ANI PHARMACEUTICALS INC
Form 424B2
March 04, 2014

Filed pursuant to Rule 424(b)(2)

Registration File No. 333-174597

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and the Company is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated March 4, 2014

Preliminary Prospectus Supplement to Prospectus dated June 17, 2011

Shares of Common Stock

The Company is offering up to shares of its common stock at a price per share of $. None of the Company's executive officers, directors or other significant investors will be selling any shares of common stock in this offering.

The Company's common stock is listed on the NASDAQ Global Market under the symbol “ANIP.” The last reported sale price of the Company's common stock on the NASDAQ Global Market on March 3, 2014 was $31.75 per share.

Investing in the Company's common stock involves a high degree of risk. See “Risk Factors” beginning on Page S-8 of this prospectus supplement and the risk factors incorporated by reference into this prospectus supplement from the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

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 prospectus to which it relates is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions (1)	$	$
Proceeds to the Company, before expenses	$	$

(1) See “Underwriting” for a describtion of compensation payable to the underwriters

The Company has granted the underwriters the option to purchase within 30 days from the date of this prospectus supplement up to 15% of the offered number of shares of common stock at the public offering price less underwriting discounts and commissions.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on March , 2014.

Oppenheimer & Co. Roth Capital Partners

The date of this prospectus supplement is
March , 2014

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any related free writing prospectus that the Company may provide to you. The Company has not authorized anyone to provide you with information that is different. The Company is offering to sell common stock and seeking offers to buy common stock only in jurisdictions where the offers and sales are permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, any related free writing prospectus and the documents incorporated by reference herein and therein is accurate only as of their respective dates.

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is comprised of two parts. The first part is this prospectus supplement, which describes the terms of the Company's offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus. The accompanying prospectus provides more general information about the securities the Company may offer from to time and is dated as of June 17, 2011; accordingly, some of the information in the accompanying prospectus does not apply to this offering. 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 prospectus or any document incorporated by reference herein and therein, on the other hand, you should rely on the information in this prospectus supplement. You should read this prospectus supplement, the accompanying prospectus and any information incorporated by reference before you make any investment decision.

Except where the context requires otherwise, in this prospectus supplement references to “ANI” or “the Company” refer, unless the context requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware limited liability company, and its consolidated subsidiary, ANIP Acquisition Company (“ANIP”). References to the "Merger" refer to the merger of BioSante Pharmaceuticals, Inc. ("BioSante") and ANIP, completed on June 19, 2013, wherein ANI Merger Sub, Inc., a wholly owned subsidiary of BioSante, merged with and into ANIP with ANIP continuing as the surviving company and becoming a wholly owned subsidiary of BioSante.

AVAILABLE INFORMATION

ANI Pharmaceuticals, Inc., and its consolidated subsidiary, ANIP Acquisition Company (together, the “Company” or "ANI"), files annual, quarterly and current reports, proxy statements and other information required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), with the Securities and Exchange Commission ("SEC"). The Company makes available free of charge on its website (www.anipharmaceuticals.com) its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those filings as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Also posted on the Company's website in the “Investors — Corporate Governance” section are the Company's Corporate Governance Guidelines, Code of Ethics and the charters for the Audit and Finance, Compensation, and Nominating and Corporate Governance Committees. Information on, or accessible through, the Company's website is not a part of, and is not incorporated into, this report or any other SEC filing. Copies of ANI's SEC filings or corporate governance materials are available without charge upon written request to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

Any materials the Company files with the SEC are also publicly available through the SEC’s website (www.sec.gov) or may be read and copied at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, DC 20549.

Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

INCORPORATION BY REFERENCE

The Company filed a registration statement on Form S-3 with the SEC to register the common stock offered by this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not include all the information contained in the registration statement because certain parts of the registration statement are omitted in accordance with the rules and regulations of the SEC.

The SEC allows the Company to incorporate information from documents that it has filed or will file with the SEC into this prospectus supplement by making reference to those documents in this prospectus supplement. This "incorporation by reference" permits the Company to disclose important information to you by referencing these filed documents. Any information referenced this way is considered to be a part of this prospectus supplement and any information filed by the Company with the SEC subsequent to the date of this prospectus supplement will automatically be deemed to update and supersede this information.

