BIOSANTE PHARMACEUTICALS INC
Form 10-K
March 16, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

x **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2008

o **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission file number 001-31812

BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
111 Barclay Boulevard **Lincolnshire, Illinois**	**60069**
(Address of principal executive offices)	(Zip Code)

(847) 478-0500

(Registrant s telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC** **(NASDAQ Global Market)**

Securities registered under Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES o NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES o NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES o NO x

The aggregate market value of the registrant s common stock, excluding shares beneficially owned by affiliates, computed by reference to the closing sales price at which the common stock was last sold as of June 30, 2008 (the last business day of the registrant s second quarter) as reported by The NASDAQ Global Market on that date was $115,885,108.

As of March 13, 2009, 27,042,764 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this annual report on Form 10-K incorporates by reference information (to the extent specific sections are referred to herein) from the registrant s Proxy Statement for its 2009 Annual Meeting of Stockholders to be held in June 2009.

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This annual report on Form 10-K contains forward-looking statements. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as may, will, should, expects, anticipates, contemplates, estimates, believes, plans, projected, predicts, potential or continue or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including those listed below under the headings Part I. Item I. Description of Business Forward-Looking Statement and Part I. Item 1A. Risk Factors. These factors may cause our actual results to differ materially from any forward-looking statement.

As used in this report, references to BioSante, the company, we, our or us, unless the context otherwise requires, refer to BioSante Pharmaceuticals, Inc.

We own or have the rights to use various trademarks, trade names or service marks, including BioSante®, Elestrin , LibiGel®, Bio-E-Gel®, Bio-E/P-Gel , LibiGel-E/T , Bio-T-Gel , The Pill-Plus , BioVant , BioLook , CAP-Oral and BioAir . This report also contains trademarks, trade

names and service marks that are owned by other persons or entities.

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PART I

Item 1. DESCRIPTION OF BUSINESS

General

We are a specialty pharmaceutical company focused on developing products for female sexual health, menopause, contraception and male hypogonadism. Our primary products are gel formulations of testosterone and estradiol. We also are engaged in the development of our proprietary calcium phosphate nanotechnology, or CaP, primarily for aesthetic medicine, novel vaccines and drug delivery.

The following is a list of our key products:

- LibiGel once daily transdermal testosterone gel in Phase III clinical development under a Special Protocol Assessment (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 in development for the treatment of hypogonadism, or testosterone deficiency, in men.

- The Pill-Plus (triple hormone contraceptive) once daily use of various combinations of estrogens, progestogens and androgens in development for the treatment of FSD in women using oral or transdermal contraceptives.

In order to market our products in the United States, we are required to obtain approval of a new drug application (NDA) or an abbreviated NDA (ANDA) for each such product from the FDA. With respect to Elestrin, we submitted an NDA in February 2006 and received non-conditional and full approval of the NDA from the FDA in December 2006. In addition, we received three years of marketing exclusivity for Elestrin. In November 2006, we entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. (Bradley) which was subsequently purchased by Nycomed US Inc. (Nycomed) in February 2008, for the marketing of Elestrin in the United States, which agreement was subsequently terminated by the parties effective August 6, 2008. Pursuant to the termination, release and settlement agreement with Nycomed, we reacquired Elestrin and assumed all manufacturing, distribution and marketing responsibilities for Elestrin. In December 2008, we entered into a sublicense agreement and an asset purchase agreement with Azur Pharma International II Limited (Azur) for the marketing of Elestrin and

the sale of certain assets related to Elestrin. Azur has agreed to promote Elestrin using its women s health sales force that targets estrogen prescribing physicians in the U.S. comprised mostly of gynecologists. In addition, Azur has agreed to minimum marketing expenditures in the first two years of the agreement.

In December 2008, we signed an exclusive agreement with PharmaSwiss SA for the marketing of Elestrin in Israel. PharmaSwiss is responsible for regulatory and marketing activities in Israel. PharmaSwiss intends to submit our approved U.S. NDA to the Israeli authorities based on our results and manufacturing information. Approval of Elestrin in Israel is expected approximately one year after such submission.

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Prior to submitting an NDA or ANDA for our other products, the products must undergo additional human clinical trials. With respect to LibiGel, we believe, based on agreements with the FDA, including a Special Protocol Assessment (SPA) received in January 2008, that two Phase III safety and efficacy trials and one year of LibiGel exposure in a Phase III cardiovascular safety study with a four-year follow-up post-NDA filing and potentially post-FDA approval are the essential requirements for submission and, if successful, approval by the FDA of an NDA for LibiGel for the treatment of FSD, specifically, hypoactive sexual desire disorder (HSDD) in menopausal women. The SPA process and agreement affirms that the FDA agrees that the LibiGel Phase III safety and efficacy clinical trial design, clinical endpoints, sample size, planned conduct and statistical analyses are acceptable to support regulatory approval. Further, it indicates that these agreed measures will serve as the basis for regulatory review and any decision by the FDA to approve an NDA for LibiGel. The SPA trials use our validated instruments to measure the clinical endpoints. The January 2008 SPA agreement covers the pivotal Phase III safety and efficacy trials of LibiGel in the treatment of FSD for surgically menopausal women. In July 2008, we received another SPA for our LibiGel program in the treatment of FSD, specifically, HSDD in naturally menopausal women.

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

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

- BioLook facial line filler in development using proprietary CaP technology in the area of aesthetic medicine.

- BioVant proprietary CaP adjuvant and delivery technology in development for improved versions of current vaccines and new vaccines against viral and bacterial infections and autoimmune diseases, among others. BioVant also serves as a delivery system for non-injected delivery of vaccines.

- BioOral a delivery system using CaP technology for oral/buccal/intranasal administration of proteins and other therapies that currently must be injected.

- BioAir a delivery system using CaP technology for inhalable versions of proteins and other therapies that currently must be injected.

One of our strategic goals is 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 from time to time, we engage in discussions with third parties regarding the licensure, sale or acquisition of our products and technologies or a merger, sale or acquisition of our company. In June 2008, we announced that we engaged Deutsche Bank Securities Inc., an investment banking firm, as our strategic advisor in connection with our ongoing process to explore strategic alternatives in order to maximize value to our stockholders. No timetable has been set for completion of the exploration of strategic alternatives, and there can be no assurance

that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive

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terms. We do not intend to disclose developments with respect to the process unless and until the exploration of strategic alternatives has been completed.

Hormone Therapy Market