INSMED INC

FORM 8-K
(Current report filing)

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Address	10 FINDERNE AVENUE BUILDING 10 BRIDGEWATER, NJ, 08807
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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): **February 23, 2018**

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, NJ**	**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):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 2.02 - Results of Operations and Financial Condition.

On February 23, 2018, Insmed Incorporated issued a press release regarding its financial results for the three months and fiscal year ended December 31, 2017. A copy of this press release is furnished herewith as Exhibit 99.1 pursuant to this Item 2.02.

The information contained herein, including the Exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 9.01 - Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Insmed Incorporated on February 23, 2018.

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.

Date: February 23, 2018

INSMED INCORPORATED
By: /s/ Christine Pellizzari
Name: Christine Pellizzari
Title: Chief Legal Officer

Insmed Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Business Update

- ***On track to file NDA before the end of March and anticipate a priority review***
- ***Extended amikacin liposome inhalation suspension (ALIS) intellectual property protection to 2035 with issuance of ninth U.S. patent***
- ***Strengthened cash position through the public offering of $450 million of convertible senior notes in January 2018***
- ***Completed the hiring of 71 therapeutic specialists and 5 key account directors to support disease state awareness efforts in the U.S.***

BRIDGEWATER, N.J., February 23, 2018 (GLOBE NEWSWIRE) — Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on the unmet needs of patients with rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2017 and provided a business update.

"Last year proved to be pivotal for Insmed in our efforts toward building a company that will transform the lives of patients living with serious rare diseases. We are preparing for an even greater transformation in 2018 as we anticipate the launch of what would be the first approved inhaled therapy for the treatment of refractory NTM lung disease caused by MAC in the United States," said Will Lewis, President and Chief Executive Officer of Insmed. "The data reported from our ALIS program, together with our ongoing regulatory and pre-commercial activities, puts us on a trajectory to significantly help patients afflicted by this disease. We look forward to further expanding our global reach from the US and Europe to include Japan. Having successfully completed a public offering in January, we are in a solid financial position to fully fund our key strategic activities, and we look forward to sharing our progress throughout the year."

Corporate Update

INS-212 and INS-312 Interim Results as of December 2017

In January, Insmed announced interim results from its INS-312 study, a 12-month extension study for patients who completed six months of treatment in the INS-212 study, but did not demonstrate culture conversion by Month 6, as well as long-term durability data from its INS-212 study evaluating ALIS + guideline-based therapy (GBT) vs. GBT alone in adult patients with nontuberculous mycobacterial (NTM) lung disease caused by *Mycobacterium avium* complex (MAC). Patients in either arm of the INS-212 study who did not achieve culture conversion by Month 6 had the option to enroll in INS-312 at Month 8.

- Sputum culture conversion results seen through December 2017 in INS-312 for GBT non-converters who crossed over to treatment with ALIS + GBT (28%) are consistent with sputum culture conversion observed in top-line results from INS-212 (29%).
- INS-312 interim descriptive data demonstrate that continued treatment with ALIS + GBT results in more patients achieving culture conversion, with 12% of prior non-converters from INS-212 ALIS + GBT achieving culture conversion by Month 6 in INS-312.
- INS-212 interim data show that durability of culture conversion three months off of all treatment, which the company believes will be the endpoint required to support full regulatory approval, is substantially higher in ALIS + GBT (61%) vs. GBT alone (0%).
- Serious treatment emergent adverse events observed in INS-312 are similar to those seen in INS-212 and remain consistent with those seen with the use of inhaled antibiotics. As of December 2017, the dropout rate in INS-312 is 24%.
- The Company plans to continue to monitor and evaluate patients throughout the duration of the INS-212 study and expects to report additional data in late 2018 or early 2019 when the INS-312 study has completed its full 12 months and the data has been analyzed pursuant to its statistical analysis plan as agreed with FDA.

New U.S. Patent Issued Extends ALIS Intellectual Property Protection

Earlier this week, Insmed announced that the United States Patent and Trademark Office issued U.S. Patent Number 9,895,385 concerning methods for treating NTM lung infections, including NTM lung infections caused by MAC, with ALIS. The claims of the patent relate to methods for treating MAC lung infections via administration of ALIS to non-cystic fibrosis patients by nebulization once daily for a defined treatment period. The patent extends previously existing patent coverage for ALIS by sixteen months, from January 2034 into May 2035.

Litigation Update

Insmed announces that the U.S. District Court for the District of New Jersey granted the Company's motion to dismiss in the 2016 securities class action lawsuit brought against the Company and certain of its officers and directors. On February 15, 2018, the court dismissed the lawsuit without prejudice, meaning that the plaintiff has 30 days from the date of the order to file a second amended complaint.

