

INSMED INC
Form 8-K
August 02, 2011

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 1, 2011

INSMED INCORPORATED
(Exact Name of Registrant as Specified in Its Charter)

Virginia
(State or Other Jurisdiction of Incorporation)

0-30739
(Commission File Number)

54-1972729
(IRS Employer Identification No.)

11 Deer Park Drive, Monmouth Junction, New Jersey
(Address of Principal Executive Offices)

08852
(Zip Code)

(732) 438-9434
(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:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange 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.

On August 1, 2011, Insmmed Incorporated (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has notified the Company that the agency has placed a clinical hold on the Company’s phase 3 clinical trials for ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections and patients with non-tuberculous mycobacterial (NTM) lung disease. The Company has been informed by FDA that this decision was based on an initial review of the interim results of a long-term rat inhalation carcinogenicity study, recently reported to the agency by the Company, with ARIKACE. In this study, rats received daily doses of ARIKACE by inhalation for up to two years. FDA has requested additional information on ARIKACE and data from the rat study. The Company anticipates being able to supply the currently requested information and data within the next 30 days.

A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
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99.1	Press release issued by Insmmed Incorporated dated August 1, 2011.
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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.

Insmmed Incorporated

Date: August 1, 2011

By: /s/ Kevin P. Tully C.G.A.

Name: Kevin P. Tully C.G.A.

Title: Executive Vice President & Chief Financial Officer