The Company incorporates by reference the following documents which it has already filed with the SEC (other than any portion of such filings that are furnished under applicable SEC rules rather than filed):

- the Company's Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2013, filed with the SEC on February 28, 2014 and March 3, 2014, respectively; and

- the description of the Company's common stock contained in the Company's Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of July 17, 2013, Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of June 1, 2012, and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc. dated as of October 14, 2009, incorporate by reference to Exhibit 3.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013.

All documents and reports that the Company files with the SEC (other than any portion of such filings that are furnished under applicable SEC rules rather than filed) pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, from the date of this prospectus supplement until the termination of the offering of common stock under this prospectus supplement, shall be deemed to be incorporated in this prospectus supplement by reference.

The Company will provide without charge upon written or oral request to each person, including any beneficial owner, to whom a prospectus supplement is delivered, a copy of any and all of the documents which are incorporated by reference into this prospectus supplement and the accompanying prospectus but not delivered with this prospectus supplement and the accompanying prospectus (other than exhibits unless such exhibits are specifically incorporated by reference in such documents).

You may request a copy of these documents by writing to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein may be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act. Such statements include, but are not limited to, statements about the potential benefits of the recent Merger, the Company’s plans, objectives, expectations and intentions with respect to future operations and products, the anticipated financial position, operating results and growth prospects of the Company and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other wo similar meaning, derivations of such words and the use of future dates. Forward-looking statements by their nature

address matters that are, to different degrees, subject to change. You should not place undue reliance on those statements because they are subject to numerous uncertainties, risks and other factors relating to the Company's operations and business environment and other factors, all of which are difficult to predict and many of which are beyond the Company's control. Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may in the future face increased difficulty in importing raw materials and/or increased competition, for its Esterified Estrogen with Methyltestosterone Tablet product; competitive conditions for the Company's other products may intensify; the Company may be required to seek the approval of the U.S. Food and Drug Administration ("FDA") for its unapproved products or withdraw such products from the market; general business and economic conditions; the Company's expectations regarding trends in markets for the Company's current and planned products; the Company's future cash flow and its ability to support its operations; the Company's ability to obtain additional financing as needed; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance of such products; and the marketing success of the Company's licensees or sublicensees. These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements and risks that are included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference, including but not limited to the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on February 28, 2014, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in the Company's filings made under the securities laws, including the Company's quarterly reports on Form 10-Q and current reports on Form 8-K. There may be additional risks, uncertainties and factors that the Company does not currently view as material or that are not known. The forward-looking statements contained in this document are made only as of the date of this document. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein. This summary sets forth the material terms of this offering, but does not contain all of the information you should consider before investing in the Company's common stock. You should read this entire prospectus supplement and the accompanying prospectus, including the documents incorporated by reference herein and therein, carefully before making an investment decision, especially the risks of investing in the Company's common stock discussed under "Risk Factors" contained herein and in the documents incorporated by reference and the consolidated financial statements and notes to those consolidated financial statements incorporated by reference herein and therein.

Unless otherwise indicated, the information contained in this prospectus supplement assumes that the underwriters' option to purchase additional shares is not exercised.

Business Description

The Company is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. The Company has its own research and development team, manufacturing facilities, and sales and regulatory compliance personnel.

The Company's two manufacturing facilities have a combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet. The facilities are specialized with diverse capabilities, enabling the Company to manufacture liquid, powder, and oral solid-dose products, topicals, narcotics and other products required to be manufactured in a fully contained environment. The Company also performs contract manufacturing for other pharmaceutical companies.

The Company's strategy is to use its assets to develop, manufacture and market branded and generic specialty pharmaceutical products. By developing and acquiring carefully-considered prescription pharmaceuticals, management believes the Company will be able to continue to grow its business, expand and diversify its product portfolio, and create long-term value for its investors.

Product Development Considerations

The Company considers a variety of criteria in determining which products to develop or acquire, all of which influence the level of competition and profitability upon product launch. These criteria include:

- ***Formulation Complexity.*** The Company's development and manufacturing capabilities enable it to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that the Company intends to leverage in selecting products to develop or manufacture.

- ***Patent Status.*** The Company seeks to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.

- ***Market Size.*** When determining whether to develop or acquire an individual product, management reviews the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. The Company endeavors to manufacture products with sufficient market size to enable the Company to enter the market with a strong likelihood of being able to price its product both competitively and at a profit.