Insmed Announces Key Management Promotions

Insmed also announces the promotions of Christine Pellizzari to the position of Chief Legal Officer from General Counsel and Corporate Secretary, and Nicole Schaeffer to Chief People Strategy Officer from Senior Vice President, Human Resources and Corporate Services.

Fourth Quarter Financial Results

For the fourth quarter of 2017, Insmed reported a net loss of $65.4 million, or $0.85 per share, compared with a net loss of $68.4 million, or $1.10 per share, for the fourth quarter of 2016.

Research and development expenses were $33.9 million for the fourth quarter of 2017, compared with $54.9 million for the fourth quarter of 2016. The decrease was primarily due to a one-time $30.0 million upfront payment related to INS1007 in October 2016, partially offset by an increase in expenses associated with the development of INS-1007 and higher compensation and related expenses due to an increase in headcount, as compared to the fourth quarter of 2016.

General and administrative expenses for the fourth quarter of 2017 were $31.4 million, compared with $12.2 million for the fourth quarter of 2016. The increase was primarily due to higher expenses related to our pre-commercial planning activities for ALIS, a one-time payment to reduce the royalty owed to PARI Pharma GmbH and higher compensation and related expenses due to an increase in headcount, as compared to the fourth quarter of 2016.

Balance Sheet and Cash Guidance

As of December 31, 2017, Insmed had cash and cash equivalents of approximately $381.2 million and debt of $55.0 million. These figures do not reflect the net proceeds of $435.8 million received in January 2018 from the public offering of $450 million of 1.75% senior convertible notes due in 2025. The Company's operating expenses for the fourth quarter of 2017 were $65.4 million and $188.9 million for the full year of 2017. The cash-based operating expenses for the fourth quarter of 2017 were approximately $59.9 million and $167.9 million for the full year of 2017. The Company intends to repay the existing debt from Hercules Capital on February 28, 2018. The total payment including the backend fee and early prepayment penalty will be approximately $58 million.

The Company is investing in the following key activities in 2018: (i) the build-out of the commercial organization to support global expansion activities for ALIS, (ii) manufacturing of commercial inventory and build out of an additional third-party manufacturing facility and (iii) clinical activities for ALIS and the phase 2 development program for INS-1007, along with advancement of other pipeline programs. As a result of these activities, Insmed expects cash based operating expenses and capital and other cash investments to be in the range of $145 million to $165 million for the first half of 2018.

Conference Call

Insmed will host a conference call beginning today at 8:30 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing (844) 707-0669 (domestic) or (703) 639-1223 (international) and referencing conference ID number 9066979. The call will also be webcast live on the Company's website at www.insmed.com.

A replay of the conference call will be accessible approximately two hours after its completion through March 2, 2018 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and referencing conference ID number 9066979. A webcast of the call will also be archived for 90 days under the Investor Relations section of the Company's website at www.insmed.com.

Non-GAAP Financial Measures

In addition to the United States generally accepted accounting principles (GAAP) results, this earnings release includes cash-based operating expenses, a non-GAAP financial measure, which Insmed defines as total operating expenses excluding stock-based compensation expense and depreciation expense. A reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure is presented in the table attached to this press release.

Management believes that this non-GAAP financial measure is useful to both management and investors in analyzing our ongoing business and operating performance. Management believes that providing non-GAAP information to investors, in addition to the GAAP presentation, allows investors to view our financial results in the way that management views financial results. Management does not intend the presentation of this non-GAAP financial measure to be considered in isolation or as a substitute for results prepared in accordance with GAAP. In addition, this non-GAAP financial measure may differ from similarly named measures used by other companies.

About NTM Lung Disease

NTM lung disease is a rare and serious disorder associated with increased rates of morbidity and mortality. There is an increasing prevalence of lung disease caused by NTM, and we believe it is an emerging public health concern worldwide. Patients with NTM lung disease may experience a multitude of symptoms such as fever, weight loss, cough, lack of appetite, night sweats, blood in the sputum, and fatigue. Patients with NTM lung disease frequently require lengthy hospital stays to manage their condition. We are not aware of any approved inhaled therapies specifically indicated for refractory NTM lung disease caused by MAC in North America, Japan or Europe. Current guideline-based approaches involve use of multi-drug regimens not approved for the treatment of NTM lung disease, and treatment can be as long as two years or more.

