

DUSA PHARMACEUTICALS INC

Form 8-K

October 23, 2008

**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): October 22, 2008

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))
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Item 8.01 Other Events.

DUSA Pharmaceuticals, Inc. ® (NASDAQ GM: DUSA) announced today results from its Phase IIB clinical trial to compare the safety and efficacy of photodynamic therapy (PDT) using DUSA's BLU-® brand light plus vehicle containing Levulan® (aminolevulinic acid HCl) to that of PDT using the BLU-U plus vehicle without Levulan (the control group) in patients with moderate to severe facial acne vulgaris. The study demonstrated that both treatments were safe and well tolerated with no serious adverse events. While both groups showed a statistically significant reduction in inflammatory lesions from baseline, the results did not demonstrate a statistically significant difference between the Levulan PDT and control groups. Based on these results, DUSA will not pursue further clinical development of Levulan PDT in combination with BLU-U for moderate to severe acne. DUSA intends to file a 510K application with the U.S. Food and Drug Administration for an expansion of its BLU-U label to include severe acne. DUSA remains committed to, and will focus its resources on continuing to grow the Levulan PDT franchise for the treatment of Grade 1-2 actinic keratoses (AKs) and pursuing other clinical development projects, such as the treatment of AKs and the prevention of squamous cell carcinomas (SCC) in immunosuppressed solid organ transplant recipients (SOTR). DUSA expects to begin enrollment in the SOTR study by year end.

More details of the results are disclosed in the press release attached as Exhibit 99.1 to this report.

Except for historical information, this report contains certain forward-looking statements that represent our current expectations and beliefs concerning future events, and involve certain known and unknown risk and uncertainties. These forward-looking statements relate to the decision not to pursue further clinical development of this acne indication, intention to support investigator studies and consideration of future clinical development, intention to file a 510K for expansion of the BLU-U label, focus of its resources on growth of the Levulan PDT franchise and other development projects, beliefs concerning the value of owning a BLU-U if the 510K for severe acne is cleared by FDA and expectations for the timing of enrollment in a SOTR study. These forward-looking statements are further qualified by important factors that could cause actual results to differ materially from future results, performance or achievements expressed or implied by those in the forward-looking statements made in this release. These factors include, without limitation, actions by health regulatory authorities, sufficiency of funds, results of clinical trials, reliance on third party manufacturers, and other risks and uncertainties identified in DUSA's Form 10-K for the year ended December 31, 2007, and other SEC filings from time to time.

Item 9.01 Financial Statement and Exhibits.

<u>Item No.</u>	<u>Description</u>
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99.1	Press Release, dated October 22, 2008
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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 22, 2008

By: /s/Robert F. Doman
Robert F. Doman, President and
Chief Executive Officer

EXHIBIT INDEX

<u>Item No.</u>	<u>Description</u>
99.1	Press Release, dated October 22, 2008