# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 14, 2010

## BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or Other Jurisdiction of Incorporation)

**001-31812** (Commission File Number)

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

111 Barclay Boulevard
Lincolnshire, Illinois
(Address of Principal Executive Offices)

**60069** (Zip Code)

(847) 478-0500

(Registrant's Telephone Number, Including Area Code)

N/A

(Former Name or Former Address, If Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Section 2 — Financial Information

## Item 2.02. Results of Operations and Financial Condition.

On May 14, 2010, BioSante Pharmaceuticals, Inc. publicly announced its financial results for the first quarter ended March 31, 2010. For further information, please refer to the news release attached hereto as Exhibit 99.1, which is incorporated by reference herein.

The information contained in this Item 2.02 and Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any filings made by BioSante Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

## **Section 9** — **Financial Statements and Exhibits**

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

#### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Phillip B. Donenberg

Phillip B. Donenberg

Chief Financial Officer, Treasurer and Secretary

Dated: May 14, 2010

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## BIOSANTE PHARMACEUTICALS, INC.

## FORM 8-K Exhibit Index

Exhibit<br/>No.DescriptionMethod of Filing99.1News Release issued May 14, 2010Furnished herewith

BioSante Pharmaceuticals, Inc.

111 Barclay Boulevard Lincolnshire, Illinois 60069 www.biosantepharma.com



FOR IMMEDIATE RELEASE NASDAQ: BPAX

#### BioSante Pharmaceuticals Reports Recent Developments and First Quarter Financial Results

**LINCOLNSHIRE, Illinois** - **(May 14, 2010)** --- BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX) today reported on its recent developments and financial results for the first quarter, and its cash balance as of March 31, 2010.

#### **Recent BioSante Developments**

- **Closed \$18 million Registered Direct Financing:** BioSante added approximately \$18 million to its cash balance as a result of its March 2010 registered direct offering, bringing its March 31, 2010 cash balance to approximately \$41.2 million.
- **Positive LibiGel® Safety Data in Ongoing Phase III Clinical Development Program**: For the second time, unblinded safety data were reviewed by the independent Data Monitoring Committee (DMC) of the LibiGel Cardiovascular and Breast Cancer Safety Study. The LibiGel safety study continues, with no modifications, based on the excellent safety profile observed to date.
- Positive GVAX Clinical Results and Two GVAX Orphan Drug Designations: BioSante reported positive Phase II clinical results for GVAX AML in the treatment of acute myeloid leukemia (AML) and GVAX CML in the treatment of chronic myeloid leukemia (CML). BioSante also received two Orphan Drug designations from the FDA's Office of Orphan Products Development for GVAX AML Vaccine in the treatment of acute myeloid leukemia and GVAX Pancreas Vaccine in the treatment of pancreatic cancer.
- **Reinitiation of Prostate Cancer Vaccine Development:** Development of GVAX Prostate Cancer Vaccine (GVAX Prostate) has been reinitiated for the treatment of prostate cancer. Manufacturing of new GVAX Prostate is in process, regulatory steps to lift the GVAX Prostate clinical hold prior to trial initiation are being taken, and prostate cancer patients are expected to be treated in a Phase II human clinical trial anticipated to begin in the fourth quarter of 2010. This is a cooperative program among BioSante, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and the Prostate Cancer Foundation.
- 2A/Furin Option Agreement: BioSante entered into an Option Agreement with an undisclosed large multi-national pharmaceutical company to obtain a non-exclusive worldwide license for the use of its 2A/Furin technology to express antibodies. BioSante's 2A/Furin technology allows rapid generation of stable, high producing antibody cell lines. The subsequent cell lines may greatly reduce the time and lower the cost of antibody production compared to current commercial technologies.

#### First Quarter 2010 Financial Results

BioSante's cash balance as of March 31, 2010 was approximately \$41.2 million, as compared to a cash balance of approximately \$29.9 million on December 31, 2009.

BioSante incurred a net loss of approximately \$10.5 million or \$(0.19) per share for the quarter ended March 31, 2010, compared to a net loss of \$4.1 million or \$(0.15) per share for the same period in 2009. This expected increase in net loss was due primarily to the conduct of the three ongoing LibiGel® (testosterone gel) Phase III clinical studies to support submission of a new drug application (NDA) and U.S. Food and Drug Administration (FDA) approval. The LibiGel Phase III safety and efficacy studies are being conducted under an FDA approved SPA (special protocol assessment).

#### About BioSante Pharmaceuticals, Inc.

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. BioSante's lead products include LibiGel® (transdermal testosterone gel) in Phase III clinical development by BioSante under a U.S. Food and Drug Administration (FDA) SPA (Special Protocol Assessment) for the treatment of female sexual dysfunction (FSD), and Elestrin<sup>TM</sup> (estradiol gel) developed through FDA approval by BioSante, indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause, currently marketed in the U.S. Also in development is a portfolio of cancer vaccines (GVAX), two of which have been granted orphan drug designation, currently in several Phase II clinical trials, at minimal cost to BioSante. Other products in development are Bio-T-Gel<sup>TM</sup>, a testosterone gel for male hypogonadism, licensed to Teva Pharmaceuticals (NASDAQ: TEVA) and an oral contraceptive in Phase II clinical development using BioSante patented technology. The current market in the U.S. for estrogen and testosterone products is approximately \$2.5 billion and for oral contraceptives approximately \$3 billion. The company also is developing its calcium phosphate technology (CaP) for aesthetic medicine (BioLook<sup>TM</sup>), as a vaccine adjuvant, including for an H1N1 (swine flu) vaccine, and drug delivery as well as seeking opportunities for its 2A/Furin and other technologies. Additional information is available online at: www.biosantepharma.com.

## **Forward-Looking Statements**

To the extent any statements made in this news release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about BioSante's plans, objectives, expectations and intentions with respect to future operations and products and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause BioSante's actual results to be materially different than those expressed in or implied by BioSante's forward-looking statements. For BioSante, particular uncertainties and risks include, among others, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the

marketing success of BioSante's licensees or sublicensees; the success of clinical testing; and BioSante's need for and ability to obtain additional financing. More detailed information on these and additional factors that could affect BioSante's actual results are described in BioSante's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. All forward-looking statements in this news release speak only as of the date of this news release. BioSante undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For more information, please contact: McKinney/Chicago Alan Zachary (312) 944-6784 ext. 316; azachary@mckinneychicago.com