price of \$2.00 per share issued to various institutional investors in connection with our registered direct offering completed on December 30, 2010;

/\*/  
Warrants to purchase an aggregate of 317,647 shares of our common stock at an exercise price of \$2.125 per share issued to our placement agent in connection with our registered direct offering completed on December 30, 2010;

/\*/  
Warrants to purchase an aggregate of 4,025,827 shares of our common stock at an exercise price of \$2.25 per share issued to various institutional investors in connection with our registered direct offering completed on March 8, 2011;

/\*/  
Warrants to purchase an aggregate of 243,990 shares of our common stock at an exercise price of \$2.576625125 per share issued to our placement agent in connection with our registered direct offering completed on March 8, 2011; and

/\*/  
Warrants to purchase an aggregate of 360,000 shares of our common stock at an exercise price of \$2.00 per share issued to an investor and public relations vendor in 2009 and 2010.

**General**

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

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

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

/\*/  
the offering price and aggregate number of warrants offered;

/\*/  
the currency for which the warrants may be purchased;

/\*/  
if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

/\*/

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

/\*/

the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

/\*/

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

/\*/

the terms of any rights to redeem or call the warrants;

Table of Contents

- /\*/  
any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- /\*/  
the dates on which the right to exercise the warrants will commence and expire;
- /\*/  
the manner in which the warrant agreement and warrants may be modified;
- /\*/  
if applicable, material U.S. federal income tax consequences of holding or exercising the warrants;
- /\*/  
the terms of the securities issuable upon exercise of the warrants;
- /\*/  
the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;
- /\*/  
the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;
- /\*/  
the anti-dilution provisions of the warrants, if any;
- /\*/  
any redemption or call provisions; and
- /\*/  
any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

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

**Exercise of Warrants**

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

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

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

**Enforceability of Rights by Holders of Warrants**

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

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

Table of Contents

**DESCRIPTION OF UNITS**

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

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

**General**

We may issue, in one or more series, units comprised of shares of our common stock or preferred stock and warrants to purchase common stock or preferred stock or any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

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

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

/\*/  
the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

/\*/  
any provisions of the governing unit agreement that differ from those described below; and

/\*/  
any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

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

Table of Contents

**Enforceability of Rights by Holders of Units**

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

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

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

These provisions, summarized below, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions also are designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

**Authorized But Unissued Capital Stock**

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

Table of Contents

**Stockholder Meetings**

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

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

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

**No Cumulative Voting Rights**

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

**Delaware Anti-Takeover Statute**

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

*/\*/*

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

*/\*/*

upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

*/\*/*

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

Section 203 defines "business combination" to include:

*/\*/*

any merger or consolidation involving the corporation and the interested stockholder;

*/\*/*

any sale, transfer, pledge or other disposition of 10% or more of our assets involving the interested stockholder;

*/\*/*

in general, any transaction that results in the issuance or transfer by us of any of our stock to the interested stockholder; or

*/\*/*

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or otherwise controlled by the entity or person.





Table of Contents

**PLAN OF DISTRIBUTION**

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

/\*/

to or through underwriters or dealers; or

/\*/

directly to purchasers, including our affiliates, or to a single purchaser.

/\*/

through one or more agents;

/\*/

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

/\*/

through a combination of any of these methods of sale.

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

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

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

/\*/

the type and amount of securities we are offering;

/\*/

the purchase price of our securities being offered and the net proceeds we will receive from the sale;

/\*/

the method of distribution of the securities we are offering;

/\*/

the name or names of any agents, underwriters or dealers;

/\*/

any over-allotment options under which underwriters may purchase additional securities from us;

/\*/

any underwriting discounts and commissions or agency fees and commissions and other items constituting underwriters' or agents' compensation;

/\*/

any discounts or concessions allowed or reallocated or paid to dealers; and

/\*/

any securities exchanges on which such securities may be listed.

**Sale Through Underwriters or Dealers**

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

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

Table of Contents

In compliance with the guidelines of the Financial Industry Regulatory Authority, or FINRA, the aggregate maximum discount, commission, agency fees, or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of any offering pursuant to this prospectus and any applicable prospectus supplement; however, we anticipate that the maximum commission or discount to be received in any particular offering of securities may be less than this amount.