- ***Profit Potential.*** Management researches the availability and cost of active pharmaceutical ingredients along with anticipated market share in determining which products to develop or acquire. In determining the potential profit of a product, management forecasts the Company's anticipated market share, pricing, which includes expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

- ***Manufacturing.*** The Company generally seeks to develop and manufacture products at its own manufacturing plants in order to maximize the capacity and utilization of its facilities, to ensure quality control in its products, and to maximize profit potential.

- ***Competition.*** When determining whether to develop or acquire an individual product, management researches the existing and expected market share of generic competitors. The Company seeks to develop products for which it can obtain a large market share, and may decline to develop a product if management anticipates that many generic competitors will be entering that product's market. The Company's highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

The Company believes its strategies are effective in leveraging the Company's human and capital assets and will result in measurable growth of the Company's business. Since 2011, the Company has successfully:

- increased prescription product sales through market share gains on established products.
- acquired the New Drug Application ("NDA") for and began marketing Reglan(R).
- developed two new contract manufacturing customer relationships.
- established two external product development partnerships to bolster the internal pipeline.
- filed five Abbreviated New Drug Applications ("ANDAs") and developed a pipeline of seven additional ANDAs.
- entered into a contract to purchase the ANDAs for 31 previously marketed generic drug products, including 20 solid-oral immediate release products, four extended release products and seven liquid products for $12.5 million. This asset acquisition will help the Company expand and diversify its product lines over the next few years, help increase revenue, and reduce the Company's percentage of revenue derived from sales of unapproved products.

Products and Markets

Products

The Company's established product portfolio consists of both branded and generic pharmaceuticals, including:

Generic Products	**Branded Products**

Esterified Estrogen with Methyltestosterone Tablets	Cortenema®
Fluvoxamine Maleate Tablets	Reglan® Tablets
Hydrocortisone Enema	
Metoclopramide Syrup	

Opium Tincture

Esterified Estrogen with Methyltestosterone ("EEMT") is used to treat moderate to severe vasomotor symptoms of menopause, such as hot flashes and heart palpations that are not improved by estrogen medications alone. For the year ended December 31, 2013, EEMT comprised 33% of the Company's net sales, a substantial increase over the prior year wherein EEMT comprised only 9% of the Company's net sales. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in the Company's market share for the product and enabled the Company to significantly increase the price it charges for the product.

Fluvoxamine Maleate is used to treat obsessions and compulsions in patients with obsessive-compulsive disorder. It is generally used when the obsessions and compulsions in a patient interfere with the patient's ability to function socially and occupationally.

Hydrocortisone Enema and its branded equivalent, Cortenema® are used for the treatment of ulcerative colitis, especially distal forms, including ulcerative proctitis, ulcerative proctosigmoiditis, and left-sided ulcerative colitis. The products have also proved useful in some cases involving the transverse and ascending colons.

Metoclopramide syrup and its branded equivalent Reglan®, in tablet form, are prescribed for periods of four to twelve weeks for heartburn symptoms with gastroesophageal reflux disease ("GERD") when certain other treatments do not work. The products relieve daytime heartburn and heartburn after meals and also help ulcers in the esophagus to heal. The products also relieve symptoms of slow stomach emptying in people with diabetes and help treat symptoms such as nausea, vomiting, heartburn, feeling full long after a meal, and loss of appetite.

Opium Tincture is used is to treat severe diarrhea by slowing the movement of the intestines and decreasing the number and frequency of bowel movements.

Markets

In determining which products to pursue for development, the Company targets markets whose products are complex to manufacture and therefore have higher barriers to entry. These market factors provide opportunities for the Company's growth consistent with its competitive strengths at the same time that they decrease the number of potential competitors in the markets. These markets currently include hormone and steroidal drugs, oncolytics, and narcotics and complex formulations, including extended release and combination products.

