# 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 28, 2005

# BIOSANTE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or Other Jurisdiction of Incorporation) 1-31812 (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 March 28, 2005, BioSante Pharmaceuticals, Inc. publicly announced its key achievements and financial results for the year ended December 31, 2004. 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 March 28, 2005	

# 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

# BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Phillip B. Donenberg
Phillip B. Donenberg
Chief Financial Officer, Treasurer and Secretary

Dated: March 28, 2005

# BIOSANTE PHARMACEUTICALS, INC.

# FORM 8-K Exhibit Index

Exhibit		
No.	Description	Method of Filing
99.1	Press Release issued March 28, 2005	Filed herewith



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

FOR IMMEDIATE RELEASE Amex: BPA

## BioSante Pharmaceuticals Announces 2004 Key Achievements and Financial Results

LINCOLNSHIRE, Illinois (March 28, 2005) — BioSante Pharmaceuticals (Amex: BPA) today announced key achievements and financial results for the year ended December 31, 2004.

"We continued to make important progress throughout the year in our late stage hormone therapy clinical programs, and CAP nanotechnology," commented Stephen M. Simes, BioSante's president and chief executive officer. "We expect our efforts to result in a new drug application filing with the FDA for Bio-E-Gel™ and the initiation of our Phase III development program for LibiGel™ in 2005."

Highlights for the last 15 months include:

## Hormone Therapy Achievements

- Completed enrollment in our pivotal Phase III clinical trial of Bio-E-Gel (bioidentical estradiol gel).
- Reported positive results of the completed Phase II clinical trial of LibiGel (bioidentical testosterone gel) for treatment of female sexual dysfunction (FSD) significantly increasing (238%) the number of satisfying sexual events.

## **CAP Nanotechnology Achievements**

- Product developments:
  - Received notice of allowance from the European Patent Office (EPO) accepting BioSante's patent application for the manufacturing process of the company's unique calcium phosphate nanoparticles (CAP).
  - Positive pre-clinical results for intranasally administered BioVant<sup>TM</sup>/anthrax vaccine, compared to an Alhydrogel/anthrax vaccine or the antigen alone
  - Positive results in animal models for the sustained-release delivery of therapeutic proteins, including long-acting buccal delivery of insulin.

-more-

- Current product development agreements:
  - U.S. Navy: Cooperative Research and Development Agreement (CRADA) for evaluation and development of a malaria vaccine.
  - U.S. Army: CRADA for evaluation and development of non-injected biodefense vaccines including anthrax, ricin, staph and bubonic plague.
  - DynPort: U.S. Department of Defense subcontract for evaluation and development of a non-injected anthrax vaccine.

#### Financial Achievements

- Raised new capital in a \$17.7 million (\$16.4 million net of transaction costs) common stock/warrant placement.
- Closed the year with \$17.3 million in cash, cash equivalents and short-term investments.

BioSante incurred a net loss of approximately \$12.0 million or (\$0.70) per share for the year ended December 31, 2004, compared to a net loss of \$6.0 million or (\$0.54) per share for the same period in 2003. The increase in the net loss is largely the result of increased research and development expenses incurred primarily as a result of (i) completing the Phase II LibiGel trial, and (ii) conducting the Phase III Bio-E-Gel trial. The company's cash, cash equivalents and short-term investments as of December 31, 2004 were approximately \$17.3 million, compared to \$9.1 million at December 31, 2003.

#### 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™ (bioidentical estradiol gel) for the treatment of women with menopausal symptoms, and LibiGel™ (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 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. For example, our statement regarding the expected timing of the filing of a new drug application with the FDA for Bio-E-Gel™ and the initiation of pivotal studies of LibiGel™ is a forward-looking statement. 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 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.

For more information, please contact:

Phillip Donenberg, BioSante Pharmaceuticals, Inc.; (847) 478-0500; donenber@biosantepharma.com
Ritu S. Baral, The Trout Group LLC; (212) 477-9007 ext 25; rbaral@troutgroup.com
Daniel Budwick, BMC Communications; (212) 477-9007 ext 14; <a href="mailto:budwick@bmccommunications.com">budwick@bmccommunications.com</a>