INSMED Inc
Form 8-K
October 05, 2016

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): **September 30, 2016**

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia	**0-30739**	**54-1972729**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

10 Finderne Avenue, Building 10
Bridgewater, New Jersey **08807**
(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code: **(908) 977-9900**

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):

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))

ITEM 1.01 Entry into a Material Definitive Agreement.

License Agreement

On October 4, 2016, Insmed Incorporated (the Company) entered into a license agreement (the License Agreement) with AstraZeneca AB, a Swedish corporation (AstraZeneca). Pursuant to the terms of the License Agreement, AstraZeneca has granted the Company global exclusive rights for the purpose of developing and commercializing AZD7986 (the Compound). The Compound is a novel oral inhibitor of dipeptidyl peptidase I (DPP1). DPP1 is an enzyme that catalyzes the activation of neutrophil serine proteases, which play a key role in pulmonary diseases such as non-cystic fibrosis bronchiectasis. The License Agreement also provides the Company with the right to grant sublicenses, subject to the satisfaction of certain conditions.

In consideration of the licenses and other rights granted by AstraZeneca, the Company will pay an upfront payment of $30 million within 30 days of signing the License Agreement, and will make a series of contingent milestone payments totaling up to an additional $85 million upon the achievement of clinical development and regulatory filing milestones. If the Company elects to develop the Compound for a second indication, the Company will make an additional series of contingent milestone payments equal to half of the contingent milestone payments in the preceding sentence. No additional milestone payments are due for any indications beyond the first and second indications. In addition, the Company will pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teen on net sales of any approved product based on the Compound and one additional payment of $35 million upon the first achievement of $1 billion in annual net sales. The License Agreement provides AstraZeneca with the option to negotiate a future agreement with the Company for commercialization of the Compound in chronic obstructive pulmonary disease or asthma.

The License Agreement is effective as of October 4, 2016 and will continue in effect until such time as the Company no longer owes any royalty payments to AstraZeneca, unless earlier terminated by either party pursuant to the terms of the License Agreement.

Either party may terminate the Agreement upon the occurrence of certain events, including, (i) insolvency or bankruptcy of the other party, or (ii) material breach of the Agreement by either party by providing six (6) months (the Notice Period) prior written notice, provided that the termination will not become effective if (a) such breach is cured within the Notice Period, or, (b) if such breach cannot be cured during the Notice Period, if the breaching party commences actions to cure such breach during the Notice Period and diligently continues such actions. In addition, the Company may terminate the Agreement (i) in its entirety immediately upon written notice to AstraZeneca if the Company in good faith determines not to develop or commercialize the Licensed Products (as defined in the License Agreement) due to safety or efficacy concerns, or (ii) in its entirety, on a Licensed Product-by-Licensed Product basis or on a country-by-country basis, for any reason, upon sixty (60) days notice to AstraZeneca.

Following termination of the License Agreement in its entirety (i) by AstraZeneca for Insmed s breach or insolvency, or (ii) by Insmed for convenience, all rights and licenses granted by AstraZeneca under the License Agreement will terminate immediately.

Following termination in a Terminated Territory (as defined in the License Agreement) by AstraZeneca for Insmed s breach or by Insmed for Insmed s convenience, all rights and licenses granted by AstraZeneca under the License Agreement shall terminate with respect to the Terminated Territory except as necessary for purposes of furthering commercialization of the Licensed Products in the remaining territory, or

any development or manufacturing in support of such commercialization.

The Agreement also contains customary representations, warranties and covenants from the Company and AstraZeneca, as well as customary provisions relating to indemnity, confidentiality and other matters.

Amended and Restated Loan and Security Agreement

On September 30, 2016, the Company and its domestic subsidiaries, as co-borrowers, entered into an Amended and Restated Loan and Security Agreement (the A&R Loan Agreement) with Hercules Capital, Inc., a Maryland corporation (Hercules). The A&R Loan Agreement includes a total commitment from Hercules of up to $55 million, of which $25 million was previously outstanding. The amount of borrowings was increased by $10 million to an aggregate total of $35 million on September 30, 2016. An additional $20 million is available at the Company s option through June 30, 2017 subject to certain conditions, including the payment of a facility fee of 0.375%. The Company intends to exercise this option in connection with its upfront payment obligation under the License Agreement. The interest rate for the term is floating and is defined as the greater of (i) 9.25% or (ii) 9.25% plus the sum of the US prime rate minus 4.50%, along with a backend fee of 4.15% of the aggregate principal amount outstanding and an aggregate facility fee of $337,500. The interest-only period was extended through May 1, 2018, but can be extended up to 12 months under certain conditions. The maturity date of the loan facility was also extended to October 1, 2020.

The A&R Loan Agreement also contains representations and warranties by the Company and Hercules and indemnification provisions in favor of Hercules and customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividend), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Hercules security interest or in the collateral, and events relating to bankruptcy or insolvency). Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and Hercules may terminate its lending commitment, declare all outstanding obligations immediately due and payable, and take such other actions as set forth in the A&R Loan Agreement. Pursuant to the A&R Loan Agreement, upon the Company s exercise of its option to increase its borrowings by $20 million, the Company is required to have a consolidated minimum cash liquidity in an amount no less than $25 million. Such requirement terminates upon the earlier of the date by which the Company completes an equity financing with at least $75 million in proceeds or the date the Company generates and announces data from the CONVERT Phase III study in a manner that could support an NDA filing. In addition, pursuant to the A&R Loan Agreement, Hercules has the right to participate, in an aggregate amount of up to $2 million, in a subsequent private financing of equity securities.

The foregoing descriptions of the terms of the License Agreement and A&R Loan Agreement are qualified in their entirety by reference to the full text of each of the License Agreement and the A&R Loan Agreement. The Company expects to file the A&R Loan Agreement as an exhibit to its quarterly report on Form 10-Q for the period ending September 30, 2016. The Company expects to file the License Agreement as an exhibit to its annual report on Form 10-K for the year ended December 31, 2016, with portions of the License Agreement omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment. A copy of the press release issued by the Company relating to the License Agreement is attached to this Current Report on Form 8-K as Exhibit 99.1.

ITEM 9.01 - Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release issued by Insmed Incorporated on October 5, 2016.

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: October 5, 2016

INSMED INCORPORATED

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