Insmed Reports Second Quarter 2016 Financial Results

BRIDGEWATER, N.J., Aug. 04, 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 June 30, 2016.

Business Update

- **Global phase 3 CONVERT study advancing on track.** The company continues to expect patient enrollment in its phase 3 study of ARIKAYCE (liposomal amikacin for inhalation) to conclude in 2016. The study, which is known as CONVERT™ or INS-212, is evaluating ARIKAYCE in nontuberculous mycobacteria (NTM) lung disease caused by Mycobacterium avium complex (MAC). CONVERT is taking place in 18 countries and involves more than 145 sites. 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.
- **Data from phase 2 study of ARIKAYCE presented at the 1st World Bronchiectasis Conference.** One-year follow-up data from the company's phase 2 study of ARIKAYCE in patients with NTM lung disease were recently presented at the 1st World Bronchiectasis Conference in Hannover, Germany. The presentation was one of nine abstracts accepted for oral presentation.
- **Data from phase 1 clinical study of INS1009 to be presented at ERS 2016.** Two abstracts have been accepted for presentation at the European Respiratory Society (ERS) International Congress taking place in LondonSeptember 3-7. The posters are titled "Single dose pharmacokinetics of C16TR for Inhalation (INS1009) vs. treprostinil inhalation solution" and "Safety and pharmacokinetics study of a single ascending dose of C16TR for inhalation (INS1009)". The presentations will take place on Monday September 5. INS1009 is one of the company's nebulized treprostinil prodrugs, which may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF), pulmonary sarcoidosis, and severe refractory asthma.
- **US Patent strengthens global patent portfolio.** The United States Patent and Trademark Office issued patent no. 9,402,845, which provides methods of treating pulmonary infections via inhalation administration of a formulation containing a liposomal quinolone antibiotic and free quinolone antibiotic, such as ciprofloxacin. For example, a method of treating a bronchiectasis patient for a Pseudomonas aeruginosa pulmonary infection with the formulation is provided. The patent complements ARIKAYCE's global intellectual property estate and further solidifies Insmed's position as an innovator of liposomal antibiotic technology for pulmonary disorders and infections.

"Our phase 3 CONVERT study is our top corporate priority and we anticipate concluding enrollment later this year," said Will Lewis, president and chief executive officer of Insmed. "Positive data from CONVERT are expected to support a broad global regulatory strategy and advance our goal of bringing ARIKAYCE to patients with NTM lung disease who are in great need of new therapeutic options."

Second Quarter Financial Results

For the second quarter of 2016, Insmed posted a net loss of $36.6 million, or $0.59 per share, compared with a net loss of $28.6 million, or $0.47 per share, for the second quarter of 2015.

Research and development expenses were $23.9 million for the second quarter of 2016, compared with $18.2 million for the second 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.

General and administrative expenses for the second quarter of 2016 were $12.3 million, compared with $9.7 million for the second 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, as well as an increase in headcount and related expenses.

Balance Sheet Highlights and Cash Guidance

"Observing the market changes from the beginning of the year, we are closely managing our operations resulting in cash operating expenses at the low end of our guidance for the first half of the year," said Andy Drechsler, chief financial officer of Insmed. "We continue to ensure that mission-critical priorities, such as the phase 3 CONVERT study and other key pre-commercial activities, are fully resourced. Given our solid cash position and disciplined approached to capital allocation, we expect to execute on our operational and strategic priorities."

As of June 30, 2016, Insmed had cash and cash equivalents of $223 million. Excluding depreciation and stock-based compensation expense, the company's cash operating expenses for the six months ended June 30, 2016 were $59 million, which was at the low end of the company's previously guided range of $58 to $68 million. Insmed ended the second quarter of 2016 with $25 million in debt and $197 million of working capital.

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 expects its cash-based operating expenses for the second half of 2016 to be in the range of $62 to $72 million.

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 INS1009, a nebulized prodrug formulation of treprostinil that the company believes may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF), sarcoidosis, and severe refractory asthma. To complement its internal research, Insmed actively seeks in-licensing opportunities for a broad range of rare diseases. For more information, visit www.insmed.com.

"Insmed" and "ARIKAYCE" are the company's trademarks. All other trademarks, trade names or service marks appearing in this press release are the property of their respective owners.

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 complete development of, receive regulatory approval for, and successfully commercialize ARIKAYCE, or liposomal amikacin for inhalation (LAI), and INS1009, nebulized treprostinil prodrug; 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; plans to develop and market new products and the timing of these development programs; 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; clinical development of product candidates; ability to obtain and maintain regulatory approval for product candidates; expectation as to the timing of regulatory review and approval; estimates regarding capital requirements and the needs for additional financing; estimates of the size of the potential markets for product candidates; selection and licensing of product candidates; 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; 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 recently 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 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 to Follow