

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 8-K

DUSA PHARMACEUTICALS INC
Form 8-K
January 18, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): January 12, 2006

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

NEW JERSEY
(State or other
jurisdiction of
incorporation)

0-19777
(Commission File
Number)

22-3103129
(IRS Employer
Identification
Number)

25 UPTON DRIVE
WILMINGTON, MASSACHUSETTS 01887
(Address of principal executive offices, including ZIP code)

(978) 657-7500
(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Securities 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))

ITEM 1.01 - ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

DUSA Pharmaceuticals, Inc. ("DUSA") issued a press release on January 18, 2006, attached to and made a part of this report as Exhibit 99, announcing that it had entered into an exclusive Marketing, Distribution and Supply Agreement (the "Agreement") with Stiefel Laboratories, Inc. ("Stiefel") covering current and future uses of DUSA's proprietary Levulan(R) Kerastick(R) for photodynamic

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 8-K

therapy (PDT) in dermatology. The Agreement, dated January 12, 2006, grants Stiefel an exclusive right to distribute, promote and sell the Levulan(R) Kerastick(R) in the western hemisphere from south of and including Mexico and all other countries in the Caribbean, excluding United States territories (collectively, the "Territory"). DUSA will manufacture and supply to Stiefel on an exclusive basis in the Territory all of Stiefel's reasonable requirements for the product.

The Agreement, which has an initial term of ten years, will expand the distribution of Levulan(R) beyond the North American market for the first time into Mexico, Central and South America. DUSA has completed its portion of the Brazilian regulatory submission for the use of Levulan PDT for actinic keratoses. Effective with the signing of the Agreement, Stiefel will complete final integration and submission of the data to the Brazilian regulatory agency with market launch expected in late 2006 or early 2007. Stiefel will prepare and file the regulatory applications in other countries in the Territory subject to the terms of the Agreement. The parties have certain rights to terminate the Agreement prior to the end of the initial term, and Stiefel has an option to extend the term for an additional ten years on mutually agreeable terms and conditions.

Under the terms of the Agreement, Stiefel will make up to \$3,000,000 in milestone payments to DUSA based upon receipt of final pricing approval of the Levulan(R) Kerastick(R) from Brazilian regulatory authorities and achievement of pre-determined minimum purchase levels in the Territory, subject to certain terms and conditions. The selling price per unit of the Levulan(R) Kerastick(R) is a percentage of Stiefel's final selling price to unrelated third parties. DUSA has the right to suspend the supply of the product if the unit price DUSA receives falls below certain levels. DUSA will manufacture the Kerastick(R) for Stiefel at its manufacturing facility in Wilmington, Massachusetts.

Except for historical information, this report, including the attached press release, contains certain forward-looking statements that involve known and unknown risk and uncertainties, which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to expansion of the distribution of the product, completion of the regulatory submission and expectation for launch, Stiefel's preparation and completion of regulatory submissions in other countries, receipt of milestone payments, DUSA's obligation to manufacture in Wilmington, Massachusetts, and Stiefel's beliefs regarding sales and profits. Furthermore, the factors that may cause differing results include the uncertainties of the regulatory process, including pricing approval, product development risks, reliance on third party manufacturers, and other risks identified in DUSA's SEC filings from time to time.

ITEM 9.01 - FINANCIAL STATEMENT AND EXHIBITS.

| Item No. | Description |
|----------|---------------------------------------|
| 99 | Press Release, dated January 18, 2006 |

SIGNATURES

Edgar Filing: DUSA PHARMACEUTICALS INC - Form 8-K

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.

DUSA PHARMACEUTICALS, INC.

Dated: January 18, 2006

By: /s/ D. Geoffrey Shulman

D. Geoffrey Shulman, MD, FRCPC
Chairman of the Board and Chief
Executive Officer

EXHIBIT INDEX

| Item No. | Description |
|----------|---------------------------------------|
| 99 | Press Release, dated January 18, 2006 |