INSMED INC
Form 8-K
October 14, 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): October 14, 2011

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

Virginia
(State or Other Jurisdiction of Incorporation)

0-30739	54-1972729
(Commission File Number)	(IRS Employer Identification No.)
11 Deer Park Drive, Monmouth Junction, New Jersey	08852
(Address of Principal Executive Offices)	(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 October 14, 2011, Insmed Incorporated (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has notified the Company that it is continuing the clinical hold previously placed on the Company's phase 3 clinical trial for ARIKACE® (liposomal amikacin for inhalation) in non-tuberculous mycobacterial (NTM) lung disease.

The Company has been informed by FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the Agency has insufficient information to assess the risks of ARIKACE in NTM patients in the planned phase 3 clinical trial. FDA is requiring that the Company conduct a phase 2 clinical trial in adult NTM patients intended to provide proof-of-concept efficacy and safety data for ARIKACE in NTM before the Company can proceed with a phase 3 clinical trial. In addition, the Company will also need to further revise the assessment of the rat carcinogenicity study findings in the investigator brochure.

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

99.1 Press release issued by Insmed Incorporated dated October 14, 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.

Insmed Incorporated

Date: October 14, 2011

By: /s/ Kevin P. Tully C.G.A.
Name: Kevin P. Tully C.G.A.
Title:
Executive
Vice
President
& Chief
Financial
Officer