# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washingtor	ı, 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): November 12, 2004

## 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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 November 12, 2004, BioSante Pharmaceuticals, Inc. publicly announced its financial results for the third quarter ended September 30, 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 November 12, 2004		

## **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: November 12, 2004

## BIOSANTE PHARMACEUTICALS, INC.

## FORM 8-K Exhibit Index

Exhibit No.	Description	Method of Filing
99.1	Press Release issued November 12, 2004	Filed herewith



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

FOR IMMEDIATE RELEASE Amex:BPA

## **BioSante Pharmaceuticals Announces Third Quarter Financial Results**

LINCOLNSHIRE, Illinois (November 12, 2004) — BioSante Pharmaceuticals, Inc. (AMEX:BPA) today reported its financial results for the fiscal third quarter and nine months ended September 30, 2004.

BioSante reported a net loss of approximately \$2.9 million (or \$0.16 per share) for the quarter, compared to a net loss of approximately \$1.4 million (or \$0.12 per share) for the same period in 2003. The increased total net loss was due primarily to planned increased expenses relating to development of the company's hormone therapy products, including the ongoing Phase III trial of Bio-E-Gel<sup>TM</sup> (bioidentical estradiol gel) for the treatment of hot flashes in menopausal women. For the first nine months of 2004, the company's net loss totaled approximately \$7.9 million (or \$0.48 per share), compared to a net loss of approximately \$4.3 million (or \$0.43 per share) for the first nine months of 2003.

BioSante's cash balance as of September 30, 2004 was approximately \$20.6 million, compared with \$9.1 million as of December 31, 2003.

"We are pleased with our continued progress in the clinical development of Bio-E-Gel and LibiGel<sup>TM</sup>," said Stephen M. Simes, president and chief executive officer of BioSante. "Our sound financial position will ensure the continued development of our hormone therapy products. Among our transdermal gel hormone therapy products, Bio-E-Gel for menopausal symptoms is in its pivotal Phase III clinical trial and LibiGel (bioidentical testosterone gel) for female sexual dysfunction is poised to enter Phase III clinical trials in early 2005. In addition, we are continuing to develop our calcium phosphate nanotechnology for innovative vaccines and drug delivery. We remain committed to increasing stockholder value and believe our continued progress in product development will assist us in this objective."

#### About BioSante Pharmaceuticals, Inc.

BioSante is developing a pipeline of hormone therapy products to treat both men and women. BioSante's hormone therapy products are gel formulations for transdermal administration that deliver bioidentical estradiol and testosterone. Symptoms treated with hormone therapy in men include impotence, diminished sex drive, muscle weakness and osteoporosis. Symptoms in menopausal women include hot flashes, vaginal atrophy, decreased libido and osteoporosis. The estrogen and testosterone markets in the United States alone account for over \$2.5 billion in annual sales.

The company also is developing its proprietary 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 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, 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 18 to 25 of BioSante's Form 10-KSB, which discussion also is incorporated herein by reference.

#### For more information, please contact:

Phillip B. Donenberg, CFO 847/478-0500 x101;doneber@biosantepharma.com or Ritu S. Baral, The Trout Group LLC 212-477-9007 ext 25;rbara1@troutgroup.com

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