

**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):
May10, 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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- 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 10, 2011, BioSante Pharmaceuticals, Inc. publicly announced its financial results for the first quarter ended March 31, 2011. 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

Description

News Release issued May 10, 2011

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: May 10, 2011

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BIOSANTE PHARMACEUTICALS, INC.

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Exhibit No.	Description	Method of Filing
99.1	News Release issued May 10, 2011	Furnished herewith

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

FOR IMMEDIATE RELEASE

NASDAQ: BPAX

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

LINCOLNSHIRE, Illinois - (May 10, 2011) — BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX) today reported on its financial results for the first quarter, cash balance as of March 31, 2011 and recent developments.

First Quarter 2011 Financial Results

BioSante's cash balance as of March 31, 2011 was approximately \$51.3 million, compared to a cash balance of approximately \$38.2 million on December 31, 2010.

BioSante incurred a net loss of approximately \$17.3 million or \$(0.20) per share for the quarter ended March 31, 2011, compared to a net loss of \$10.5 million or \$(0.19) per share for the same period in 2010. 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) for U.S. Food and Drug Administration (FDA) approval.

Recent BioSante Developments

- **LibiGel® Phase III Efficacy Trials Enrollment Completed:** BioSante completed enrollment of subjects in its two pivotal Phase III LibiGel (testosterone gel) efficacy trials in the first quarter. The efficacy trials are being conducted under an FDA-approved special protocol assessment (SPA) agreement. 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.
- **LibiGel Phase III Safety Study Continues:** For the fifth time, unblinded safety data were reviewed by the independent Data Monitoring Committee (DMC) of the LibiGel Cardiovascular and Breast Cancer Safety Study. As per DMC recommendation, the LibiGel safety study continues, with no modifications.
- **Bio-T-Gel™ New Drug Application (NDA) Filed by BioSante Licensee, Teva Pharmaceuticals:** An NDA for Bio-T-Gel (testosterone gel) for the treatment of male hypogonadism, was accepted for filing by the FDA following submission by a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA). The FDA has assigned a PDUFA date of November 14, 2011. The PDUFA date is the target date for the FDA to complete its review of the NDA.
- **Pancreas Cancer Vaccine Positive Clinical Results and Melanoma Orphan Drug Designation:** BioSante reported positive Phase II clinical results for its Pancreas Cancer Vaccine. The vaccine increased the median survival of resected pancreatic cancer patients from 15 to 20 months, as reported in published data, to 24.8 months, an increase of more than 25 percent. In addition, the vaccine demonstrated a 35 percent increase in one year survival, from 63 percent to 85 percent. BioSante also received Orphan Drug designation from the FDA's Office of Orphan Products Development for its Melanoma Cancer Vaccine.
- **Closed \$25.1 million Registered Direct Financing:** BioSante closed a registered direct offering in March 2011, bringing its March 31, 2011 cash balance to approximately \$51.3 million. BioSante's management believes this cash balance will be sufficient to finance operations and LibiGel clinical development well into 2012, without the need for additional funds.

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) 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's first FDA-approved product is Elestrin™ (estradiol gel) indicated for the treatment of hot flashes associated with menopause, marketed in the U.S. by Azur Pharma, BioSante's licensee. 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 BioSante products are Bio-T-Gel™, a testosterone gel for male hypogonadism, for which an NDA is pending with a PDUFA date of November 14, 2011, licensed to Teva Pharmaceuticals, and an oral contraceptive in Phase II clinical development using BioSante patented technology. 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 how long BioSante's cash balance should last, 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 burn rate, 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:

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For Media:

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