

INSMED INC  
Form 8-K  
June 18, 2014

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 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): **June 17, 2014**

**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**  
(I.R.S. Employer Identification  
No.)

**9 Deer Park Drive, Suite C,**  
  
**Monmouth Junction, New Jersey**  
(Address of principal executive offices)

**08852**  
(Zip Code)

Registrant's telephone number, including area code: **(732) 997-4600**

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**Not Applicable**

(Former name or former address, if changed since last report.)

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 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))
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**Item 8.01. Other Events.**

Insmmed Incorporated (the Company) announced today that the U.S. Food and Drug Administration (the FDA) granted ARIKAYCE, or liposomal amikacin for inhalation, Breakthrough Therapy Designation for the treatment of adult patients with nontuberculous mycobacterial (NTM) lung disease who are treatment refractory. This designation is based on findings from the Company's U.S. phase 2 clinical trial of ARIKAYCE to treat NTM lung infections. The Company has plans to meet with the FDA to discuss the regulatory pathway for ARIKAYCE.

**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.

Dated: June 17, 2014

INSMED INCORPORATED

|        |   |
|--------|---|
| By:    | /s/ Christine Pellizzari                |
| Name:  | Christine Pellizzari                    |
| Title: | General Counsel and Corporate Secretary |