DUSA PHARMACEUTICALS INC
Form 8-K
August 06, 2010

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): August 5, 2010

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

New Jersey	**001-31533**	**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)

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Securities Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

DUSA Pharmaceuticals, Inc.® (NASDAQ GM: DUSA), a dermatology company developing and marketing Levulan® Photodynamic Therapy (PDT), today announced that on the afternoon of August 5, 2010, the U.S. Food and Drug Administration (FDA) notified DUSA that it has not granted DUSA s request for Orphan Drug Designation for the use of Levulan PDT for the prevention of cutaneous squamous cell carcinomas (SCCs) in patients who have a proven history of multiple localized cutaneous SCCs over a 12 month period. The FDA acknowledged that cutaneous SCC is a serious problem in patients at high risk for developing SCCs, such as solid organ transplant recipients (SOTRs), and that aminolevulinic acid would be a potential preventative therapy in these patients. However, the FDA also stated that they believe there are other factors which place patients at high risk of developing SCCs that should be included in determining the target population. As a result, DUSA plans to close out its SOTR pilot clinical trial program for this indication.

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 DUSA s plan to close out its SOTR pilot clinical trial program. 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 regulatory authorities, the status of our patent portfolio, action of third parties, the impact of competitive products, and other risks and uncertainties identified in DUSA s Form 10-K for the year ended December 31, 2009 and other SEC filings from time to time.

Item 9.01. Financial Statement and Exhibits.

Item No.	Description
99.1	Press Release, dated August 6, 2010

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: August 6, 2010

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

EXHIBIT INDEX

Item No.	Description
99.1	Press Release, dated August 6, 2010