Insmed Reports First Quarter 2017 Financial Results and Provides Business Update

Advancing Toward Top-Line Results from CONVERT Study in 2H 2017
Conference call today at 8:30 AM ET

BRIDGEWATER, N.J., May 03, 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 quarter ended March 31, 2017 and provided a business update.

Business Update

- **Advancing toward top-line data for phase 3 CONVERT study in the second half of 2017.** The CONVERT study, or INS-212, is evaluating ARIKAYCE® (liposomal amikacin for inhalation, or LAI) in treatment refractory nontuberculous mycobacteria (NTM) lung disease caused by Mycobacterium avium complex (MAC). The primary efficacy endpoint is the proportion of subjects who achieve culture conversion at Month 6 in the LAI plus multi-drug regimen arm compared to the multi-drug regimen without LAI arm.
- **Plan to initiate a 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. Insmed is also evaluating the potential of INS1007 in other indications. Plans to initiate any phase 2 studies are pending dialogue with the FDA.

"We remain focused on the execution of the phase 3 CONVERT study of LAI in NTM lung disease and on nonclinical activities for INS1007 as a treatment for non-CF bronchiectasis in preparation for the planned initiation of a phase 2 dose-ranging study," said Will Lewis, president and chief executive officer of Insmed. "As we advance toward our top-line results for the CONVERT study in the second half of 2017, we are also making progress in our regulatory and pre-commercial plans to support LAI. We continue to be committed to a disciplined use of capital while carrying out these important clinical, pre-commercial and operational activities."

First Quarter Financial Results

For the first quarter of 2017, Insmed posted a net loss of $37.4 million, or $0.60 per share, compared with a net loss of $33.5 million, or $0.54 per share, for the first quarter of 2016.

Research and development expenses were $22.3 million for the first quarter of 2017, compared with $20.5 million for the first quarter of 2016. The increase was primarily due to compensation and related expenses in connection with an increase in headcount as compared to the prior year period.

General and administrative expenses for the first quarter of 2017 were $13.7 million, compared with $12.5 million for the first quarter of 2016. The increase was primarily due to higher expenses related to our pre-commercial activities for LAI as compared to the prior year period.

Balance Sheet Highlights and Cash Guidance

As of March 31, 2017, Insmed had cash and cash equivalents of approximately $126 million. The Company's operating expenses for the first quarter of 2017 were approximately $36 million, and its cash-based operating expenses (as defined below) for the first quarter of 2017 were approximately $31 million. Insmed ended the first quarter of 2017 with approximately $55 million in debt.

As a result of these activities, Insmed continues to expect its cash-based operating expenses to be in the range of $67 million to $77 million for the first half of 2017. This range primarily reflects spending for the CONVERT study, the follow-on INS-312 study for those NTM patients that do not convert, and continued regulatory and commercial development of LAI. The estimates also include expenses related to INS1007, including clinical inventory purchases as well as preclinical and clinical start-up activities.

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 3999935. 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 May 17, 2017 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and referencing conference ID number 3999935. 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 ARIKAYCE® 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, 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