The prevalence of human disease attributable to NTM has increased over the past two decades. In a decade long study (1997 to 2007), researchers found that the prevalence of NTM lung disease in the U.S. was increasing at approximately 8% per year and that NTM patients on Medicare over the age of 65 were 40% more likely to die over the period of the study than those who did not have the disease. In the U.S., we estimate there will be between 75,000 and 105,000 patients with diagnosed NTM lung disease in 2018, of which we expect 40,000 to 50,000 will be treated for NTM lung disease caused by MAC. We expect that between 10,000 and 15,000 of these patients will be refractory to treatment. In Japan, we estimate there will be between 125,000 and 145,000 patients with diagnosed NTM lung disease in 2018, with approximately 60,000 to 70,000 of those patients being treated for NTM lung disease caused by MAC and 15,000 to 18,000 of these treated patients being refractory to treatment. We also estimate there will be approximately 14,000 patients with diagnosed NTM lung disease in the EU5 (comprised of France, Germany, Italy, Spain and the United Kingdom) in 2018, of which we estimate approximately 4,400 will be treated for NTM lung disease caused by MAC and approximately 1,400 of these treated patients will be refractory to treatment.

About ALIS

ALIS is a novel, inhaled, once-daily formulation of amikacin that is in late-stage clinical development for adult patients with treatment-refractory NTM lung disease caused by MAC. Amikacin solution for parenteral administration is an established drug that has activity against a variety of NTM; however, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function. Insmed's advanced pulmonary liposome technology uses charge neutral liposomes to deliver amikacin directly to the lung where it is taken up by the lung macrophages where the NTM infection resides. This prolongs the release of amikacin in the lungs while minimizing systemic exposure thereby offering the potential for decreased systemic toxicities. ALIS's ability to deliver high levels of amikacin directly to the lung distinguishes it from intravenous amikacin. ALIS is administered once daily using an optimized, investigational eFlow® Nebulizer System manufactured by PARI Pharma GmbH (PARI), a portable aerosol delivery system.

About CONVERT (INS-212) and INS-312

CONVERT is a randomized, open-label, global Phase 3 trial designed to confirm the culture conversion results seen in Insmed's Phase 2 clinical trial of ALIS in patients with refractory NTM lung disease caused by MAC. CONVERT is being conducted in 18 countries at more than 125 sites. The primary efficacy endpoint is the proportion of patients who achieve culture conversion at Month 6 in the ALIS plus GBT arm compared to the GBT-only arm. Patients who achieve culture conversion by Month 6 will continue in the CONVERT study for an additional 12 months of treatment following the first monthly negative sputum culture. Patients who do not culture convert have the option of enrolling in our INS-312 study. INS-312 is a single-arm open-label extension study for patients who completed six months of treatment in the INS-212 study, but did not demonstrate culture conversion by Month 6. Under the study protocol, patients in the ALIS plus GBT arm of the INS-212 study will receive an additional 12 months of ALIS plus GBT. Patients who crossed over from the GBT-only arm of the INS-212 study will receive 12 months of treatment of ALIS + GBT.

About Insmed

Insmed Incorporated is a global biopharmaceutical Company focused on the unmet needs of patients with rare diseases. The Company's lead product candidate is ALIS, which is in late-state development for adult patients with treatment refractory NTM lung disease caused by MAC, which is a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral reversible inhibitor of dipeptidyl peptidase 1 with therapeutic potential in non-cystic fibrosis bronchiectasis and other inflammatory diseases, and INS1009, an inhaled nanoparticle formulation of a treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders, including pulmonary arterial hypertension. For more information, visit www.insmed.com.

Forward-looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. “Forward-looking statements,” as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “intends,” “potential,” “continues,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) may identify forward-looking statements.

The forward-looking statements in this press release are based upon the Company’s current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause the Company’s actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such risks, uncertainties and other factors include, among others, the following: risks that the full six-month data from the INS-212 study or subsequent data from the remainder of the study’s treatment and off-treatment phases will not be consistent with the top-line six-month results of the study; uncertainties in the research and development of the Company’s existing product candidates, including due to delays in data readouts, such as the full data from the INS-212 study, patient enrollment and retention or failure of the Company’s preclinical studies or clinical trials to satisfy pre-established endpoints, including secondary endpoints in the INS-212 study and endpoints in the INS-212 extension study (the 312 study); risks that subsequent data from the 312 study will not be consistent with the interim results; failure to obtain, or delays in obtaining, regulatory approval from the U.S. Food and Drug Administration, Japan’s Ministry of Health, Labour and Welfare, Japan’s Pharmaceuticals and Medical Devices Agency, the European Medicines Agency, and other regulatory authorities for the Company’s product candidates or their delivery devices, such as the eFlow Nebulizer System, including due to insufficient clinical data, selection of endpoints that are not satisfactory to regulators, complexity in the review process for combination products or inadequate or delayed data from a human factors study required for U.S. regulatory approval; failure to maintain regulatory approval for the Company’s product candidates, if received, due to a failure to satisfy post-approval regulatory requirements, such as the submission of sufficient data from confirmatory clinical studies; safety and efficacy concerns related to the Company’s product candidates; lack of experience in conducting and managing preclinical development activities and clinical trials necessary for regulatory approval, including the regulatory filing and review process; failure to comply with extensive post-approval regulatory requirements or imposition of significant post-approval restrictions on the Company’s product candidates by regulators; uncertainties in the rate and degree of market acceptance of product candidates, if approved; inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of the Company’s product candidates, if approved; inaccuracies in the Company’s estimates of the size of the potential markets for the Company’s product candidates or limitations by regulators on the proposed treatment population for the Company’s product candidates; failure of third parties on which the Company is dependent to conduct the Company’s clinical trials, to manufacture sufficient quantities of the Company’s product candidates for clinical or commercial needs, including the Company’s raw materials suppliers, or to comply with the Company’s agreements or laws and regulations that impact the Company’s business; inaccurate

