

INSMED Inc
Form 8-K
January 05, 2015

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): **December 30, 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.)

10 Finderne Avenue, Building 10
Bridgewater, NJ
(Address of principal executive offices)

08807
(Zip Code)

Registrant's telephone number, including area code: **(908) 997-9900**

Not Applicable

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(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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01. Entry into a Material Definitive Agreement.

On December 30, 2014, Insmed Incorporated, a Virginia corporation (the Company), entered into Work Order 1 (the Work Order), pursuant to a Master Agreement for Services (MSA) with SynteractHCR, Inc., a California corporation (Synteract), dated as of August 27, 2014 (the Effective Date), as amended on December 23, 2014, pursuant to which the Company retained Synteract to perform implementation and management services in connection with certain clinical trials pursuant to a specific protocol of pharmaceutical products under development by or under the control of the Company (each, a Study).

Pursuant to the Work Order, Synteract will provide comprehensive services for Protocol INS-212, a randomized, open-label, multicenter study of liposomal amikacin for inhalation in adult patients with nontuberculous mycobacterial (NTM) lung infections caused by mycobacterium avium complex that are refractory to treatment. Prior to the execution of the Work Order, Synteract was providing such services pursuant to a Letter of Intent, dated August 25, 2014. The Work Order covers services related to INS-212 only and any additional Study will be subject to the negotiation and execution of an additional work order. It is anticipated that aggregate costs to the Company relating to the Work Order will be approximately \$33 million over the period of the study.

The MSA continues until the three year anniversary of the Effective Date, unless sooner terminated as permitted therein. The Company may terminate the MSA and/or Work Order for any reason and without cause by providing 30-days written notice to Synteract. Either party may terminate the MSA and/or Work Order (i) for a material breach of the MSA by the other party effective upon giving 30-days prior written notice of termination if such breach is not cured within the 30 day notice period, and (ii) upon the other party filing a voluntary petition in bankruptcy or having an involuntary bankruptcy petition filed against it, which is not dismissed within 30 days after its institution. In addition, either party may terminate the MSA and/or Work Order effective immediately upon written notice to the other party, (i) if continuation of the Services (as defined in the MSA) would pose an undue risk to the health and/or well-being of a Study participant, (ii) if any certificate, authorization, approval or exemption from a regulatory authority required for the conduct of the Services is revoked, suspended, or expires without renewal, or (iii) if such party is of the reasonable opinion that the continuation of the Services would be in violation of applicable law. All intellectual property rights generated or derived from a Study shall be owned solely by the Company. The MSA and Work Order also contain customary representations, warranties and covenants from the Company and Synteract, as well as customary provisions relating to indemnity, confidentiality and other matters.

The description of the MSA and Work Order are summaries only and are qualified in their entirety by the full and complete terms of such MSA and Work Order, which the Company expects will be filed as exhibits to the Company's annual report on Form 10-K for the year ended December 31, 2014.

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: January 5, 2015

INSMED INCORPORATED

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