Hormone and Steroidal Drugs

The market for hormone and steroidal drugs includes hormone therapy to alleviate menopausal symptoms in women, contraceptives, testosterone replacement therapies for men, and therapies for treating hormone-sensitive and other cancers. Hormone Therapy ("HT") has been an accepted medical treatment for alleviating the symptoms of menopause since the 1930s, with formal FDA approval for that use granted in 1942. Initially, HT consisted of estrogen only, but has evolved to include combination therapies of estrogen, progesterone and androgens. The Company targets niche products in the HT and steroidal products market for several reasons, including:

- hormone and steroid products are a core competency based on the Company’s manufacturing and product development teams' long history of manufacturing these types of products; and

- the aging baby boom population, of which women represent a majority, is expected to support continued growth in the HT market.

Oncolytics

The Company is positioned to develop and manufacture niche oncolytic (anti-cancer) drugs due to the capabilities of the Company's containment facility and its expertise in manufacturing segregation. In particular, the Company is targeting products subject to priority review by the FDA – those with no blocking patents and no generic competition. In addition to one such product already under development, the Company has identified additional priority review opportunities in oncolytics.

Narcotics

The Company's main manufacturing facility in Baudette, Minnesota is licensed by the DEA for the manufacture and distribution of Schedule II narcotics, i.e., drugs considered to have a high abuse risk but that also have safe and accepted medical uses in the United States. In addition to its existing pipeline of four ANDAs, the Company has identified additional product development opportunities in this market.

Contract Manufacturing

The Company manufactures pharmaceutical products for several branded and generic companies, which outsource production to the Company in order to:

- free-up internal resources to focus on sales and marketing as well as research and development;
- employ internal capacity to manufacture higher volume or more critical products; and
- utilize the Company’s specialized equipment and expertise

The Company considers contract manufacturing to be an important component of its ongoing business. Given its highly specialized manufacturing capabilities, the Company is focused on attracting niche contract manufacturing opportunities that fill idle capacity and offer high margins.

Corporate Information

The Company's principal executive offices are located at 210 Main Street West, Baudette, Minnesota 56623 and the Company's telephone number is (218) 634-3500. The Company's Internet address is www.anipharmaceuticals.com. The information on or accessible through the Company's website is not part of this prospectus supplement or the accompanying prospectus.

On June 19, 2013, pursuant to a merger agreement dated as of April 12, 2013, ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. became a wholly-owned subsidiary of BioSante Pharmaceuticals, Inc. in an all-stock, tax-free reorganization. The Merger was accounted for as a reverse acquisition, pursuant to which ANIP was considered the acquiring entity for accounting purposes. The Company is operating under the leadership of the ANIP management team and its board of directors is comprised of two former directors from BioSante and five former ANIP directors. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in the Company’s consolidated financial statements for all periods after completion of the Merger. In addition, in July 2013, the Company's stockholders approved and the Company subsequently effected (i) a one-for-six reverse stock split of the Company's common stock and class C special stock, with a proportional reduction in the number of authorized shares of its common stock, class C special stock and blank check preferred stock, and (ii) a change of the Company's name from “BioSante Pharmaceuticals, Inc.” to “ANI Pharmaceuticals, Inc.”

THE OFFERING

Common stock offered by the Company	shares of common stock.
Common stock to be outstanding immediately after this offering[(1)]	shares of common stock.
Over-allotment option	The Company has granted the underwriters the option to purchase within 30 days from the date of this prospectus supplement up to 15% of the offered number of shares of common stock at the public offering price less underwriting discounts.
Use of proceeds	The Company estimates that it will receive net proceeds of approximately $ million from the sale of common stock in this offering, after deducting underwriting discounts. If the underwriters exercise in full their option to purchase additional shares of common stock, we estimate that the net proceeds to the Company will be approximately $ million. The Company intends to apply all of the proceeds received in the offering, including any proceeds from the exercise of the underwriters' option to purchase additional shares of common stock to fund its operations, including: · to research, develop, commercialize and expand its drug products; · to acquire complementary businesses and technologies; and · for other working capital and other general corporate purposes.
Dividend policy	The Company does not anticipate paying any cash dividends on its common stock in the foreseeable future.
Risk factors	

	Investing in the Company's common stock involves significant risk. Please read the section entitled “Risk Factors” on page S-7 of this prospectus supplement and in the documents incorporated by reference, including the “Risk Factors” section in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 (as such may be supplemented or amended from time to time), for a discussion of some of the factors and material risks that you should consider before deciding to invest in the Company's common stock.
NASDAQ Global Market Symbol	ANIP

(1) Based on 9,647,441 shares of the Company's common stock outstanding as of March 3, 2014, and assumes that all of the shares offered hereby are sold. The number of shares of common stock outstanding:

- excludes 248,195 shares of common stock reserved for issuance under the Company's equity incentive plans, under which 112,554 shares of common stock are subject to outstanding awards as of March 3, 2014;
- excludes 666,473 shares of common stock reserved for issuance under currently outstanding warrants as of March 3, 2014; and
- assumes that the underwriters do not exercise the option to purchase up to an additional 15% of the offered number of shares of common stock at the public offering price less underwriting discounts.

