

BIOSANTE PHARMACEUTICALS INC
Form POS AM
May 14, 2010
[Table of Contents](#)

As filed with the Securities and Exchange Commission on May 14, 2010

Registration No. 333- 156276

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1

TO

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

58-2301143
(I.R.S. Employer
Identification Number)

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

111 Barclay Boulevard

Lincolnshire, Illinois 60069

(847) 478-0500

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Phillip B. Donenberg

Chief Financial Officer, Treasurer and Secretary

BioSante Pharmaceuticals, Inc.

111 Barclay Boulevard

Lincolnshire, Illinois 60069

(847) 478-0500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Amy E. Culbert, Esq.

Oppenheimer Wolff & Donnelly LLP

45 South Seventh Street, Suite 3300

Minneapolis, Minnesota 55402-1509

(612) 607-7287

Approximate date of commencement of proposed sale to the public:

From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

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

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

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

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

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

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

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

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated May 14, 2010

PRELIMINARY PROSPECTUS

5,705,840 Shares

Common Stock

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

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholder may resell its shares of our common stock in the section titled "Plan of Distribution" beginning on page 33. Kingsbridge is an underwriter within the meaning of the Securities Act of 1933 with respect to any shares it resells under this prospectus. Although we will pay the expenses incurred in registering the shares, we will not be paying any underwriting discounts or commissions in this offering.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

Our common stock is listed on the Nasdaq Global Market under the symbol BPAX. On May 12, 2010, the reported closing price of our common stock was \$2.37 per share.

Investing in our common stock involves a high degree of risk. We refer you to Risk Factors, beginning on page 11.

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 _____, 2010

Table of Contents

TABLE OF CONTENTS

	Page
<u>PROSPECTUS SUMMARY</u>	4
<u>RISK FACTORS</u>	11
<u>CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS</u>	11
<u>USE OF PROCEEDS</u>	13
<u>SELLING STOCKHOLDER</u>	13
<u>PLAN OF DISTRIBUTION</u>	14
<u>LEGAL MATTERS</u>	16
<u>EXPERTS</u>	16
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	17
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	18

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

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

You should rely only on the information contained in this prospectus. We have not authorized any other person to provide you with different information. This prospectus may only be used where it is legal to sell these securities. The information in this prospectus is accurate as of the date on the front cover. You should not assume that the information contained in this prospectus is accurate as of any other date.

This prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus or the solicitation of a proxy, in any jurisdiction to or from any person to whom or from whom it is unlawful to make an offer, solicitation of an offer or proxy solicitation in that jurisdiction.

Table of Contents

PROSPECTUS SUMMARY

The following summary highlights information contained in this prospectus or incorporated by reference. While we have included what we believe to be the most important information about BioSante and this offering, the following summary may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the risks of investing discussed under Risk Factors beginning on page 11, and the information to which we refer you and the information incorporated into this prospectus by reference, for a complete understanding of our business and this offering.

Our Company

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

BioSante Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception, male hypogonadism and oncology. We also are developing our calcium phosphate technology (CaP) for aesthetic medicine (BioLook), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery as well as seeking opportunities for our 2A/Furin and other technologies.

Our products, either approved or in development, include:

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

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of a new drug application (NDA) for LibiGel for the treatment of FSD, specifically, HSDD in menopausal women. Currently, three LibiGel Phase III studies are underway and enrolling women: two LibiGel Phase III safety and efficacy clinical trials and one Phase III cardiovascular and breast cancer safety study. We have three SPAs in place concerning LibiGel. The first SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. The second SPA covers our LibiGel program in the treatment of FSD, specifically HSDD, in naturally menopausal women. The third SPA agreement covers the LibiGel stability, or shelf life, studies for the intended commercialization of LibiGel product.

Table of Contents

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 which permanently reduced the royalty percentage due to us related to Azur's sales of Elestrin. We received approximately \$3.16 million in non-refundable payments in exchange for the elimination of all remaining future royalty payments due us under the terms of the original license. 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.

GVAX cancer vaccines are designed to stimulate the patient's immune system to effectively fight 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 prostate cancer, pancreatic cancer, leukemia and breast cancer. Two of these vaccines have been granted orphan drug designation

Our CaP technology is based on the use of extremely small, solid, uniform particles, which we call nanoparticles. We are pursuing the development of various potential initial applications for our CaP technology. First, CaP technology is being tested in the area of aesthetic medicine. Second, our CaP technology is being tested for its adjuvant activity that enhances the ability of a vaccine to stimulate an immune response. The same nanoparticles allow for delivery of the vaccine via alternative routes of administration including non-injectable routes of administration. Third, we are pursuing the creation of oral, buccal, intranasal, inhaled and longer acting delivery of drugs that currently must be given by injection (e.g., insulin).

