INSMED INC
Form 8-K
January 23, 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): January 20, 2012

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.)
9 Deer Park Drive, Monmouth Junction, New Jersey	08852
(Address of Principal Executive Offices)	(Zip Code)

(732) 997-4600
(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 January 20, 2012, Insmed Incorporated (the "Company") issued a press release providing a Corporate update announcing that the U.S. Food and Drug Administration (the "FDA") has notified the Company that it has lifted the clinical hold previously placed on ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacteria (NTM) lung disease. In addition the Company announced that as part of its on-going assessment of the appropriate path forward for the ARIKACE program, including the phase 2 trial of ARIKACE in NTM patients, that the Company is continuing communication with FDA regarding the CF clinical hold. The Company also announced as part of the update that it will move ahead with the 9-month dog inhalation toxicity study of ARIKACE as previously requested by FDA to determine if the findings of a long-term rat inhalation carcinogenicity study, which was completed in 2011, are observed in a non-rodent model. The press release also noted as part of the update that the Company's IPLEX® inventory has now been fully depleted and the Company is currently evaluating possible out-licensing opportunities for IPLEX®.

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 January 20, 2012.

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: January 20, 2012

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