RISK FACTORS

Investing in the Company's common stock involves a high degree of risk. Before deciding to invest in the Company's common stock, you should carefully consider the risk factors incorporated by reference into this prospectus supplement from the section entitled “Risk Factors” in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, as well as other information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus. The occurrence of any of these risks could materially and adversely affect the Company's business, prospects, financial condition, results of operations and cash flow, in which case the trading price of the Company's common stock would decline and you could lose all or part of your investment. Additionally, risks not currently known to the Company or that the Company now deems immaterial may also harm the Company and negatively affect investments in the Company.

Risk related to this offering

Management will have broad discretion as to the use of the proceeds from this offering, and the Company may not use the proceeds effectively.

The Company intends to use the net proceeds from this offering to research, develop, commercialize and expand its drug products, including in response to changing regulatory and competitive pressures. To accelerate its growth, the Company may determine to acquire complementary businesses and technologies. The Company intends to use the net proceeds from this offering for any such acquisitions. The Company also intends to use the net proceeds for other working capital and general corporate purposes.

The Company has not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. The Company's management will have broad discretion with respect to the use of proceeds of this offering. Purchasers in this offering will be relying on the judgment of the Company's management with regard to the use of these net proceeds. The results and effectiveness of the use of proceeds are uncertain, and the Company could spend the proceeds in ways that purchasers in this offering do not agree with or that do not improve the Company's results of operations or enhance the value of its common stock. The Company's failure to apply these funds effectively could have a material adverse effect on its business, prospects, financial condition and results of operations and cause the price of its common stock to decline. Until the net proceeds are used, they may be placed in investments that may not produce income or that may lose value.

Purchasers in this offering will experience immediate and substantial dilution in the net tangible book value per share of the common stock they purchase.

Since the price per share being offered is substantially higher than the net tangible book value per share of the Company's common stock outstanding prior to this offering, purchasers in this offering will suffer substantial dilution in the net tangible book value of the common stock they purchase in this offering. Based on the public offering price of $ per share, if you purchase shares in this offering, you will suffer immediate and substantial dilution of $ per share in the net tangible book value of the common stock. See the section entitled “Dilution.”

A substantial number of shares of common stock may be sold in the market following this offering, which may depress the market price for the Company common stock.

Sales of a substantial number of shares of the Company's common stock in the public market following this offering could cause the market price of the Company's common stock to decline. A substantial majority of the outstanding shares of the Company's common stock are, and the shares of common stock sold in this offering will be, freely tradable without restriction or further registration under the Securities Act. In addition, as of December 31, 2013, 806,527 shares of the Company's common stock were issuable upon exercise of outstanding options and warrants.

Purchasers in this offering may experience dilution if the Company issues additional equity securities in future fundraising transactions.

If the Company issues additional common stock, or securities convertible into or exchangeable or exercisable for common stock, whether in public offerings or private placements, the Company's stockholders, including investors who purchase shares in this offering, will experience dilution, and any such issuances may result in downward pressure on the price of the Company's common stock.

The Company’s ability to utilize its net operating loss and tax credit carryforwards in the future is subject to substantial limitations and, as a result of the offering, the Company may not be able to use certain identified net operating loss and tax credit carryforwards in the future, which the Company expects could result in increased tax payments in future periods.