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

- BioLook facial line filler in development using proprietary CaP technology in the area of aesthetic medicine, e.g., a facial line filler.
- BioVant proprietary CaP adjuvant and delivery technology in development for improved vaccines against viral and bacterial infections and autoimmune diseases, among others. BioVant also serves as a delivery system for non-injected delivery of vaccines.
- BioOral a delivery system using CaP technology for oral/buccal/intranasal administration of proteins and other therapies that currently must be injected.
- BioAir a delivery system using CaP technology for inhalable versions of proteins and other therapies that currently must be injected.

Risks Affecting Us

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

You should carefully consider the matters discussed in the section **Risk Factors** beginning on page 11, including the following, before you invest in our common stock. For example:

- We have a history of operating losses, expect continuing losses and may never become profitable.
- We may need to raise substantial additional capital to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.
- Although we believe LibiGel has the potential to be a successful product, its Phase III clinical study program requires significant resources and there are significant risks involved in

Table of Contents

conducting the clinical studies, obtaining regulatory approval and commercializing the product, if approved.

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, 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.biosantepharma.com. We make available on our website free of charge a link to our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as practicable after we electronically file such material with the Securities and Exchange Commission, or SEC. Except for the documents specifically incorporated by reference into this prospectus, information contained on our website or that can be accessed through our website does not constitute a part of this prospectus. We have included our website address only as an inactive textual reference and do not intend it to be an active link to our website.

Committed Equity Financing Facility with Kingsbridge

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

On December 15, 2008, we entered into a committed equity financing facility, or CEFF, with Kingsbridge Capital Limited, pursuant to which Kingsbridge committed to purchase, subject to certain conditions, up to the lesser of \$25 million or 5,405,840 shares of our common stock. In connection with the CEFF, we entered into a common stock purchase agreement and registration rights agreement with Kingsbridge, both dated December 15, 2008. In addition, on that date, as consideration for the execution and delivery of the common stock purchase agreement, we also issued a warrant to Kingsbridge to purchase up to 300,000 shares of our common stock at an exercise price of \$4.00 per share. This warrant is exercisable beginning on June 15, 2009 and for a period of five years thereafter. Although the common stock purchase agreement and registration rights agreement were since amended subsequent to December 15, 2008, such amendments were not material and are incorporated into the descriptions of such agreements in this prospectus.

The shares of common stock that may be issued to Kingsbridge under the common stock purchase agreement and upon exercise of the warrant will be issued pursuant to an exemption from registration under the Securities Act of 1933, as amended, or the Securities Act. As of the date of this prospectus, no shares of our common stock have been issued to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. Pursuant to the registration rights agreement, we have filed a registration statement of which this prospectus is a part, covering the possible resale by Kingsbridge of any shares that we may issue to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. Through this prospectus, Kingsbridge may offer to the public for resale shares of our common stock that we may issue to Kingsbridge pursuant to the common stock purchase agreement or that Kingsbridge may acquire upon exercise of the warrant. The obligations of Kingsbridge under the common stock purchase agreement to purchase shares of our common stock may not be transferred and the registration statement does not cover sales of such shares by transferees of Kingsbridge. The rights of Kingsbridge to purchase shares of our common stock under the warrant may not be assigned or transferred except, under certain conditions, to an affiliate of Kingsbridge. If the warrant is transferred to an affiliate of Kingsbridge, the registration statement will cover sales of any shares of our common stock that we issue to such affiliate of Kingsbridge under the warrant, but will not cover resale of shares of our common stock by transferees of such affiliate of Kingsbridge.

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

Table of Contents

The common stock purchase agreement entitles us to sell and obligates Kingsbridge to purchase, from time to time through December 30, 2010 shares of our common stock for cash consideration up to an aggregate of the lesser of \$25 million or 5,405,840 shares of our common stock, subject to certain conditions and restrictions. We are not obligated to sell any shares to Kingsbridge under the common stock purchase agreement.

Through December 30, 2010 we may, from time to time, at our sole discretion, and subject to certain conditions that we must satisfy, draw down funds under the CEFF by selling shares of our common stock to Kingsbridge. The purchase price of these shares will be at a discount ranging from eight to 14 percent of the volume weighted average of the price of our common stock for each of the eight consecutive trading days following our election to sell shares or draw down under the CEFF. The discount on each of these consecutive eight trading days will be determined as follows:

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

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

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

In connection with a settlement of a draw down, we are not obligated to pay or reimburse Kingsbridge for any transaction fees or commissions.

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

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

Our ability to require Kingsbridge to purchase our common stock is subject to various limitations. We can make individual draw downs of a maximum amount of, at our discretion, 1.5% of our market capitalization as of the date the applicable drawn down notice is given. Unless we and Kingsbridge agree

Table of Contents

otherwise, a minimum of 15 trading days must elapse between the expiration of any draw down pricing period and the beginning of the next succeeding draw down pricing period. Kingsbridge is not obligated to purchase shares of our common stock when the volume weighted average of the price of our common stock is below \$1.15 per share. Accordingly, there is no assurance that we will be able to access the CEFF, if ever, at such times and in amounts that are necessary to fund our activities.