estimates regarding the Company's future capital requirements, including those necessary to fund the Company's ongoing clinical development, regulatory and commercialization efforts as well as milestone payments or royalties owed to third parties; failure to develop, or to license for development, additional product candidates, including a failure to attract experienced third-party collaborators; uncertainties in the timing, scope and rate of reimbursement for the Company's product candidates; changes in laws and regulations applicable to the Company's business and failure to comply with such laws and regulations; inability to repay the Company's existing indebtedness or to obtain additional capital when needed on desirable terms or at all; failure to obtain, protect and enforce the Company's patents and other intellectual property and costs associated with litigation or other proceedings related to such matters; restrictions imposed on the Company by license agreements that are critical for the Company's product development, including the Company's license agreements with PARI Pharma GmbH and AstraZeneca AB, and failure to comply with the Company's obligations under such agreements; competitive developments affecting the Company's product candidates and potential exclusivity related thereto; the cost and potential reputational damage resulting from litigation to which the Company is or may be a party, including, without limitation, the class action lawsuit against the Company that recently was dismissed without prejudice; loss of key personnel; and lack of experience operating internationally.

The Company may not actually achieve the results, plans, intentions or expectations indicated by the Company's forward-looking statements because, by their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. For additional information about the risks and uncertainties that may affect the Company's business, please see the factors discussed in Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 and any subsequent filings with the Securities and Exchange Commission.

The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date of this press release. The Company disclaims any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Financial Statements and Reconciliation to Follow
INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except par value and share data)

	As of December 31, 2017	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 381,165	$ 162,591
Prepaid expenses and other current assets	8,279	5,816
Total current assets	389,444	168,407
In-process research and development	58,200	58,200
Fixed assets, net	12,432	10,020
Other assets	1,971	1,329
Total assets	$ 462,047	$ 237,956
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 14,671	$ 10,439
Accrued expenses	29,339	16,822
Other current liabilities	646	728
Total current liabilities	44,656	27,989
Debt, long-term	55,567	54,791
Other long-term liabilities	765	693
Total liabilities	100,988	83,473
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 76,610,508 and 62,019,889 issued and outstanding shares at December 31, 2017 and December 31, 2016, respectively	766	620
Additional paid-in capital	1,318,181	919,164
Accumulated deficit	(957,885)	(765,236)
Accumulated other comprehensive loss	(3)	(65)
Total shareholders' equity	361,059	154,483
Total liabilities and shareholders' equity	$ 462,047	$ 237,956

INSMED INCORPORATED
Consolidated Statements of Net Loss
(in thousands, except per share data)

	Three Months Ended December 31,		Years Ended December 31,	
	2017	2016	2017	2016
	(Unaudited)			
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	33,949	54,870	109,749	122,721
General and administrative	31,404	12,181	79,171	50,679
Total operating expenses	65,353	67,051	188,920	173,400
Operating loss	(65,353)	(67,051)	(188,920)	(173,400)
Investment income	975	132	1,624	604
Interest expense	(1,466)	(1,483)	(5,925)	(3,498)
Other income, net	94	27	300	119
Loss before income taxes	(65,750)	(68,375)	(192,921)	(176,175)
Income tax (benefit) provision	(366)	27	(272)	98
Net loss	$ (65,384)	$ (68,402)	$ (192,649)	$ (176,273)
Basic and diluted net loss per share	$ (0.85)	$ (1.10)	$ (2.89)	$ (2.85)
Weighted average basic and diluted common shares outstanding	76,596	61,955	66,576	61,892

INSMED INCORPORATED
Reconciliation of GAAP to Non-GAAP Results
(in thousands)
(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2017	**2016**	**2017**	**2016**
Operating expenses reconciliation:				
Total operating expenses - GAAP	$ 65,353	$ 67,051	$ 188,920	$ 173,400
Stock-based compensation expense	(4,741)	(4,160)	(18,073)	(18,039)
Depreciation	(733)	(682)	(2,901)	(2,438)
Cash-based operating expenses - Non-GAAP	$ 59,879	$ 62,209	$ 167,946	$ 152,923

Contact:

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