Under Section 382 of the Internal Revenue Code of 1986, as amended (“the Code”), if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. On June 19, 2013, BioSante experienced an ownership change. Accordingly, the Company's ability to utilize BioSante’s net operating loss and tax credit carryforwards attributable to periods (or portions thereof) prior to June 19, 2013 is subject to substantial limitations. Although the Company does not currently believe that ANIP Acquisition Company also experienced an ownership change on such date, due to the complexity in the application of certain aspects of the law, there is no assurance that the IRS will not successfully challenge this determination, and if successfully challenged, the Company's ability to utilize ANIP's net operating loss and tax credit carryforwards attributable to periods (or portions thereof) prior to June 19, 2013 could be subject to substantial limitations. In addition, as a result of the offering, the Company believes that ANIP will likely experience an ownership change. Accordingly, the Company's ability to utilize ANIP's net operating loss and tax credit carryforwards attributable to periods (or portions thereof) prior to the offering will likely be subject to substantial limitations. These limitations, in turn, could result in increased future tax payments for the Company, which could be material.

The Company does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in the Company's common stock must come from increases in the fair market value and trading price of the Company's common stock.

The Company does not intend to pay any cash dividends in the foreseeable future; and, therefore, any return on an investment in the Company's common stock must come from increases in the fair market value and trading price of the Company's common stock.

Regulatory risk

The FDA in 2003 published a notice that it was initiating a proceeding to determine whether there was substantial evidence that combination products like the Company's EEMT product are effective. Since that time, the FDA has not taken any further actions. If the FDA were to make an adverse finding, the Company would be required to suspend or terminate its sales of EEMT products, which would have a material adverse impact on the Company's business, results of operations and financial position.

On April 14, 2003, the FDA published a notice in the Federal Register that it was initiating a proceeding to determine whether there was substantial evidence that combination products like the Company's EEMT product was effective for treatment of moderate to severe vasomotor symptoms associated with menopause not improved by estrogen alone. An adverse finding by the FDA with respect to the Company's EEMT product could result in it the product losing its Drug Efficacy Study Implementation, or DESI, classification. Such notice further provided that any party affected could request a hearing. Solvay Pharmaceuticals Inc., from which the Company acquired all of its rights in respect of the

EEMT products in 2007, timely requested such a hearing. As successor in interest to Solvay, the Company believes it is permitted to continue to sell and market its EEMT product pending any further action by FDA. There have been no further actions taken by FDA since 2003 in respect of the proceeding referred to in the notice and a hearing has not been held or scheduled. The Company is unsure what actions, if any, the FDA may take in respect of this matter in the future, or whether the information on which the FDA proceeded in 2003 remains valid.

USE OF PROCEEDS

The Company estimates that the net proceeds it will receive from this offering, based on the public offering price of $ per share, will be approximately $, after deducting the underwriting discount and estimated offering expenses payable by the Company, or approximately $, if the underwriters exercise their option to purchase additional shares in full.

The Company intends to use the net proceeds from this offering:

- to research, develop, commercialize and expand its drug products;
- to acquire complementary businesses and technologies; and

· for other working capital and general corporate purposes.

As of the date of this prospectus supplement, the Company has not identified any specific material proposed uses of the anticipated proceeds.

PRICE RANGE OF THE COMPANY'S COMMON STOCK

The Company’s common stock trades on the NASDAQ Global Market under the symbol “ANIP.” The following table shows the high and low sales price for ANIP common stock as reported by the NASDAQ Global Market for each quarter in the years ended December 31, 2013 and 2012, as adjusted for the one-for-six reverse stock splits that occurred on June 4, 2012 and July 17, 2013:

	High	Low
Year Ending December 31, 2013		
Fourth Quarter	$23.00	$9.75
Third Quarter	$9.94	$5.46
Second Quarter	$8.64	$4.80
First Quarter	$9.48	$6.60
Year Ending December 31, 2012		
Fourth Quarter	$11.82	$6.48
Third Quarter	$15.72	$7.26
Second Quarter	$27.36	$12.00
First Quarter	$44.28	$15.84

On March 3, 2014, the closing sale price of the Company's common stock as reported on the NASDAQ Global Market was $31.75 per share. The foregoing table shows only historical comparisons. These comparisons may not provide meaningful information to you in determining whether to purchase shares of the Company's common stock. You are urged to obtain current market quotations for the Company's common stock and to review carefully the other information contained in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in each, and any related free writing prospectus.

