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# 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

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Date of Report (Date of earliest event reported): MARCH 9, 2004

BIOSANTE PHARMACEUTICALS, INC. (Exact name of registrant as specified in its charter)

DELAWARE (State or Other Jurisdiction of Incorporation)

Number (I.R.S. Employer Incorporation)

Number (I.R.S. Employer Identification Number)

1-31812

58-2301143

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)

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# ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On March 9, 2004, BioSante Pharmaceuticals, Inc. announced its key achievements and financial results for the year ended December 31, 2003. Attached to this Current Report on Form 8-K as Exhibit 99.1 is a copy of BioSante Pharmaceutical's press release in connection with the announcement. The information in this report is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference by any general statements by BioSante Pharmaceuticals, Inc. incorporating by reference this report or future filings into any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent BioSante Pharmaceuticals, Inc. specifically incorporates the information by reference.

# 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 Chief Financial Officer,

Treasurer and Secretary

Dated: March 9, 2004

[BIOSANTE LOGO]

BIOSANTE PHARMACEUTICALS, INC. 111 Barclay Boulevard Linconshire, Illinois 60069 www.biosantepharma.com

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FOR IMMEDIATE RELEASE

AMEX: BPA

## BIOSANTE PHARMACEUTICALS ANNOUNCES 2003 KEY ACHIEVEMENTS AND FINANCIAL RESULTS

LINCOLNSHIRE, ILLINOIS (MARCH 9, 2004) -- BioSante Pharmaceuticals (Amex: BPA) today announced key achievements and financial results for the year ended December 31, 2003.

"We are quite pleased with our achievements and progress in the last year. Recent FDA actions and hormone therapy market indications are very encouraging," said Stephen M. Simes, president and chief executive officer of BioSante. "The most exciting recent event affecting the estrogen market is the FDA's approval of an estrogen gel developed by Solvay Pharmaceuticals, Inc. The approval indicates that the FDA is willing to approve new estrogen products and specifically estrogen gel products. Moreover, in light of recently reported safety data from the Women's Health Initiative studies of orally administered estrogen products, all of the hormone therapy products we are developing are expected to offer important safety advantages because of their transdermal route of administration and their use of bioidentical estradiol and testosterone.

"We expect Solvay's approval to help increase the size of the transdermal segment of the estrogen market, which is now about \$300 million," Simes continued. "Our goal is to be the next gel to market and to capture a significant share of the large and valuable transdermal estrogen segment. This year we will continue to aggressively develop our late-stage hormone therapy products as well as pursue additional government grants and contracts for development of our nanotechnology-based vaccine adjuvant and delivery system and protein delivery technologies."

Highlights for the last 14 months include:

Hormone Therapy Achievements

- o Announced licensing agreement with TEVA Pharmaceuticals for development and marketing of a hormone therapy product; TEVA-managed development continues.
- o Completed Phase II/III clinical trial of Bio-E-Gel(TM) for post-menopausal symptoms and identified effective dose of Bio-E-Gel.

- o Initiated pivotal Phase III trial of Bio-E-Gel representing the last stage before submission to the FDA.
- o Initiated a Phase II clinical trial of LibiGel(TM) for treatment of female sexual dysfunction; reported on positive blinded interim results indicating increases in sexual desire and numbers of sexual events.

"Proctor and Gamble has indicated publicly that they will spend \$100 million on launch of their testosterone patch in development for female sexual dysfunction," said Simes. "Our objective is to be the first testosterone gel to market in order to maximize our share of what is estimated to be a multi-billion dollar market."

## CAP Nanotechnology Achievements

#### product developments:

- -- Positive results in several animal models using BioSante's calcium phosphate nanotechnology (CAP) as a safer vaccine adjuvant to improve the efficacy of vaccines versus no adjuvant and versus alum, the only FDA approved vaccine adjuvant.
- -- Positive results in animal models for the sustained-release delivery of therapeutic proteins, including long-acting injectable insulin, inhaled insulin and oral insulin, among other proteins tested.

#### o 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 needle-free biodefense vaccines including anthrax, ricin, staph and bubonic plague.
- -- DynPort: U.S. Department of Defense subcontract (\$658,000) for evaluation and development of a needle-free anthrax vaccine.
- -- NIH: SBIR grant (\$100,000) for oral insulin development.

## Financial Achievements

- o Raised new capital in a \$10.3 million private common stock/warrant placement.
- Common stock listed on the American Stock Exchange.

BioSante incurred a net loss of approximately \$6.0 million or (\$0.54) per share for the year ended December 31, 2003, compared to a net loss of \$3.8 million or (\$0.51) per share for the same period in 2002. The overall increase in the net loss is largely the result of the receipt in 2002 of approximately \$2.5 million in licensing revenues associated with BioSante's hormone therapy products, which did not

recur in 2003. The company's cash balance as of December 31, 2003 was approximately \$9.1 million, compared to \$4.9 million at December 31, 2002.

"We are pleased with the progress made in 2003 and we are off to a promising start this year," Simes said. "We have made great strides toward the development of important new hormone therapies, vaccines and oral delivery, and are well positioned for meeting our key objective of substantial growth in stockholder value in the months and years ahead."

#### ABOUT BIOSANTE PHARMACEUTICALS, INC.

BioSante is developing a pipeline of hormone therapy products to treat both men and women. BioSante also is developing its calcium phosphate nanotechnology (CAP) for novel vaccines including biodefense vaccines such as ricin and anthrax and drug delivery systems. Additional information is available online at www.biosantepharma.com.

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 and especially of new vaccines, 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 17 to 23 of BioSante's Form 10-KSB, which discussion also is incorporated herein by reference. The information contained in this press release does not necessarily reflect the position or the policy of the U.S. Government and no official endorsement should be inferred.

FOR MORE INFORMATION, PLEASE CONTACT:

Phillip B. Donenberg, CFO

847-478-0500 ext 101