Insmed Reports Third Quarter 2016 Financial Results and Provides Business Update

Enrollment objective achieved in phase 3 CONVERT study
Conference call today at 8:30 AM ET

BRIDGEWATER, N.J., Nov. 03, 2016 (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 September 30, 2016 and provided a business update.

Business Update

- **Achieved enrollment objective in global phase 3 study of ARIKAYCE™.** Today the company announced that it has achieved its patient enrollment objective in the phase 3 study of ARIKAYCE (liposomal amikacin for inhalation). The study, which is known as CONVERT or INS-212, is evaluating ARIKAYCE 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 ARIKAYCE plus multi-drug regimen arm compared to the multi-drug regimen without ARIKAYCE arm.
- **Published phase 2 study of ARIKAYCE.** In October 2016, the American Journal of Respiratory and Critical Care Medicine published the company's phase 2 study of ARIKAYCE in NTM lung disease. The manuscript, which is entitled "Randomized Trial of Liposomal Amikacin for Inhalation in Nontuberculous Mycobacterial Lung Disease" by Olivier et al. is accessible online at http://www.atsjournals.org/.
- **Presented new analyses of phase 2 study of ARIKAYCE at CHEST.** A poster describing the stability and consistency of effect with ARIKAYCE treatment in the phase 2 study was recently presented at the CHEST annual meeting.
- **Presented new NTM disease burden data at ISPOR European Congress.** Three posters describing the burden of NTM lung disease were recently presented at the International Society for Pharmacoeconomic and Outcomes Research (ISPOR) Annual European Congress.
- **Secured global exclusive rights to novel oral inhibitor of dipeptidyl peptidase I.** In October, the company acquired the global exclusive rights to INS1007 (formerly known as AZD7986) from AstraZeneca. INS1007 is a small molecule, reversible inhibitor of dipeptidyl peptidase I (DPP1), an enzyme responsible for activating neutrophil serine proteases (NSPs) in neutrophils when they are formed in the bone marrow. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. The company expects to begin a phase 2 dose-ranging study of INS1007 in non-cystic fibrosis (non-CF) bronchiectasis in 2017. Non-CF bronchiectasis is a rare, progressive, neutrophil-driven pulmonary disorder with no approved therapies.
- **Presented phase 1 study of INS1009 at ERS 2016.** In September, results from a phase 1 study of INS1009 were presented at the European Respiratory Society International Congress. The study was a randomized, double-blind, placebo-controlled single ascending dose study of INS1009 to determine its safety, tolerability, and pharmacokinetics in healthy volunteers. The pharmacokinetic characteristics supported once- or twice-daily whereas existing inhaled therapies are dosed four to nine times per day. The adverse event profile was consistent with other inhaled prostanoids. INS1009 is the company's inhaled treprostinil prodrug, which may offer therapeutic potential in rare pulmonary disorders.
- **Appointed chief commercial officer.** The company enhanced its senior leadership team with the appointment of Roger Adsett as chief commercial officer. Prior to joining Insmed, Mr. Adsett was senior vice president, head of the gastrointestinal and internal medicine business unit at Shire plc. In that capacity he oversaw Shire's global commercial P&L across six specialty and two rare disease brands. Before joining Shire, Mr. Adsett worked at AstraZeneca for 11 years. Mr. Adsett will be charged with overseeing the development and execution of Insmed's global commercial strategy.

"Recent months have been marked by strong progress across all aspects of our business," said Will Lewis, president and chief executive officer of Insmed. "We are pleased to report that the enrollment phase of the CONVERT study is now complete, which positions us for top-line data next year. There is a significant need for new treatments for patients with refractory NTM lung disease and we look forward to advancing the development of ARIKAYCE. With respect to our earlier-stage pipeline, we are encouraged by the high-level of inbound physician interest in our clinical program for INS1007 in non-CF bronchiectasis. Physicians are eagerly awaiting new treatment options for this debilitating disorder and we believe INS1007 has the potential to achieve disease modification by impeding tissue destruction, inflammation, and mucus hypersecretion through the inhibition of DPP1."

Third Quarter Financial Results

For the third quarter of 2016, Insmed posted a net loss of $37.8 million, or $0.61 per share, compared with a net loss of $31.0 million, or $0.50 per share, for the third quarter of 2015.

