

**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): **December 14, 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)

Registrant's telephone number, including area code: **(847) 478-0500**

Not Applicable

(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))

Item 8.01 Other Events.

On December 14, 2011, BioSante Pharmaceuticals, Inc. issued a news release announcing top-line results from its two pivotal Phase III efficacy trials for LibiGel (testosterone gel) for the treatment of hypoactive sexual desire disorder in postmenopausal women. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Release dated December 14, 2011 (filed herewith)

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: December 14, 2011

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BIOSANTE PHARMACEUTICALS, INC.

FORM 8-K

Exhibit Index

Exhibit No.	Description	Method of Filing
99.1	News Release dated December 14, 2011	Filed herewith

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

FOR IMMEDIATE RELEASE

NASDAQ: BPAX

**BioSante Pharmaceuticals Announces
 Results from LibiGel® Efficacy Trials**

*LibiGel does not achieve primary endpoints in the treatment of
 hypoactive sexual desire disorder in postmenopausal women*

Conference call and webcast scheduled for 5:30 p.m. EST today

LINCOLNSHIRE, Illinois (December 14, 2011) — BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX) today announced top-line results from its two pivotal Phase III LibiGel (testosterone gel) efficacy trials. Initial analysis of the data from these trials shows that the trials did not meet the co-primary or secondary endpoints. Although there were no statistical differences in the endpoints, all results were in the appropriate directions. LibiGel is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in postmenopausal women, for which there is no FDA-approved product.

Subjects in the first trial, called BLOOM-1, who were treated with LibiGel showed an increase of 1.47 days with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.26 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.463. In BLOOM 1 there was an increase in the total number of satisfying sexual events of 3.87 from baseline (an increase of 83 percent) in the LibiGel group and in the placebo group there was an increase of 3.52 satisfying sexual events from baseline (an increase of 65 percent) for a p value of 0.698.

Subjects in BLOOM-2 who were treated with LibiGel showed an increase of 1.0 day with a satisfying sexual event compared to baseline, while those receiving placebo gel showed an increase of 1.28 days with a satisfying sexual event compared to baseline. The difference between these increases demonstrated a p value of 0.214.

Subjects in BLOOM-1 showed an increase in mean sexual desire of 0.03 over placebo, a p value of 0.672, while subjects in BLOOM-2 demonstrated an increase in mean sexual desire of 0.03 compared to placebo, a p value of 0.48. Subjects in both trials demonstrated a decrease in sexual distress when treated with LibiGel (p=0.569 and p=0.26) compared to baseline.

Importantly, and as seen in previous pharmacokinetic data, the LibiGel groups in both trials showed an increase in free testosterone levels compared to baseline and placebo. In BLOOM-1 mean free testosterone at baseline was approximately 1.19 pg/ml and 1.10 pg/ml in the placebo and LibiGel groups, respectively. In month six of the trial, free testosterone levels were approximately 1.35 pg/ml and 4.01 pg/ml in the placebo and LibiGel groups, respectively. In BLOOM-2 mean free testosterone at baseline was approximately 1.06 pg/ml and 1.19 pg/ml in the placebo and LibiGel group, respectively. In month six of the trial, free testosterone levels were approximately 1.09 pg/ml and 3.70 pg/ml in the placebo and LibiGel groups, respectively.

The trials demonstrated that LibiGel was generally well tolerated with a safety profile that appears to be comparable to placebo.

“We obviously are very disappointed by the Phase III LibiGel efficacy trial results. We have been committed to LibiGel for many years and we are committed to determining the future of LibiGel,” stated Stephen M. Simes, BioSante’s president & CEO. “We will continue to analyze the efficacy trial data fully and determine plans for our next steps in the LibiGel development plan, and provide an update at a later time. While the LibiGel Phase III cardiovascular and breast cancer safety study currently continues as planned, we will be analyzing the best

path forward for the study given the results reported today. I want to thank our entire BioSante clinical team and the clinical investigators for their tireless efforts in these trials, and I also want to thank the women enrolled in the BLOOM trials for their participation.”

