DUSA PHARMACEUTICALS INC
Form 8-K
December 14, 2012

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): December 14, 2012

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):

¨ 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 8.01 Other Events.

DUSA Pharmaceuticals, Inc.® (NASDAQ GM: DUSA), is reporting preliminary results of a Phase 2 clinical trial investigating the use of the Levulan® Kerastick® in conjunction with BLU-U® blue light illumination for the treatment of actinic keratoses (AKs) of the face and scalp when utilizing short drug incubation. The study demonstrated that treatment with Levulan Kerastick after incubating for one, two or three hours resulted in a statistically significant number of patients with complete lesion clearance and a statistically significant reduction in AK lesion count when compared to treatment with vehicle 12 weeks post treatment.

The multi-center, randomized, blinded, vehicle-controlled study across 13 trial sites enrolled a total of 235 subjects and followed them for up to six months. The results showed that at 12 weeks, after receiving up to 2 photodynamic therapy (PDT) treatments, subjects treated with Levulan® using incubation times of 1, 2, or 3 hours all demonstrated similar degrees of efficacy, with up to 79% AK lesion clearance rates, while subjects receiving vehicle alone had up to a 14% lesion clearance. Analysis of the 24 week follow up data showed that up to 78% of subjects treated using broad area, short drug incubation (BASDI) who were completely clear of AK lesions at 12 weeks remained free of lesions at 24 weeks. This compares to 13% of subjects treated using a spot application method.

The safety profile seen in this study is consistent with what has been seen in previous clinical studies involving Levulan® PDT and is similar to that seen in the current labeling. There were no treatment-related serious adverse events reported in the study and only one subject did not complete the study. The study utilized the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20% with the BLU-U® Blue Light Photodynamic Therapy Illuminator which is FDA approved for the treatment of minimally to moderately thick actinic keratoses (AKs) of the face or scalp.

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 safety and efficacy results of the trial. 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, clinical trial risks and results, the status of our patent portfolio, reliance on third parties, and other risks and uncertainties identified in DUSA s Form 10-K for the year ended December 31, 2011.

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: December 14, 2012

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