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

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

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

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

- Each of our representations and warranties in the common stock purchase agreement must be true and correct in all material respects as of the date when made as though made at that time, except for representations and warranties that are expressly made as of a particular date.
- We must have performed, satisfied and complied in all material respects with all covenants, agreements and conditions required by the common stock purchase agreement, the registration rights agreement and the warrant to be performed, satisfied or complied with by us.
- We must have complied in all respects with all applicable federal, state and local governmental laws, rules, regulations and ordinances in connection with the execution, delivery and performance of the common stock purchase agreement and the consummation of the transactions contemplated by it, except for such failures to comply as would not have a

Table of Contents

material adverse effect on the business, operations, properties or financial condition of us and our subsidiaries as a whole or prohibit or otherwise interfere with our ability to perform any of our obligations under the common stock purchase agreement, the registration rights agreement or the warrant in any material respect.

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

Edgar Filing: BIOSANTE PHARMACEUTICALS INC - Form POS AM

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

We also entered into a registration rights agreement with Kingsbridge, dated December 15, 2008, which agreement was later amended. Pursuant to the amended registration rights agreement, we have filed the registration statement, of which this prospectus is a part, with the SEC relating to the resale by Kingsbridge of any shares of common stock purchased by it under the common stock purchase agreement or issued to it upon the exercise of its warrant. The effectiveness of this registration statement is a condition precedent to our ability to sell common stock to Kingsbridge under the common stock purchase

Table of Contents

agreement. We are entitled in certain circumstances, including the existence of certain kinds of material nonpublic information, to deliver a blackout notice to Kingsbridge to suspend the use of this prospectus and prohibit Kingsbridge from selling shares under this prospectus for a period of not more than 30 days. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down or if the registration statement, of which this prospectus is a part, is not effective in circumstances not permitted by the registration rights agreement, then we must pay amounts to Kingsbridge or issue Kingsbridge additional shares in lieu of payment. The payment or issuance would be calculated by means of a varying percentage of an amount based on the number of shares held by Kingsbridge that were purchased pursuant to such draw down and the change in the market price of our common stock between the date the blackout notice is delivered (or the registration statement is not effective) and the date the prospectus again becomes available.

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

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

As of May 13, 2010, we had not issued any shares of our common stock to Kingsbridge under the CEFF.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risk factors described in Part I, Item 1A, Risk Factors in our 2009 Annual Report on Form 10-K 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. 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 common stock 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, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are subject to the safe harbor created by those sections. All statements other than statements of historical facts included in or incorporated by reference into this prospectus that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like believe, may, could, might, possible, potential, project, will, should, expect, intend, plan, predict, anticipate, estimate or continue and other words and terms of similar meaning. Our forward-looking statements generally relate to:

- 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 FDA 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 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;

Table of Contents

- our need, ability and expected timing of any actions to raise additional capital through future equity and other financings; and
- our substantial and continuing losses.

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading **Risk Factors** included elsewhere in this prospectus, and include, among others: 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; 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 wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described under the heading **Risk Factors** included elsewhere in this prospectus, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading **Risk Factors** included elsewhere in this prospectus. The risks and uncertainties described under the heading **Risk Factors** included elsewhere in this prospectus are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements, except if we otherwise are required by law. We advise you, however, to consult any further disclosures we make on related subjects in our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K we file with or furnish to the SEC.

Table of Contents

USE OF PROCEEDS

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

Unless otherwise provided in the applicable prospectus supplement, we intend to use the proceeds from our sales, if any, to Kingsbridge for general corporate purposes, including working capital, to finance our Phase III clinical studies for LibiGel, capital expenditures and the repayment, repurchase or redemption of outstanding indebtedness. 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 temporarily in our non-interest bearing checking account or to invest them temporarily in short-term or marketable securities until we use them for their stated purpose.

SELLING STOCKHOLDER

As of the date of this prospectus, no shares of our common stock have been issued to Kingsbridge under the common stock purchase agreement or upon exercise of the warrant. To the extent any shares are issued to Kingsbridge, this prospectus relates to the possible resale by the selling stockholder, Kingsbridge, of shares of common stock that we may issue pursuant to the common stock purchase agreement we entered into with Kingsbridge in December 2008 or upon exercise of the warrant that we issued to Kingsbridge in December 2008. We are filing the registration statement, of which this prospectus is a part, pursuant to the provisions of the registration rights agreement we entered into with Kingsbridge. The selling stockholder may from time to time offer and sell pursuant to this prospectus any or all of the shares that it acquires under the common stock purchase agreement or upon exercise of the warrant.

The following table presents information regarding Kingsbridge, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of May 13, 2010. As used in this prospectus, the term "selling stockholder" includes Kingsbridge and any donees, pledges, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column "Number of Shares Being Offered" represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Table of Contents

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1934, as amended. The percentage of shares of common stock beneficially owned prior to the offering shown in the table below is based both on an aggregate of 63,667,194 shares of our common stock outstanding on May 13, 2010, and on the assumption that all shares of common stock issuable under the common stock purchase agreement with Kingsbridge and all shares of common stock issuable upon exercise of the warrant are outstanding as of that date.