

**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): **June 11, 2012**

**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**

**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))

**Item 8.01. Other Events.**

On June 11, 2012, BioSante Pharmaceuticals, Inc. ("BioSante") announced its intention to initiate two new LibiGel Phase III efficacy trials. A copy of the news release issued by BioSante is attached to this current report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

*Forward-Looking Statements*

This current report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about BioSante's plans with respect to the LibiGel clinical development program and other statements identified by words such as "plans," "intends," "anticipates," "continue," "believes," "expects," "may," "could," "will," 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, uncertainties regarding clinical testing, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the marketing and other success of BioSante's licensees or sublicensees and BioSante's future revenues, if any, from its licensees and sublicensees; uncertainties relating to the future and costs of BioSante's product development programs 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 report on Form 10-Q. The risks and uncertainties described in BioSante's most recent annual report on Form 10-K and subsequent quarterly report on Form 10-Q are not exclusive and further information concerning BioSante and its business, including factors that potentially could materially affect its financial results or condition, may emerge from time to time. All forward-looking statements in this report speak only as of the date of this report 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. BioSante advises you, however, to consult any further disclosures BioSante

makes on related subjects in its future annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K that BioSante files with or furnishes to the Securities and Exchange Commission.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Release issued June 11, 2012 by BioSante Pharmaceuticals, Inc. (filed herewith)

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**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: June 11, 2012

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**BIOSANTE PHARMACEUTICALS, INC.**

**FORM 8-K**

**Exhibit Index**

<u>Exhibit No.</u>	<u>Description</u>	<u>Method of Filing</u>
99.1	News Release issued June 11, 2012 by BioSante Pharmaceuticals, Inc.	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 New  
 LibiGel® Phase III Efficacy Trials**

*Conference call and webcast scheduled for 8:30 a.m. EDT today*

LINCOLNSHIRE, Illinois (June 11, 2012) — BioSante Pharmaceuticals, Inc. (NASDAQ: BPAX), announced today that the Company plans to initiate two new LibiGel Phase III efficacy trials. This decision is based on an extensive analysis of previous efficacy data, consultation with key opinion leaders (KOLs) in female sexual dysfunction, testosterone therapy and placebo effects, as well as a meeting with the U.S. Food and Drug Administration (FDA). BioSante also intends to continue the on-going LibiGel Phase III cardiovascular and breast cancer safety study as per protocol. LibiGel (testosterone gel) is in development for the treatment of female sexual dysfunction (FSD), specifically, hypoactive sexual desire disorder (HSDD) in menopausal women.

The protocol for the two new efficacy trials is in development, and BioSante intends to provide additional trial design information and timing of trial initiation once finalized. BioSante also intends to apply for an FDA Special Protocol Assessment (SPA) agreement prior to initiating the efficacy trials. Currently, it is expected that the efficacy trials will include the same FDA-required efficacy endpoints as prior Phase III efficacy trials: an increase in the number of satisfying sexual events and sexual desire, and decreased distress associated with low desire.

“We continue to believe that HSDD is an important unmet medical need for women and that LibiGel can provide a meaningful treatment option,” said Stephen M. Simes, BioSante’s president & chief executive officer. “In addition, the ongoing LibiGel Phase III safety study, the largest testosterone trial of its kind, has accumulated over 6,500 women-years of data to support the safety of LibiGel. It is our intention to conduct the primary analysis of the safety study in the second half of 2012.”

Phillip Donenberg, BioSante’s senior vice president of finance and chief financial officer added, “Our cash balance of \$49.5 million on March 31, 2012 puts us in a strong financial position to launch this new LibiGel strategy. We are committed to the continued development of LibiGel and to maximizing value for our stockholders.”

As announced on December 14, 2011, the Company’s previous LibiGel Phase III efficacy trials indicated that LibiGel increased satisfying sexual events and sexual desire and decreased distress. However, the placebo response in the two previous efficacy trials was greater than expected; therefore, LibiGel’s results were not shown to be statistically different from placebo. BioSante is committed to ensuring that the design of the new Phase III efficacy trials addresses the higher than expected placebo response observed in the prior trials.

**Conference Call and Webcast Information**

A conference call and webcast will be held today at 8:30 a.m. EDT to discuss the new LibiGel Phase III efficacy trials strategy. Interested parties may join the call from within the U.S. by dialing (877) 407-8031; outside the U.S., dial +1-201-689-8031. A live audio webcast will be available through BioSante’s website at [www.biosantepharma.com](http://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 about two hours 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). Two Phase III efficacy trials of LibiGel have been completed and a cardiovascular (CV) events and breast cancer study that has completed enrollment of 3,656 subjects is ongoing. The two completed efficacy trials were double-blind, placebo-controlled

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trials that enrolled over 500 surgically menopausal women each for six-months of therapy. In the two completed Phase III efficacy trials, LibiGel performed as predicted based on previous experience with testosterone products for FSD, including an increase in satisfying sexual activity and sexual desire and a decrease in distress. However, the placebo response in the two efficacy trials was greater than expected; and therefore, LibiGel’s results were not shown to be statistically different from placebo. The completed efficacy trials were conducted according to an FDA 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.

**About the LibiGel Phase III Cardiovascular and Breast Cancer Safety Study**

The Phase III LibiGel safety study is a randomized, double-blind, placebo-controlled, multi-center, cardiovascular (CV) events and breast cancer study that has completed enrollment of 3,656 subjects. 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, for example, hypertension and diabetes. The objective of the safety study is to show 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. BioSante intends to conduct the primary analysis of the safety study in the second half of 2012.

**About BioSante Pharmaceuticals, Inc.**

BioSante is a specialty pharmaceutical company focused on developing products for female sexual health and oncology. BioSante’s 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. BioSante also is developing a portfolio of cancer vaccines, with 17 Phase I and Phase II clinical trials currently ongoing. Four of these vaccines have been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA). BioSante's other products include an FDA-approved testosterone gel for male hypogonadism, which is licensed to Teva Pharmaceuticals USA, Inc., and the Pill-Plus™, an oral contraceptive in Phase II clinical development by Pantarhei Bioscience B.V. BioSante's first FDA-approved product, Elestrin™ (estradiol gel) indicated for the treatment of hot flashes associated with menopause, is marketed in the U.S. by Jazz Pharmaceuticals, BioSante's licensee. Additional information is available online at: [www.biosantepharma.com](http://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 with respect to the LibiGel clinical development program and other statements identified by words such as "plans," "intends," "anticipates," "continue," "believes," "expects," "may," "could," "will," 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, uncertainties regarding clinical testing, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; the marketing and other success of BioSante's licensees or sublicensees and BioSante's future revenues, if any, from its licensees and sublicensees; uncertainties relating to the future and costs of BioSante's product development programs 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 report 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.*

For more information, please contact:

For Investors:  
The Trout Group LLC  
Tricia Swanson  
(646) 378-2953  
[tswanson@troutgroup.com](mailto:tswanson@troutgroup.com)

For Media:  
Harris D. McKinney, Inc.  
Alan Zachary  
312-506-5220  
[azachary@harrisdcmckinney.com](mailto:azachary@harrisdcmckinney.com)

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