BIOSANTE PHARMACEUTICALS INC
Form 8-K
November 08, 2006

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):
November 7, 2006

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

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

111 Barclay Boulevard **Lincolnshire, Illinois**	**60069**
(Address of principal executive offices)	(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 1 — Registrant's Business and Operations

Item 1.01 Entry into a Material Definitive Agreement

On November 7, 2006, BioSante Pharmaceuticals, Inc. entered into an exclusive sublicense agreement with Bradley Pharmaceuticals, Inc. for the marketing of Bio-E-Gel®, which is a transdermal gel estradiol product for the treatment of hot flashes, in the United States. Upon execution of the agreement, Bradley paid BioSante a $2.625 million upfront signing payment and agreed to pay BioSante certain regulatory and sales based milestone payments. In addition, Bradley agreed to pay BioSante royalties on sales of Bio-E-Gel, if and when Bio-E-Gel is approved by the U.S. Food and Drug Administration, or FDA, and marketed by Bradley. The upfront payment amount is net of BioSante's obligations to Antares Pharma IPL AG, BioSante's licensor of the transdermal estradiol gel formulation in Bio-E-Gel.

BioSante has prepared and filed a New Drug Application, or NDA, with the FDA, with respect to Bio-E-Gel, and the NDA was accepted by the FDA as filed in April 2006, and is currently under review. Under the license agreement, BioSante agreed to use commercially reasonable efforts for the good faith prosecution of its pending NDA for Bio-E-Gel for the treatment of hot flashes, including performing all regulatory and clinical work required by the FDA for approval of Bio-E-Gel in the United States, at its sole expense, not to exceed, however, a certain specified amount, and has agreed to fund, in part up to a certain specified amount, any Phase IV study that may be required by the FDA.

The license agreement will expire on the later of the 12th anniversary of the first commercial sale of Bio-E-Gel in the United States or the expiration of the last patent right to Bio-E-Gel. Either party may terminate the agreement earlier upon the other party's breach of the agreement after written notice specifying the alleged breach and a reasonable opportunity to cure the breach or upon the other party's insolvency or bankruptcy. In addition, if further or additional regulatory work and clinical studies are required by the FDA in order to obtain FDA approval of Bio-E-Gel and the cost of such work and studies to BioSante would exceed a specified amount, and if neither Bradley nor BioSante funds the excess of such amount, either party will have the right to terminate the agreement. Upon such termination, BioSante would be required to refund to Bradley the upfront signing payment previously paid to BioSante. In addition, if FDA approval of Bio-E-Gel is obtained, but Bradley's share of the costs of any post-approval studies required by the FDA, together with Bradley's share of the costs of any additional studies required to obtain approval by the FDA, exceeds a specified amount, Bradley will have the right to terminate the agreement upon 90 days prior written notice to BioSante and the payment to BioSante of a specified termination fee.

The license agreement also contains other terms and conditions that are standard and customary for agreements of this type, including certain representations, warranties and covenants.

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/ Stephen M. Simes
Stephen M. Simes
President and Chief Executive Officer

Dated: November 8, 2006