# 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): August 12, 2005

## BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

1-31812

58-2301143

(Commission File Number)

(I.R.S. Employer Identification Number)

111 Barclay Boulevard
Lincolnshire, Illinois
(Address of principal executive offices)

60069

res) (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 August 12, 2005, BioSante Pharmaceuticals, Inc. publicly announced its financial results for the second quarter ended June 30, 2005. For further information, please refer to the press release attached hereto as Exhibit 99.1, which is incorporated by reference herein.

The information contained in this report and the exhibit hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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

(c) Exhibits.

Exhibit No.	Description
99.1	Press release issued August 12, 2005.

## **SIGNATURE**

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

## BIOSANTE PHARMACEUTICALS, INC.

Date: August 12, 2005	By: /s/ Phillip B. Donenberg
	Chief Fire and Officer Transcript and Company
	Chief Financial Officer, Treasurer, and Secretary

## BIOSANTE PHARMACEUTICALS, INC. FORM 8-K EXHIBIT INDEX

Exhibit No. Filing	<u>Description</u>		Method of
99.1	Press Release issued August 12, 2005	Filed herewith	



## BioSante Pharmaceuticals Reports Product Development Highlights and Second Quarter 2005 Financial Results

**LINCOLNSHIRE**, **Illinois** (August 12, 2005) - BioSante Pharmaceuticals (AMEX: BPA) today reported on certain product development highlights and announced financial results for the second quarter ended June 30, 2005.

"Our positive topline data from the Bio-E-Gel<sup>TM</sup>Phase III trial and progress made with our CaP nanotechnology program drove this successful quarter for BioSante," said Stephen M. Simes, BioSante's president and chief executive officer. "We plan to present full Bio-E-Gel data at a medical meeting this fall, with publication in a peer-reviewed journal to follow. Currently, we are preparing a New Drug Application for submission to the U.S. Food and Drug Administration for Bio-E-Gel, and anticipate initiating Phase III LibiGel<sup>TM</sup> studies by year end."

#### **Product and Corporate Highlights**

- BioSante announced significant safety and efficacy results of its 12-week, randomized, double-blind, placebo-controlled Phase III clinical trial of Bio-E-Gel (bioidentical estradiol transdermal gel) for the treatment of moderate-to-severe hot flashes in menopausal women. The 484-patient study, which included three doses of Bio-E-Gel to maximize the safety profile by identifying the lowest effective dose, had four co-primary endpoints of a significant decrease over placebo in both the number and severity of hot flashes at Week 4 and Week 12 of treatment. By Week 4, the mid and high doses of Bio-E-Gel showed highly significant decreases in the number and severity of hot flashes versus placebo (p<0.0001), a response that was maintained until Week 12. At Week 5, the low dose showed a highly significant decrease in the number (p<0.001) and severity (p<0.01) of hot flashes verses placebo. These significant responses were maintained through Week 12 (p<0.0001), therefore suggesting identification of the lowest effective dose. There were no significant differences in the safety profile of any dose of Bio-E-Gel compared to placebo.
- The Company presented a review of progress toward the use of BioVant<sup>™</sup>, BioSante's patented calcium phosphate (CaP) nanoparticle technology, in viral and bacterial vaccine candidates at the International Conference on Immunopotentiators in Modern Vaccines in Spain. BioSante also presented BioVant data at the annual World Vaccine Congress in Montreal, focusing on the intranasal mucosal surface delivery of an anthrax vaccine, and highlighting the simultaneous immune adjuvant effects and non-injected vaccine delivery potential of BioVant.
- BioSante announced a new manufacturing agreement with a U.S.-based current good manufacturing practices (cGMP) manufacturer for large-scale quantities of CaP nanotechnology.
- BioSante was added to the Russell Microcap<sup>™</sup> Index, which measures the performance of the microcap segment and includes the smallest 1,000 securities in the small-cap Russell 2000 Index plus the next 1,000 securities, based on descending market capitalization. As of the latest reconstitution, the average market capitalization of the Index was approximately \$217 million.

#### Second Quarter 2005 Financial Overview

BioSante incurred a net loss of approximately \$2.58 million, or \$(0.13) per basic and diluted share for the quarter ended June 30, 2005, compared to a net loss of approximately \$2.57 million, or \$(0.15) per basic and diluted share for the second quarter of 2004. For the first six months of 2005, the Company's net loss totaled approximately \$5.35 million, or \$(0.28) per basic and diluted share, compared to a net loss of approximately \$5.02 million, or \$(0.32) per basic and diluted share, for the first six months of 2004. As of June 30, 2005, the Company's cash, cash equivalents and short-term investments were approximately \$12.1 million. The Company anticipates a cash burn rate of approximately \$750,000 per month for the remainder of 2005.

### About BioSante Pharmaceuticals, Inc.

BioSante is developing a pipeline of hormone therapy products to treat both men and women. These hormone therapy products are gel formulations for transdermal administration that deliver bioidentical estradiol and testosterone. BioSante's lead products include Bio-E-Gel<sup>TM</sup> (bioidentical estradiol gel) for the treatment of women with menopausal symptoms, and LibiGel<sup>TM</sup> (bioidentical testosterone gel) for the treatment of female sexual dysfunction (FSD). The current market in the U.S. for estrogen and testosterone products is approximately \$2.5 billion. The transdermal gel formulations used in the women's gel products are licensed by BioSante from Antares Pharma Inc. (Amex: AIS). The company also is developing its calcium phosphate nanotechnology (CaP) for novel vaccines, including biodefense vaccines for toxins such as anthrax and ricin, and drug delivery systems. Additional information is available online at <a href="https://www.biosantepharma.com">www.biosantepharma.com</a>.

This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The statements regarding BioSante contained in this press release that are not historical in nature, particularly those that utilize terminology such as "may," "will," "should," "likely," "expects," "anticipates," "estimates," "believes" or "plans," or comparable terminology, are forward-looking statements. Forward-looking statements are based on current expectations and assumptions, and entail various risks and uncertainties that could cause actual results to differ materially from those expressed in such forward-looking statements. Important factors known to BioSante that cause actual results to differ materially from those expressed in such forward-looking statements are the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance, and

other factors identified and discussed from time to time in BioSante's filings with the Securities and Exchange Commission, including those factors discussed on pages 19 to 31 of BioSante's Form 10-KSB, which discussion also is incorporated herein by reference. All forward-looking statements 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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