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DUSA PHARMACEUTICALS INC

Form 8-K

October 10, 2001

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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): October 10, 2001

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)

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ITEM 5. OTHER EVENTS.

The Registrant, DUSA Pharmaceuticals, Inc. ("DUSA") reports that it has updated investors today at the UBS Warburg Global Life Sciences Conference in New York City. Dr. Geoffrey Shulman, DUSA's President and CEO, announced the initiation of DUSA's second Phase I/II clinical trial for the treatment of Barrett's Esophagus using Levulan(R) (ALA, or aminolevulinic acid) photodynamic therapy (PDT).

With respect to DUSA's first approved therapy using Levulan(R) PDT to treat non-hyperkeratotic actinic keratoses of the face and scalp, he also announced that as of September 30, 2001, the total number of units of DUSA's proprietary light device, the BLU-U(R), which were in use was 238, and the total number of Kerastick(R) units sold to medical doctors during the quarter ended September 30, 2001 was 1,638. He also reported that the Company expects to incur an operating loss in the range of \$6,000,000 to \$7,000,000 for the fiscal year ending December 31, 2001, in line with previous expectations.

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Except for historical information, the presentation and this report contain certain forward-looking statements that involve known and unknown risks and uncertainties which may cause actual results to differ materially and adversely from the future results, performance or achievements expressed or implied by the statements made. These forward-looking statements relate to the Company's position for future growth, the Company's strengths including its products' unique features and benefits, multiple potential applications and potential revenues associated with them, ongoing royalty and supply fees from Schering AG, payment of research and development funding from Schering AG; expectations for third party reimbursement in comparison to other current therapies, expectation for timing of state and federal reimbursement; the belief that products are gaining acceptance; commencement of foreign sales, AK marketing goals through 2003, expectations for initiation and completion of various clinical trials under DUSA INDs and investigator studies, and indications being considered for development, the hope to be able to use results for further development, anticipated enrollment and protocol procedures in existing studies, the goals for the clinical study, expectations for the fiscal year end operational loss, consideration of corporate partner and acquisition opportunities, beliefs regarding creation of value, expectations for success with pipeline products and anticipated development milestones, and market potential for various indications. Such risks and uncertainties include, but are not limited to the results of the product marketing efforts and international launches, whether clinical trials will be commenced and whether the results will be positive, Schering AG's priorities, changing market conditions, the impact of competitive products, healthcare reimbursement and pricing, the development, FDA and foreign regulatory approval and market acceptance of the Company's products, the Company's dependence on third-party manufacturers of the Kerastick(R), BLU-U(R), and Levulan(R), the ability to increase the market for the products, and Schering AG's marketing efforts and commitment to support the Company's dermatology development program, the ability to maintain its proprietary rights and its patent portfolio and other risks detailed from time to time in the Company's United States Securities and Exchange Commission (SEC) filings.

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ITEM 7. FINANCIAL STATEMENTS AND OTHER EXHIBITS.

(c) Exhibits.

[99.1] Press Release dated October 10, 2001.

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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: October 10, 2001

By: /s/ D. Geoffrey Shulman

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