DILUTION

At December 31, 2013, the Company's net tangible book value was approximately $28.7 million, or approximately $2.98 per share. Net tangible book value is calculated as the Company's total tangible assets minus the Company's total liabilities at December 31, 2013, and net tangible book value per share is the net tangible book value as divided

by the total common shares outstanding as of December 31, 2013. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of shares of common stock in this offering at a sales price of $ per share, and after deducting the underwriting discount and estimated offering expenses, the Company's pro forma as adjusted net tangible book value at December 31, 2013 would have been approximately $, or approximately $ per share. The following table illustrates this dilution:

Public offering price per share	$	
Net tangible book value per share at December 31, 2013		$2.98
Increase per share attributable to new investors for this offering		$
Pro forma as adjusted net tangible book value per share as of December 31, 2013 after giving effect to this offering	$	
Dilution per share to new investors	$	

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value would increase to approximately $ or $ per share representing dilution to purchasers in this offering of $ per share.

The number of shares of common stock to be outstanding after the offering is based on 9,619,941 shares of the Company's common stock outstanding as of December 31, 2013, and assumes that all of the shares offered hereby are sold. The number of shares of common stock outstanding:

- excludes 255,695 shares of common stock reserved for issuance under the Company's equity incentive plans, under which 120,054 shares of common stock are subject to outstanding awards as of December 31, 2013;
- excludes 686,473 shares of common stock reserved for issuance under currently outstanding warrants as of December 31, 2013; and
- assumes that the underwriters do not exercise the option to purchase up to an additional 15% of the offered number of shares of common stock at the public offering price less underwriting discounts.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement to be dated on or about March , 2014, between ANI and Oppenheimer & Co. and Roth Capital Partners, as representatives of the underwriters named in the table below, the Company has agreed to sell to the underwriters and the underwriters have severally agreed to purchase from the Company, the number of common shares set forth opposite its name in the table below:

Underwriter	Number of Shares
Oppenheimer & Co. Inc.	
Roth Capital Partners, LLC	
Total	

The underwriters have agreed to purchase all of the shares offered by this prospectus supplement (other than those covered by the over-allotment option described below) if any are purchased. Under the underwriting agreement, if an underwriter defaults in its commitment to purchase shares, the commitment of the non-defaulting underwriter may be increased or the underwriting agreement may be terminated, depending on the circumstances.

The shares offered hereby should be ready for delivery on or about March , 2014 against payment in immediately available funds. The underwriters are offering the shares subject to various conditions and may reject all or part of any order. The representatives have advised the Company that the underwriters propose to offer the shares directly to the public at the public offering price that appears on the cover page of this prospectus. In addition, the representatives may offer some of the shares to other securities dealers at such price less a concession of $ per share. The underwriters may also allow, and such dealers may reallow, a concession not in excess of $ per share to other dealers. After the shares are released for sale to the public, the representatives may change the offering price and other selling terms at various times.

The Company has granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase a maximum of additional shares from us to cover overallotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the initial public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to public will be $ and the total proceeds to the Company will be $. The underwriters have severally agreed that, to the extent the over-allotment option is exercised, each will purchase a number of additional shares proportionate to the underwriter’s initial amount reflected in the foregoing table.

The following table provides information regarding the amount of the discount to be paid by the Company to the underwriters:

Per Share	Total Without Exercise of Over-Allotment Option	Total With Full Exercise of Over-Allotment Option
$	$	$

In addition, the Company has agreed to reimburse the underwriters for certain out-of-pocket expenses incurred by them in connection with this offering up to $75,000 in the aggregate.

The Company estimates that the total expenses of the offering, excluding the underwriting discount, will be approximately $.

