INSMED INC

FORM 8-K
(Current report filing)

Filed 08/03/17 for the Period Ending 08/03/17

Address	10 FINDERNE AVENUE BUILDING 10 BRIDGEWATER, NJ 08807
Telephone	908-977-9900
CIK	0001104506
Symbol	INSM
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **August 3, 2017**

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:

☐ 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 August 3, 2017, Insmed Incorporated issued a press release regarding its financial results as of and for the three months and six months ended June 30, 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 August 3, 2017.

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: August 3, 2017

INSMED INCORPORATED

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

Exhibit 99.1

Insmed Reports Second Quarter 2017 Financial Results and Provides Business Update

- ***On Track to Report Top-Line Results from Phase 3 CONVERT Study in September plus or minus one month***
- ***Plan to Initiate Enrollment of Phase 2 Dose-ranging Study of INS1007 in Non-Cystic Fibrosis (non-CF) Bronchiectasis in the Second Half of 2017***
- ***U.S. Food and Drug Administration (FDA) Provides Established Name for Lead Development Program — ALIS (amikacin liposome inhalation suspension)***

BRIDGEWATER, N.J., August 3, 2017 (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 second quarter ended June 30, 2017 and provided a business update.

Business Update

- ***On track to report top-line results from phase 3 CONVERT study in September plus or minus one month.*** The CONVERT study, or INS-212, is evaluating amikacin liposome inhalation suspension (ALIS) in treatment refractory NTM lung disease caused by MAC. The primary efficacy endpoint is the proportion of subjects who achieve culture conversion at Month 6 in the ALIS plus multi-drug regimen arm compared to the multi-drug regimen without ALIS arm. The Company reported that the last patient in the study has progressed beyond the Month 6 measure. Additionally, Insmed reported that the dropout rate observed in the study was lower than the initially assumed dropout rate.

- **Plan to initiate enrollment of phase 2 dose-ranging study of INS1007 in non-cystic fibrosis (non-CF) bronchiectasis in the second half of 2017.** INS1007 is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase I (DPP1), an enzyme responsible for activating neutrophil serine proteases in neutrophils when they are formed in the bone marrow. Pending dialogue with the FDA, Insmed plans to evaluate two doses of INS1007 (10mg and 25mg) vs. placebo over 24 weeks. The primary endpoint is expected to evaluate time to first exacerbation while secondary endpoints are expected to evaluate mechanistic, clinical and outcomes-based measures. Insmed is also evaluating the potential of INS1007 in other indications.

- **The FDA provides established name for lead development program.** The FDA recently advised Insmed that the established name for its phase 3 product candidate in development for the treatment of refractory nontuberculous mycobacteria (NTM) lung disease caused by *Mycobacterium avium* complex (MAC) will be amikacin liposome inhalation suspension, or ALIS.

- **Enhanced management team with appointment of chief financial officer, chief medical officer and chief product strategy officer.** During the second quarter the company announced changes to its senior leadership team with the appointment of Paolo Tombesi as chief financial officer and Paul Streck, M.D., as chief medical officer. Additionally, Eugene Sullivan, M.D., assumed the newly created role of chief product strategy officer.

"Throughout 2017 we have remained committed to our mission of transforming the lives of patients with rare diseases. We continue to focus on the execution and evaluation of our phase 3 CONVERT study for which we continue to anticipate top-line results in September plus or minus one month. If the study meets the primary endpoint, we intend to complete preparation for a U.S. regulatory filing with the FDA, under Subpart H, for the treatment of patients with refractory NTM," said Will Lewis, president and chief executive officer of Insmed. "Our pre-commercialization activities are also accelerating, as is our assessment of the regulatory pathway beyond the U.S. with a particular focus on Japan. We are also moving ahead with our planning for life cycle management for ALIS and advancing our pipeline."

Second Quarter Financial Results

For the second quarter of 2017, Insmed reported a net loss of $44.7 million, or $0.72 per share, compared with a net loss of $36.6 million, or $0.59 per share, for the second quarter of 2016.

Research and development expenses were $26.9 million for the second quarter of 2017, compared with $23.9 million for the second quarter of 2016. The increase was primarily due to an increase in expenses related to INS1007 and higher compensation and related expenses due to an increase in headcount partially offset by decreases in ALIS manufacturing expenses.

General and administrative expenses for the second quarter of 2017 were $16.6 million, compared with $12.3 million for the second quarter of 2016. The increase was primarily due to higher expenses related to our pre-commercial planning activities for ALIS and higher compensation and related expenses due to an increase in headcount, as compared to the prior year period.

Balance Sheet and Other Financial Highlights

As of June 30, 2017, Insmed had cash and cash equivalents of approximately $91 million. The Company's operating expenses for the second quarter of 2017 were approximately $44 million, and its cash-based operating expenses (as defined below) for the second quarter of 2017 were approximately $38 million. Insmed ended the second quarter of 2017 with approximately $55 million in debt.