The two completed Phase III efficacy trials were randomized, double-blind, placebo-controlled trials which enrolled 597 and 575 surgically menopausal women, respectively, for six-months of therapy. These trials were conducted according to an FDA-agreed special protocol assessment (SPA) agreement. The co-primary endpoints of both LibiGel efficacy trials were the change in the total number of days with a satisfying sexual event from baseline, and the change in mean sexual desire from baseline. The secondary endpoint for both trials was the change in sexual distress from baseline. Subjects recorded their sexually satisfying events in a validated daily diary, during a baseline period and during the full six months of therapy.

Conference Call and Webcast Information

A conference call and webcast will be held today at 5:30 p.m. EST to discuss the LibiGel efficacy trial results. Interested parties may join the call from within the U.S. by dialing 877-407-9205; outside the U.S., dial +1-201-689-8054. A live audio webcast will be available through BioSante’s website at www.biosantepharma.com. For those who are unable to participate in the live broadcast, a replay of the webcast will be available on BioSante’s website beginning 30 minutes thereafter.

About LibiGel®

LibiGel is a testosterone gel in Phase III clinical development for the treatment of women who suffer from female sexual dysfunction (FSD), specifically hypoactive sexual desire disorder (HSDD). The completed Phase III efficacy trials were double-blind, placebo-controlled trials that enrolled over 500 surgically menopausal women each for six-months of therapy, approximately half of whom were taking concomitant estrogen therapy and half of whom took no concomitant estrogen therapy. The completed efficacy trials were conducted according to an FDA-agreed special protocol assessment (SPA) agreement.

LibiGel is absorbed quickly through the skin after applying a once-daily pea-sized topical application on the upper arm that delivers testosterone to the bloodstream evenly over time.

BioSante continues to conduct the Phase III LibiGel safety study, a randomized, double-blind, placebo-controlled, multi-center, cardiovascular (CV) events and breast cancer study that has completed enrollment of 3,656 women and has accrued over 5,100 women-years of exposure, to date. The study is designed for a total of five years; however, BioSante could use the safety study data as part of a New Drug Application (NDA) submission after the last subject enrolled has completed 12 months of exposure to LibiGel or placebo.

The LibiGel safety study is tracking a predefined list of CV events, in agreement with the FDA, including CV death, myocardial infarction and stroke in women 50 years of age or older and suffering from at least two CV risk factors including hypertension and diabetes. The objective of the safety study is to demonstrate the relative safety of testosterone compared to placebo in the number of CV events. The incidence of breast cancer also is being tracked over the course of the study. The study represents the largest data base of the safety of testosterone in women.

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), specifically hypoactive sexual desire disorder (HSDD), which is in Phase III clinical development according to a U.S. Food and Drug Administration (FDA) Special Protocol Assessment (SPA). 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 a New Drug Application (NDA) is pending, licensed to Teva Pharmaceuticals, and an oral contraceptive in Phase II clinical development. Additional information is available online at: www.biosantepharma.com.

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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 the results of the two pivotal Phase III LibiGel efficacy trials, BioSante's plans, objectives, expectations and intentions with respect to the LibiGel development program, including in particular the LibiGel safety study and the anticipated timing of such study, and BioSante's other products, and other statements identified by words such as "will," "continue," "could," "believe," "intends," "expects," "anticipates," "plans," "may," "potential," other words of 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, 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, additional analyses of data from the LibiGel efficacy trials and any other LibiGel clinical trials may be inconsistent with previously announced results or previously conducted clinical trials or may produce negative or inconclusive results; there may be varying interpretations of data produced by clinical trials; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the success of clinical testing, the marketing success of BioSante's licensees or sublicensees; uncertainties relating to the future and costs of our product development programs and BioSante's need for and ability to obtain additional financing if needed. 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 and are based on BioSante's current beliefs and expectations. BioSante undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.