The Company has agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

The Company and its officers and directors have agreed to a 90-day “lock up” with respect to shares of common stock that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus, the Company and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of the representatives. The lock-up restriction will not apply to: (i) sales of up to 169,185 shares of common stock by Meridian Venture Partners II, L.P. ("MVP II"), a stockholder of the Company that beneficially owned 2,819,744 shares of the Company's common stock as of March 3, 2014. Robert E. Brown, Jr., a director of ANI, is the President, sole stockholder and sole director of Meridian Venture Partners II, Co. ("MVP Corp."), the sole stockholder, sole director and President of MVP Management Company ("MVP Management") d/b/a MVP Capital Partners, which is the management company for MVP II, as well as a limited partner of Meridian Venture Partners II GP, L.P. ("GP") and one of two principals of MVP II. Thomas A. Penn, a director of ANI, is a Vice President of MVP Corp. and an employee of MVP Management, a limited partner of GP and one of the two principals of MVP II; (ii) sales of up to 48,506 shares of common stock by FA Private Equity Fund IV, L.P., FA Private Equity Fund IV GmbH & Co. Beteiligungs KG, The Productivity Fund IV Liquidating Trust, The Productivity Fund IV Advisors Fund Liquidating Trust (collectively, the "First Analysis Funds"), stockholders of the Company that beneficially owned 808,440 shares of the Company's common stock as of March 3, 2014. Tracy Marshbanks, a director of ANI, is an employee of the First Analysis Funds; (iii) sales of up to 33,458 shares of common stock by Argentum Capital Partners II, L.P., a stockholder of the Company that owned 557,640 shares of the Company's common stock as of March 3, 2014. Daniel Raynor, a director of ANI, is the co-managing member of the general partner of Argentum Capital Partners II, L.P. and (iv) sales by Ms. Arnold of up to 2,000 shares of common stock. In addition, Arthur S. Przybyl, ANI's President and Chief Executive Officer, and Charlotte C. Arnold, ANI's Chief Financial Officer, each established Rule 10b5-1 sales plans on August 12, 2013, the proceeds of which sales are used to pay required tax withholding amounts related to shares received by them in

connection with the Merger. During the lock-up period, Mr. Przybyl may sell up to 5,641 shares of Common Stock and Ms. Arnold may sell up to 1,357 shares of common stock, in each case under their existing Rule 10b5-1 Plans.

Rules of the Securities and Exchange Commission may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions—The representatives may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

- Over-allotments and syndicate covering transactions—The underwriters may sell more shares of the Company's common stock in connection with this offering than the number of shares that they have committed to purchase. This overallotment creates a short position for the underwriters. This short sales position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close 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 over-allotment option. Naked short sales are short sales in excess of the over-allotment option. 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, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

- Penalty bids—If the representatives purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.

- Passive market making—Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of the Company's common stock may have the effect of raising or maintaining the market price of the Company's common stock or preventing or mitigating a decline in the market price of the Company's common stock. As a result, the price of the Company's common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither the Company nor the underwriters makes any representation or prediction as to the effect that the transactions described above may have on the price of the Company's common stock. These transactions may occur on the NASDAQ Global Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

The Company's common stock is traded on the NASDAQ Global Market under the symbol "ANIP."

Electronic Delivery of Prospectus. A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter's web site and any information contained in any other web site maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part.

Certain Relationships. In the ordinary course of their various business activities, the underwriters and certain of their 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 Company. The underwriters and certain of their 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.

VALIDITY OF THE COMMON STOCK

The validity of the shares of common stock offered hereby will be passed upon for the Company by Dentons US LLP, New York, New York. Goodwin Procter LLP, New York, New York is acting as counsel to the underwriters in this offering.

EXPERTS

The consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity/(deficit), and cash flows for each of the years in the two-year period ended December 31, 2013, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated by reference, in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

FILED PURSUANT TO RULE 424(b)(2)

FILE NUMBER 333-174597

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

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

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.

1

We believe LibiGel remains the lead pharmaceutical product in the U.S. in active development for the treatment of hypoactive sexual desire disorder (HSDD) in menopausal women, and that it has the potential to be the first product approved by the FDA for this common and unmet medical need. We believe based on agreements with the FDA, including an SPA, that two Phase III safety and efficacy trials and a minimum average exposure to LibiGel per subject of 12 months in a Phase III cardiovascular and breast cancer safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval and product launch, are the essential requirements for submission and, if successful, approval by the FDA of 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.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.

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, expect, intend, plan, predict, anticipate, estimate, approximate, contemplate or continue or the negat 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, 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.

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.

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.

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;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price (or its manner of calculation) and conversion period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- whether interests in the preferred stock will be represented by depositary shares;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

Transfer Agent and Registrar

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

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally

to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below.

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

- 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

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or

warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

DESCRIPTION OF UNITS

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

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

General

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.

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.

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.

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 reallowed or paid to dealers; and

- any securities exchanges on which such securities may be listed.

15

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 reallowed 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.

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.

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 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.

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

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.

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.

$150,000,000

Common Stock

Preferred Stock

Warrants

Units

PROSPECTUS

June 17, 2011