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 53207980. The call will also be webcast live on the internet 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 August 17, 2017 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and referencing conference ID number 53207980. 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 Insmed

Insmed Incorporated is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The Company is advancing a global phase 3 clinical study of amikacin liposome inhalation suspension (ALIS) for adult patients with treatment refractory NTM lung disease caused by MAC, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. There are currently no approved inhaled products specifically indicated for the treatment of refractory NTM lung infections caused by MAC in the United States or European Union (EU). Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral reversible inhibitor of DPP1 with therapeutic potential in non-CF bronchiectasis, 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 (PAH). For more information, visit www.insmed.com.

Forward-looking statements

This press release contains forward looking statements. "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 factors include, among others: uncertainties in the research and development of our existing product candidates, including due to delays in patient enrollment or failure of our preclinical studies or clinical trials to satisfy pre-established endpoints; failure to develop, or to license for development, additional product candidates, including a failure to attract experienced third party collaborators; failure to obtain, or delays in obtaining, regulatory approval from the United States Food and Drug Administration, Japan's Pharmaceuticals and Medical Devices Agency, the European Medicines Agency, and other regulatory authorities for our product candidates or their delivery devices, including due to insufficient clinical data or selection of endpoints that are not satisfactory to regulators; failure of third parties on which we are dependent to conduct our clinical trials and to manufacture sufficient quantities of our product candidates for clinical or commercial needs; failure to comply with license agreements that are critical for our product development, including our license agreements with PARI Pharma GmbH and AstraZeneca AB; lack of safety and efficacy of our product candidates; inaccuracies in our estimate of the size of the potential markets for our product candidates; failure to maintain regulatory approval for our product candidates, once received, due to a failure to satisfy post-approval regulatory requirements, such as the need for post-clinical trials; uncertainties in the rate and degree of market acceptance of product candidates, if approved; uncertainties in the timing, scope and rate of reimbursement for our product candidates; competitive developments affecting our product candidates; inaccurate estimates regarding our future capital requirements, including those necessary to fund milestone payments or royalties owed to third parties; inability to repay our existing indebtedness or to obtain additional financing when needed; failure to obtain, protect and enforce our patents and other intellectual property; inability to create an effective direct sales and marketing infrastructure or to partner with a third party that offers such an infrastructure for distribution of our product candidates; the cost and potential reputational damage resulting from litigation to which we are a party, including, without limitation, the class action lawsuit pending against us; failure to comply with the laws and regulations that impact our business; loss of key personnel; and changes in laws and regulations applicable to our business, including those related to pricing and reimbursement of our product candidates. For additional information about the risks and uncertainties that may affect our 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, 2016.

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 Follow

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	26,871	23,871	49,125	44,418
General and administrative	16,644	12,262	30,359	24,782
Total operating expenses	43,515	36,133	79,484	69,200
Operating loss	(43,515)	(36,133)	(79,484)	(69,200)
Investment income	169	164	323	334
Interest expense	(1,489)	(624)	(2,963)	(1,246)
Other income, net	200	32	105	47
Loss before income taxes	(44,635)	(36,561)	(82,019)	(70,065)
Income tax provision	37	18	67	46
Net loss	$ (44,672)	$ (36,579)	$ (82,086)	$ (70,111)
Basic and diluted net loss per share	$ (0.72)	$ (0.59)	$ (1.32)	$ (1.13)
Weighted average basic and diluted common shares outstanding	62,209	61,878	62,126	61,868

INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except par value and share data)

	As of June 30, 2017 (Unaudited)	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 91,064	$ 162,591
Prepaid expenses and other current assets	5,470	5,816
Total current assets	96,534	168,407
In-process research and development	58,200	58,200
Fixed assets, net	9,234	10,020
Other assets	1,672	1,329
Total assets	$ 165,640	$ 237,956
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 11,030	$ 10,439
Accrued expenses	14,548	16,822
Other current liabilities	694	728
Total current liabilities	26,272	27,989
Debt, long-term	55,194	54,791
Other long-term liabilities	729	693
Total liabilities	82,195	83,473
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 62,376,416 and 62,019,889 issued and outstanding shares at June 30, 2017 and December 31, 2016, respectively	624	620
Additional paid-in capital	930,185	919,164
Accumulated deficit	(847,322)	(765,236)
Accumulated other comprehensive loss	(42)	(65)
Total shareholders' equity	83,445	154,483
Total liabilities and shareholders' equity	$ 165,640	$ 237,956

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Operating expenses reconciliation:				
Total operating expenses - GAAP	$ 43,515	$ 36,133	$ 79,484	$ 69,200
Stock-based compensation expense	(4,559)	(4,615)	(8,591)	(8,834)
Depreciation	(738)	(568)	(1,454)	(1,082)
Cash-based operating expenses - Non-GAAP	$ 38,218	$ 30,950	$ 69,439	$ 59,284

Investor Contact:

Blaine Davis
Vice President, Head of Investor Relations
Insmed Incorporated
(908) 947-2841
blaine.davis@insmed.com