Insmed Announces Financial Results for Third Quarter and Nine-Months Ended September 30, 2011

MONMOUTH JUNCTION, N.J., Nov. 8, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today reported financial results for the third quarter and nine-months ended September 30, 2011.

Key Recent Highlights:

- FDA clinical hold remains in place in the U.S. for ARIKACE® (liposomal amikacin for inhalation) phase 3 program in Cystic Fibrosis (CF) patients with Pseudomonas lung infections and patients with non-tuberculous mycobacterial (NTM) lung disease
- Insmed continuing with evaluation of potential next steps with ARIKACE program
- Insmed was informed during further dialogue with the Agency that, if the Company chooses to proceed, the required 9-month dog inhalation toxicity study of ARIKACE can be conducted in parallel with the CF phase 3 clinical trials in human subjects
- Company takes non-cash accounting charge of approximately $26 million to reflect the impairment of goodwill and in-process research and development due to delays in the ARIKACE clinical development program and added costs caused by the FDA clinical hold

"Insmed is currently undertaking a comprehensive evaluation of next steps for our ARIKACE program, which we expect to conduct in an expeditious manner," said Timothy Whitten, Insmed's President and CEO. "We are keeping all of our options open in regards to the potential future of ARIKACE, and intend to update the market after we have more definitive insight regarding our path forward."

Financial Results:

In the third quarter ended September 30, 2011, the Company determined that the clinical hold and resulting additional costs associated with the clinical hold was an indicator of possible intangible asset impairment. In compliance with Financial Accounting Standards Board topic 350, external impairment testing was performed as of September 30, 2011. The impairment review resulted in a non-cash charge of $26.0 million in the three and nine-months ended September 30, 2011 to reflect a $19.7 million decline in the fair value of in-process research and development intangible assets and a complete write off of goodwill totalling $6.3 million, both due to the material impact of the clinical hold on our ARIKACE development program.

For the third quarter of 2011, Insmed posted a net loss attributable to common stockholders of $34.6 million ($26.0 million of which represents the non-cash charge resulting from the impairment adjustment described above), or $1.39 per share — basic and diluted, compared to a net loss of $0.3 million, or $0.03 per share — basic and diluted, for the three-months ended September 30, 2010.

Net loss attributable to common stockholders for the nine-months ended September 30, 2011 was $60.7 million (including the $26.0 million non-cash charge resulting from the impairment adjustment required to be taken in the third quarter 2011), or $2.66 per common share — basic and diluted, compared to a net loss of $0.6 million, or $0.05 per common share — basic and diluted, for the nine-months ended September 30, 2010. The net loss attributable to common shares in 2011 also 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 Conditional Convertible 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 $0.40. The charge represents the $1.00 difference between the conversion price of the Series B Conditional Convertible Preferred Stock of $7.10 per share and its carrying value of $6.10 per share. The carrying value of the Series B Conditional Convertible 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 September 30, 2011 were $0.4 million, as compared to $1.8 million for the quarter ended September 30, 2010. The $1.4 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 nine-months ended September 30, 2011 totalled $3.0 million, as compared to $5.6 million for the nine-months ended September 30, 2010. The $2.6 million decrease was also primarily due to a year-over-year decrease of $2.8 million in cost recovery from the IPLEX EAP in Europe, partially offset by $0.2 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 $6.9 million for the third quarter of 2011, compared to $0.8 million in the third quarter of 2010. The increase of $6.1 million is attributable to the R&D activities for ARIKACE, including the preparation for the initiation of the phase 3 clinical studies, which are currently on clinical hold in the U.S., and the manufacturing of supply to support the studies. General and administrative (G&A) expenses were $2.5 million for the third quarter of 2011, compared to $1.6 million for the same period in 2010. The $0.9 million increase was primarily attributable to the increased headcount associated with the administrative support for the full-scale development of ARIKACE.

R&D expenses increased to $21.4 million in the nine-months ended September 30, 2011 from $2.3 million for the nine-months ended September 30, 2010. The increase of $19.1 million in 2011 is also attributable to R&D of ARIKACE, including the preparation of the phase 3 studies, which are currently on clinical hold in the U.S., and the manufacturing of supply to support the studies. Within the R&D expenses, clinical development and regulatory expenses increased $9.0 million for the first nine-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 lung disease study. There was also a $3.8 million increase in clinical manufacturing expenses from 2011 to 2010, attributable to the manufacturing of ARIKACE for use in the phase 3 studies. Also, compensation expenses rose $3.4 million due to an increased headcount of 20 year following the merger year on year to a current R&D total of 28. In addition, Insmed incurred the final payments of $1.1 million for the completion of the rat carcinogenicity study in the nine-months

ended September 30, 2011. G&A expenses increased to $8.5 million in the nine-months ended September 30, 2011 from $5.1 million for the nine-months ended September 30, 2010. The $3.4 million increase was due largely to the increased finance, legal and consulting fees related to the business combination with Transave, Inc., which was consummated on December 1, 2010, as well as the reverse stock split transaction effected on March 2, 2011, and the increased administrative support for the ARIKACE development program.

As of September 30, 2011, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $85.3 million, consisting of $83.2 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 $24.9 million decrease in total cash was primarily due to the net cash used in operating activities of $24.1 million during the first nine-months of 2011.

Conference Call

To participate in today's live conference call at 8:30 AM ET, please dial 866-362-4831 (U.S. callers) or 617-597-5347 (international), and provide passcode 11382552. A live webcast of the call will also be available at: http://www.media-server.com/m/p/8yh5aes3. 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 11:30 AM ET, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 25135317.

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, evaluations, 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 September 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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