Insmed Announces Financial Results for Second Quarter and Six-Months Ended June 30, 2011

MONMOUTH JUNCTION, N.J., Aug. 8, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today reported results for the second quarter and six-months ended June 30, 2011.

Key Recent Highlights:

- Announced positive results through six cycles of data from the open-label phase 2 study of Arikace™ (liposomal amikacin for inhalation) in the treatment of cystic fibrosis (CF) patients with Pseudomonas lung infections
- Added to Russell 3000, Russell 2000, Russell Global, and Russell Microcap Indexes
- Clinical hold placed on Arikace™ phase 3 program by FDA; Insmed to supply currently requested information and data to the Agency by end of August; FDA's response expected within 30 days of receipt of the Company's complete response to the Agency's requests

"We continue to believe Arikace™ has the potential to be an important treatment option for CF patients and those suffering from non-tuberculous mycobacterial (NTM) lung disease based on the efficacy and safety data generated from our phase 2 clinical trial program," said Timothy Whitten, Insmed's President and CEO. "We believe that we are taking the appropriate steps with FDA to address the findings from the interim results of our long-term rat inhalation carcinogenicity study that led to the clinical hold. Moreover, after reviewing the data, we believe we have a sound scientific rationale for those findings and look forward to working closely with our experts and with FDA to provide the Agency with all relevant information and data required to expedite their review and evaluation. Depending upon the timing and results of FDA's review, we are hopeful that we can resume our phase 3 clinical trial program for Arikace™ during the fourth quarter of 2011."

Financial Results:

For the second quarter of 2011, Insmed posted a net loss attributable to common stockholders of $10.0 million, or $0.40 per share — basic and diluted, compared to a net loss of 0.4 million, or $0.03 per share — basic and diluted, for the three months ended June 30, 2010.

Net loss attributable to common stockholders for the six-months ended June 30, 2011 was $26.1 million, or $1.19 per common share — basic and diluted, compared to a net loss of $0.3 million, or $0.02 per common share — basic and diluted, for the six-months ended June 30, 2010. The net loss attributable to common stockholders in 2011 includes the conversion of the Series B Conditional Convertible Preferred Stock, and a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of $9.2 million, which increased the net loss and, in turn, reduced our earnings per common share on a basic and diluted basis by $0.48. The charge represents the $1.00 difference between the conversion price of the preferred stock of $7.10 per share and its carrying value of $6.10 per share. The carrying value of the preferred stock was based on its fair value at issuance, which was estimated using the common stock price reduced for a lack of marketability between the issuance date and the anticipated date of conversion.

Revenues for the three-months ended June 30, 2011 were $1.0 million, as compared to $1.9 million for the quarter ended June 30, 2010. The $0.9 million reduction in revenue was primarily attributable to a year-over-year decrease in cost recovery from Insmed's IPLEX™ Expanded Access Program (EAP) in Europe, due to the smaller number of patients being supplied IPLEX™.

Revenues for the six-months ended June 30, 2011 totalled $2.6 million, as compared to $3.8 million for the six-months ended June 30, 2010. The $1.2 million decrease was also primarily due to a year-over-year decrease of $1.5 million in cost recovery from the IPLEX™ EAP in Europe, partially offset by $0.3 million in license fees received in 2011 for the out-licensing of patent technology related to Insmed's CISPLATIN Lipid Complex.

Research and development (R&D) expenses were $8.7 million for the second quarter of 2011, compared to $0.9 million in the second quarter of 2010. The increase of $7.8 million is attributable to the full scale R&D activities for Arikace™, including the preparation for the initiation of the phase 3 clinical studies planned for the second half of 2011, and the manufacturing of supply to support the studies. General and administrative (G&A) expenses were $2.7 million for the second quarter of 2011, compared to $1.9 million for the same period in 2010. The $0.8 million increase was primarily attributable to the increased headcount associated with the administrative support for the full-scale development of Arikace™.

Research and development expenses increased to $14.5 million in the six-months ended June 30, 2011 from $1.5 million for the six-months ended June 30, 2010. The increase of $13.0 millionin 2011 is also attributable to full scale R&D of Arikace™, including the preparation of the phase 3 studies planned for the second half of 2011 and the manufacturing of supply to support the studies. Of note within the R&D expenses, clinical development and regulatory expenses increased $6.6 million for the first six-months of 2011 compared to 2010 as a result of the planning efforts for the two phase 3 CF studies and one phase 3 NTM study. There was also a $3.0 million increase in clinical manufacturing expenses from 2011 to 2010 attributable to the manufacturing of Arikace™ for use in the phase 3 studies while compensation expenses rose $2.4 million due to an increased headcount of 12 year on year, and additionally we incurred the final $1.0 million payment for the recently completed rat carcinogenicity study. G&A expenses increased to $6.0 million in the six-months ended June 30, 2011 from $3.4 million for the six-months ended June 30, 2010. The $2.6 million increase was due largely to the increased finance, legal and consulting fees related to the business combination with Transave on December 1, 2010, as well as the reverse stock split transaction on March 2, 2011, and the increased administrative support for the Arikace™ development program.

As of June 30, 2011, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $94.0 million, consisting of $91.9 million in cash and short-term investments and $2.1 million in a certificate of deposit, as compared to $110.2 million of cash on hand as of December 31, 2010. The $16.2 million decrease in total cash was primarily due to the net cash used in operating activities of $16.9 million in the first half of 2011, which was partially offset by a $0.5 million increase in payables and a $0.2 million reduction in receivables.

Conference Call

To participate in today's live conference call at 8:30 AM ET, please dial 800-901-5247 (U.S. callers) or 617-786-4501 (international), and provide passcode 14391743. A live webcast of the call will also be available at:

http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=4160458. 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 at 11:30 AM ET on August 8th, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 57316274.

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, and has a proprietary protein platform aimed at niche markets with high unmet medical need. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. 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, results of operations, the status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein, the timing of responses to information and data requests from FDA, 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, 2010 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011. 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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