Insmed Announces First Quarter 2012 Financial Results

MONMOUTH JUNCTION, N.J., May 8, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSM), a biopharmaceutical company, today reported results for the first quarter ended March 31, 2012.

Key Recent Highlights:

- U.S. Food and Drug Administration (FDA) lifted clinical hold on ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections;
- Initiated dosing in CLinical Evaluation of ARIKACE phase 3 study (CLEAR-108) of ARIKACE for CF patients;
- U.S. phase 2 clinical trial for ARIKACE in the non-tuberculous mycobacterial (NTM) lung disease indication on track to begin in mid-2012;
- Commenced dosing for nine-month inhalation dog toxicity study.

"We are pleased FDA has lifted the clinical hold on ARIKACE in CF patients, and are excited about the important recent progress we have made with our ARIKACE development program," said Timothy Whitten, President and CEO of Insmed. "Many of the trial sites for CLEAR-108 are up and running, including those in key European countries and we are also proceeding with this study in Canada. We anticipate top-line efficacy and safety data in mid-2013. In addition, we are working towards initiating our phase 2 U.S. clinical trial for ARIKACE in NTM patients in mid-2012."

"We are at a point of significant focused activity with our ARIKACE development program, and continue to believe that ARIKACE provides a late-stage, potentially highly differentiated opportunity, with significant global commercial potential in both CF and NTM," continued Mr. Whitten. "Importantly, we believe our current cash position is sufficient to generate top-line data from CLEAR-108 and the randomized portion of the U.S. phase 2 clinical trial for ARIKACE in NTM."

Financial Results:

For the first quarter of 2012, Insmed posted a net loss attributable to common shareholders of $6.8 million, or $0.28 per common share — basic and diluted, compared to net loss of $16.1 million, or $0.85 per common share — basic and diluted, for the three months ended March 31, 2011. The $9.3 million reduction in the net loss quarter on quarter was primarily due to a $9.2 million non-cash charge for the beneficial conversion feature of the Series B Conditional Convertible Preferred Stock incurred in the first quarter of 2011, which increased net loss attributable to holders of common shares and, in turn, reduced loss per common share on a basic and diluted basis by $0.48.

Insmed did not record any revenues for the three months ended March 31, 2012. Insmed reported $1.6 million in revenues for the three months ended March 31, 2011. The $1.6 million decrease was due to a combination of the elimination of IPLEX® Expanded Access Program-related revenues following the depletion of IPLEX inventory in December 2011, and the receipt of $250,000 in license fees for our CISPLATIN lipid complex in the first quarter of 2011 as compared to zero in the current quarter.

Research and development (R&D) expenses decreased to $4.5 million in the three months ended March 31, 2012 from $5.8 million for the three months ended March 31, 2011. The decrease of $1.3 million in 2012 is attributable primarily to the lower development and manufacturing costs associated with initiating two ARIKACE-related clinical trials at present as compared to the same period in 2011, when three trials were being planned. Insmed is currently conducting the CLEAR-108 clinical trial in Europe and Canada, and is in the process of initiating the U.S. phase 2 NTM trial. In May 2012, FDA lifted the clinical hold on the U.S. phase 3 CF trial. The Company is continuing discussions with the Agency to finalize additional details of the phase 3 study protocol for a potential clinical trial for CF patients and Insmed is evaluating possible next steps for the ARIKACE U.S. CF clinical program.

General and administrative expenses decreased to $2.8 million in the three months ended March 31, 2012 from $3.3 million for the same period in 2011. The $0.5 million decrease was due largely to lower finance, legal and consulting fees related to post-merger matters with Transave and the reverse stock split transaction in March 2011.

As of March 31, 2012, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $72.9 million, consisting of $70.8 million in cash and short-term investments and $2.1 million in a certificate of deposit, as compared to $78.4 million of cash on hand as of December 31, 2011. The $5.5 million decrease in total cash was due primarily to the funding of operations, which consisted primarily of R&D activities.

Conference Call

To participate in today's live 8:30 AM ET conference call, please dial 800-901-5213 (U.S. callers) or 617-786-2962 (international), and provide passcode 51732598. A live webcast of the call will also be available at http://www.media-server.com/m/p/avwy53ma. Please allow extra time prior to the webcast to register, download and install any necessary audio software. The webcast will be archived for 30 days, and a telephone replay of the call will be available for seven days, beginning today at 10:30 AM ET, at 1-888-286-8010 (U.S. callers) or +1-617-801-6888 (international), using passcode 10283919.

About Insmed

Insmed Incorporated is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced liposomal pulmonary technology in areas of high unmet need. For more information, please visit http://www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to our financial position, the sufficiency of our cash and cash equivalents to fund our preclinical studies and clinical trials, results of operations, the status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein, the timing of and costs associated with pre-clinical studies and clinical trials, the development of our products, and the business strategies, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. Our results may be affected by such factors as the receipt and timing of FDA and other regulatory reviews and approvals, if at all, competitive developments affecting our product development, delays in product development or clinical trials, and patent disputes involving currently developing products. The risks and uncertainties include, without limitation, we may experience unexpected regulatory actions, delays or requests, our future clinical trials may not be successful, we may be unsuccessful in developing our product candidates or receiving necessary regulatory approvals, we may experience delays in our product development or clinical trials, our product candidates may not prove to be commercially successful, our expenses may be higher than anticipated and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012. Investors are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

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