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

**Sale Through Dealers**

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

**Direct Sales**

We may directly solicit offers to purchase the securities offered by this prospectus. In this case, no underwriters or agents would be involved. We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act of 1933 with respect to any sale of those securities. The terms of any such sales will be described in the prospectus supplement.

**Sales Through Agents**

Securities also may be offered and sold through agents designated from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and will describe any commissions payable to the agent. Unless otherwise indicated in the applicable prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment. Any agent may be deemed to be an underwriter within the meaning of the Securities Act of 1933 with respect to any sale of those securities.

**Delayed Delivery Contracts**

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

Table of Contents

**Market Making, Stabilization and Other Transactions**

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

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

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

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

**Derivative Transactions and Hedging**

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

**Electronic Auctions**

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

Such electronic system may allow bidders to directly participate, through electronic access to an auction site, by submitting conditional offers to buy that are subject to acceptance by us, and which may directly affect the price or other terms and conditions at which such securities are sold. These bidding or ordering

Table of Contents

systems may present to each bidder, on a so-called "real-time" basis, relevant information to assist in making a bid, such as the clearing spread at which the offering would be sold, based on the bids submitted, and whether a bidder's individual bids would be accepted, prorated or rejected. Of course, many pricing methods can and may also be used.

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

**General Information**

Agents, underwriters, and dealers may be entitled, under agreements entered into with us, to indemnification by us against specified liabilities, including liabilities under the Securities Act of 1933, or to contribution by us to payments they may be required to make in respect to such liabilities. The applicable prospectus supplement will describe the terms and conditions of indemnification or contribution. Some of our agents, underwriters, and dealers, or their affiliates, may be customers of, engage in transactions with or perform services for us, in the ordinary course of business. We will describe in the prospectus supplement the nature of any such relationship and the name of the parties involved. Any lockup arrangements will be set forth in the applicable prospectus supplement.

Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in three business days, unless the parties to any such trade expressly agree otherwise. The applicable prospectus supplement may provide that the original issue date for your securities may be more than three scheduled business days after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the third business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than three scheduled business days after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

Table of Contents

**LEGAL MATTERS**

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

**EXPERTS**

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

**WHERE YOU CAN FIND MORE INFORMATION**

We are a public company and file annual, quarterly and current reports, proxy statements and other information with the SEC. 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 of the Canadian Securities Administrators are available at its web site <http://www.sedar.com>.

In addition, we maintain a web site that contains information regarding our company, including copies of reports, proxy statements and other information we file with the SEC. The address of our web site is [www.biosantepharm.com](http://www.biosantepharm.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.

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

/\*/  
inspect a copy of this prospectus, including the exhibits and schedules, without charge at the public reference room;

/\*/  
obtain a copy from the SEC upon payment of the fees prescribed by the SEC; or

/\*/  
obtain a copy from the SEC website.

Table of Contents

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

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

- /\*/  
our annual report on Form 10-K for the year ended December 31, 2010 (including information specifically incorporated by reference into our Form 10-K from our definitive proxy statement for our 2011 annual meeting of stockholders);
- /\*/  
our quarterly report on Form 10-Q for the quarter ended March 31, 2011;
- /\*/  
our current report on Form 8-K as filed with the SEC on January 27, 2011, March 4, 2011; and May 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 and prior to the termination of the offering of the securities to which this prospectus relates. In addition, we also are incorporating by reference any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 after the date of the initial registration statement of which this prospectus is a part and prior to effectiveness of such registration statement. In no event, however, will any of the information that we "furnish" to the SEC in any current report on Form 8-K or any other report or filing be incorporated by reference into, or otherwise included in, this prospectus.

You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statement, and amendments, if any, to those documents filed or furnished pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act with the SEC free of charge at the SEC's website or our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

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



Table of Contents

**Shares**

**Common Stock**

---

**PROSPECTUS SUPPLEMENT**

---

*Sole Book-Running Manager*

**Jefferies**

, 2011

---