Research and development expenses were $23.4 million for the third quarter of 2016, compared with $19.2 million for the third quarter of 2015. The increase was primarily due to the advancement of the company's global phase 3 CONVERT study of ARIKAYCE in NTM lung disease, as well as an increase in headcount and related expenses. These increases were partially offset by a decrease in manufacturing expenses primarily due to the completion of the build-out of additional production capacity at a contract manufacturer in 2015.

General and administrative expenses for the third quarter of 2016 were $13.7 million, compared with $11.0 million for the third quarter of 2015. The increase was primarily related to pre-commercial activities, namely the buildout of the company's infrastructure and NTM disease awareness activities.

Balance Sheet Highlights and Cash Guidance

As of September 30, 2016, Insmed had cash and cash equivalents of $201 million. Excluding depreciation and stock-based compensation expense, the company's cash operating expenses for the nine months ended September 30, 2016 were $91 million. Insmed ended the third quarter of 2016 with $35 million in debt and $183 million of working capital.

On September 30, 2016, Insmed closed a $55 million debt agreement with Hercules Capital, Inc. The transaction refinanced the company's existing debt of $25 million and added a total of $30 million of new debt, $20 million of which was funded in early October in connection with the upfront payment for the global exclusive rights to INS1007.

The company is investing in the following activities in 2016: (i) clinical development of ARIKAYCE, (ii) regulatory and pre-commercial initiatives for ARIKAYCE, and (iii) preclinical and clinical activities for its earlier-stage pipeline. Insmed continues to expect its cash-based operating expenses for the second half of 2016 to be in the range of $62 to $72 million.

Conference Call

Insmed will host a conference call beginning today at8:30 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing (877) 698-3991 (domestic) or (817) 522-1636 (international) and referencing conference ID number 4675771. 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 throughNovember 17, 2016 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and referencing conference ID number 4675771. 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.

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 (liposomal amikacin for inhalation) in nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. There are currently no products indicated for the treatment of NTM lung disease in the United States or European Union (EU). Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral inhibitor of dipeptidyl peptidase I with therapeutic potential in non-cystic fibrosis bronchiectasis, and INS1009, an inhaled prodrug formulation of treprostinil that may offer a differentiated product profile for rare pulmonary disorders. 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) identify forward-looking statements.

Forward-looking statements are based upon the company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause 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, the factors discussed in Item 1A "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2015 and subsequent quarterly reports on Form 10-Q, and the following: the ability to successfully develop INS1007 (formerly known as AZD7986) for the treatment of non-CF bronchiectasis; the ability to complete development of, receive, and maintain regulatory approval for, and successfully commercialize ARIKAYCE, INS1007, and INS1009; the number of patients enrolled and the timing of patient enrollment in the company's global phase 3 clinical study of ARIKAYCE; estimates of expenses and future revenues and profitability; status, timing, and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the sufficiency of preclinical and clinical data in obtaining regulatory approval for the company's product candidates; the timing of responses to information and data requests from the US Food and Drug Administration, the European Medicines Agency, and other regulatory authorities; expectation as to the timing of regulatory review and approval; estimates regarding capital requirements, including milestone payments and royalty obligations due to AstraZeneca, and the needs for additional financing, the ability to repay our existing indebtedness, estimates of the size of the potential markets for product candidates; selection and licensing of product candidates; the ability to attract third parties with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate license agreements and other third party efforts, including those relating to the development and commercialization of product candidates; the degree of protection afforded to the company by its intellectual property portfolio; the safety and efficacy of product candidates; sources of revenues and anticipated revenues, including contributions from license agreements and other third party efforts for the development and commercialization of products; the ability to create an effective direct sales and marketing infrastructure for products the company elects to market and sell directly; the rate and degree of market acceptance of product candidates; the impact of any litigation the company is a party to, including, without limitation, the class action lawsuit filed against the company; the timing, scope and rate of reimbursement for product candidates; the success of other competing therapies that may become available; and the availability of adequate supply and manufacturing capacity and quality for product candidates.

The company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Insmed disclaims any obligation, except as specifically required by law and the rules of theSecurities 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 to Follow