## 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): March 16, 2011

## **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:

o 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 March 16, 2011, BioSante Pharmaceuticals, Inc. publicly announced its financial results for the year ended December 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.

99.1

News Release issued March 16, 2011

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 Senior Vice President of Finance, Chief Financial Officer and Secretary

Dated: March 16, 2011

3

### **BIOSANTE PHARMACEUTICALS, INC.**

## FORM 8-K Exhibit Index

Exhibit No.	Description	Method of Filing
99.1	News Release issued March 16, 2011	Furnished herewith
	4	



## FOR IMMEDIATE RELEASE

**BioSante Pharmaceuticals, Inc.** 111 Barclay Boulevard Lincolnshire, Illinois 60069 www.biosantepharma.com

#### NASDAQ: BPAX

## BioSante Pharmaceuticals Reports Financial Results for 2010 and Clinical Development and Business Highlights

Lincolnshire, Illinois — March 16, 2011 — BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX) today announced financial results for the year ended December 31, 2010 and clinical development and business highlights.

### **Financial Results for 2010**

As of December 31, 2010, BioSante's cash balance was approximately \$38.2 million as compared to \$29.9 million at December 31, 2009. Subsequently, on March 9, 2011, the company completed a registered direct offering, resulting in net proceeds of approximately \$23.8 million. Consequently, on March 10, 2011, BioSante's cash balance was approximately \$54 million. "We are very pleased with our progress over the last year as well as our current cash balance," said Stephen M. Simes, BioSante's president and CEO. "Through careful cash management and our financing strategy, we believe we now have removed any near-term financial risk from BioSante, and our current cash balance is sufficient to finance our operations and LibiGel clinical development well into 2012, without need for additional funds."

BioSante's net loss was \$46.2 million or \$0.70 per share for the year ended December 31, 2010, compared to a net loss of \$47.5 million or \$1.40 per share for 2009. This decrease in net loss was due primarily to transaction and non-cash technology related expenses in 2009, associated with the company's merger with Cell Genesys, Inc., offset by increased LibiGel<sup>®</sup> clinical development expenses in 2010.

## LibiGel<sup>®</sup> Clinical Highlights

The increased LibiGel clinical development expenses during 2010 was the result of steady progress in BioSante's LibiGel Phase III clinical program. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women, for which there is no FDA-approved product. In February 2011, the company announced completion of enrollment in the first of two LibiGel Phase III efficacy trials, and expects enrollment in the second efficacy trial to be completed in the near future. BioSante continues to expect data from the two efficacy trials in Fall 2011.

BioSante also is conducting a Phase III safety study of LibiGel which has enrolled almost 3,000 women resulting in 3,200 women-years of safety data. A maximum of 4,000 patients will be enrolled in the study and be followed for a total of five years. However, BioSante can use the safety study data as part of a New Drug Application (NDA) submission after an average of 12 months of exposure to LibiGel or placebo. The study's independent data monitoring committee (DMC) has met five times and voted unanimously each time that the study should continue as per FDA-agreed protocol, without modification.

#### **Pipeline Updates**

In addition to the LibiGel clinical program, BioSante has a number of pipeline candidates in development, including a broad portfolio of cancer vaccines. Clinical trials of BioSante's Cancer Vaccines are being conducted to treat leukemia, pancreatic cancer and breast cancer, among other cancer types. These studies are being conducted in cooperation with The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, and are sponsored or funded at little or no cost to BioSante. Through March 2011, four of these cancer vaccines, the Pancreas Cancer Vaccine, Chronic Myeloid Leukemia Cancer Vaccine, Melanoma Cancer Vaccine, and Acute Myeloid Leukemia Cancer Vaccine, have received FDA Orphan Drug designations.

BioSante's pipeline also includes Bio-T-Gel<sup>™</sup>, a testosterone gel for male hypogonadism, which is licensed to Teva Pharmaceuticals for development and marketing. BioSante also has a licensing agreement with Pantarhei Bioscience for the development of the Pill-Plus triple component oral contraceptive which uses patented technology from BioSante. Pantarhei is engaged in several Phase II/III clinical studies with this product.

### 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<sup>®</sup> (transdermal testosterone gel) for the treatment of female

sexual dysfunction (FSD) which is in Phase III clinical development under a U.S. Food and Drug Administration (FDA) Special Protocol Assessment. BioSante also is developing a portfolio of cancer vaccines, four of which have been granted Orphan Drug designation, and are currently in several Phase II clinical trials. Other products in development are Bio-T-Gel<sup>TM</sup>, a testosterone gel for male hypogonadism licensed to Teva Pharmaceuticals and an oral contraceptive in Phase II clinical development using BioSante patented technology. The company also is seeking opportunities for its 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 "expects," "continues," "plans," "will," "potential," "could," "can," "believe," "intends," "plans," "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. 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.

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