DUSA PHARMACEUTICALS INC
Form 8-K
January 15, 2003

FORM 8-K

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 30, 2002

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

NEW JERSEY	0-19777	22-3103129
(State or other jurisdiction of incorporation)	(Commission File Number)	(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)

ITEM 5. OTHER EVENTS.

DUSA Pharmaceuticals, Inc. ("DUSA") issued a press release on January 14, 2003 attached to and made part of this report, announcing that it entered into a License and Development Agreement with Photonamic GmbH & Co. KG, a recently formed subsidiary of medac GmbH, a German pharmaceutical company, and a Supply Agreement with medac. These agreements provide for the licensing to DUSA of Photonamic's proprietary technology related to aminolevulinic acid (ALA), the compound used in DUSA's Levulan(R) Photodynamic Therapy (PDT) and Photodetection (PD) for particular indications, and the supply of the product.

Under the terms of the License and Development Agreement, DUSA receives a license for the United States and several other countries, to use Photonamic's technology and data related to ALA for systemic dosing in the field of brain cancer and other indications which the parties may jointly develop during the term of their collaboration. Photonamic is currently conducting a European Phase III clinical trial in which ALA-induced fluorescence is used to guide surgical tumor resection in patients suffering from the most aggressive form of adult brain tumor, glioblastoma multiforme (GBM). Completion of these trials is expected within two years. DUSA's license covers both this primary clinical indication as well as other brain cancers. DUSA is also entitled to use the licensed technology including pre-clinical data in connection with other additional indications DUSA is developing on its own.

The Supply Agreement with medac covers medac's current systemic dosage formulation for use in brain cancer, Barrett's esophagus, if DUSA requires it, as well as other potential formulations which the parties may jointly develop.

DUSA paid an up-front license fee, and will be obligated to pay certain regulatory milestones and royalties on net sales of a brain cancer product under the terms of the License and Development Agreement. DUSA will also purchase product under the Supply Agreement for mutually agreed upon indications. Should Photonamic's clinical studies be successful, DUSA will be obligated to proceed with development of the product in the United States in order to retain the license for the use of the technology to treat brain cancer.

Except for historical information, this report and the exhibits contain 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 the expectation for completion of Photonamic clinical trials; DUSA's obligations to pay milestones, royalties and to purchase product; obligations to develop the indication in the U.S.; Photonamic's intention to follow patients' survival rates; expectation for patient accrual; potential for neurosurgeons and for use by DUSA in its development of ALA for Barrett's esophagus. These statements are further qualified by important factors which may cause actual results to differ materially from any future results, performance or achievements expressed or implied by the statements made. These factors include, without limitation, changing market and regulatory conditions, actual clinical results, the impact of competitive products and pricing, the timely development, FDA and foreign regulatory approval, reliance on third-parties for the production and manufacture of products, and the maintenance of our

patent portfolio, none of which can be assured, and other risks identified in DUSA's SEC filings from time to time.

ITEM 7. FINANCIAL STATEMENTS AND OTHER EXHIBITS.

(c) Exhibits.

[10.1] License and Development Agreement between DUSA Pharmaceuticals, Inc. and Photonamic GmbH & Co. KG dated as of December 30, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange Act of 1934, as amended.

[10.2] Supply Agreement between DUSA Pharmaceuticals, Inc. and Medac GmbH dated as of December 30, 2002, portions of which have been omitted pursuant to a request for confidential treatment under Rule 24(b) of the Securities Exchange

Act of 1934, as amended.

[99] Press Release dated January 14, 2003.

SIGNATURES

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 14, 2003

By: /s/ D. Geoffrey Shulman

D. Geoffrey Shulman, MD, FRCPC
President, Chief Executive Officer