Insmed Announces Fourth Quarter and Full-Year 2011 Financial Results

MONMOUTH JUNCTION, N.J., March 13, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today reported results for the fourth quarter and fiscal year ended December 31, 2011.

Key Recent Highlights:

- Clinical hold lifted by U.S. Food and Drug Administration (FDA) for ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacterial (NTM) lung disease
- Insmed proceeding with four key ARIKACE studies:
  - Phase 2 clinical trial in NTM patients
  - Pivotal phase 3 clinical study in Europe in Cystic Fibrosis (CF) patients with Pseudomonas lung infections
  - Follow-on multi-cycle open-label study primarily to measure safety and tolerability for patients who complete the European pivotal phase 3 CF study
  - 9-month dog inhalation toxicity study
- Company submits complete response to FDA requests regarding CF clinical hold

"We have recently made significant progress with our ARIKACE program," said Timothy Whitten, President and CEO of Insmed. "In January of this year, FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections and we plan to initiate enrolment in the phase 2 clinical trial for ARIKACE in NTM patients in mid-2012. In addition, we expect to begin enrolment in the European pivotal phase 3 clinical study of ARIKACE in CF patients in the second quarter of this year. Insmed is also on track to initiate the nine-month dog inhalation toxicity study during the second quarter of this year."

"Additionally, we have submitted our complete response to FDA's requests with regard to the CF clinical hold," noted Mr. Whitten. "We continue to believe that ARIKACE has the potential to be an important treatment option for patients who have NTM lung infections and CF patients who have Pseudomonas lung infections, as well as an opportunity to create significant long-term value for our shareholders."

Financial Results:

For the fourth quarter of 2011, Insmed posted a net loss attributable to common stockholders of $8.2 million, or $0.33 per share — basic and diluted, compared to a net loss of $5.8 million, or $0.42 per share — basic and diluted, for the three months ended December 31, 2010. The fourth quarter of 2011 net loss includes a $1.2 million non-cash charge related to the lease write-down following the closure of the Richmond, Virginia office due to the cessation of IPLEX® activities in December 2011.

Net loss attributable to common stockholders for the year ended December 31, 2011 was $68.8 million, which includes the $1.2 million non-cash charge from the Richmond office closure and a $26.0 million non-cash charge resulting from an impairment adjustment in the third quarter, or $2.95 per common share — basic and diluted, compared to a net loss of $6.4 million, or $0.49per common share — basic and diluted, for the year ended December 31, 2010. The impairment charge in the third quarter of 2011 was due to the material impact of the FDA clinical hold on our ARIKACE development program. The net loss attributable to common stockholders in 2011 also includes the conversion of the Series B 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 earnings of Insmed 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 Preferred Stock of $7.10 per share and its carrying value of $6.10 per share. The carrying value of the Series B 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 December 31, 2011 were $1.4 million, as compared to $1.3 million for the quarter ended December 31, 2010. The $0.1 million increase in revenue was primarily attributable to the receipt of $0.8 million from the licensing of patent technology related to Insmed's CISPLATIN Lipid Complex, which was partially offset by a year-over-year decrease of $0.7 million in cost recovery from Insmed's IPLEX Expanded Access Program (EAP) in Europe, which ended in early December 2011.

Revenues for the year ended December 31, 2011 totalled $4.4 million, as compared to $6.9 million for the year ended December 31, 2010. The $2.5 million decrease was also primarily due to a year-over-year decrease of $3.5 million in cost recovery from the IPLEX EAP in Europe, partially offset by $1.0 million in license fees received in 2011 for the licensing of patent technology related to Insmed's CISPLATIN Lipid Complex.

Research and development (R&D) expenses were $6.5 million for the fourth quarter of 2011, compared to $2.5 million in the fourth quarter of 2010. The increase of $4.0 million is attributable to the clinical and manufacturing R&D activities for ARIKACE in the CF and NTM indications. General and administrative (G&A) expenses were $3.8 million for the fourth quarter of 2011, compared to $5.2 million for the same period in 2010. The $1.4 million decrease was primarily attributable to the non-recurring external finance, legal and consulting expenses related to the business combination in the fourth quarter of 2010, which were partially offset by the Richmond office closure costs and increased headcount expenses in the current quarter.

R&D expenses increased to $27.9 million in the year ended December 31, 2011 from $4.8 million for the year ended December 31, 2010. The increase of $23.1 million in 2011 is also attributable to clinical research and development of the ARIKACE program and the manufacturing of supply to support the studies in 2011. Of note within the R&D expenses, clinical development and regulatory expenses increased $15.4 million in 2011 compared to 2010 as a result of the planning efforts for the ARIKACE studies. There was also a $4.5 million increase in clinical manufacturing expenses from 2011 to 2010 attributable to the manufacturing of ARIKACE for use in these studies while compensation expenses rose $3.2 million due to an increased headcount of 17 year on year to 28. G&A expenses increased to $12.2 million in the year

ended December 31, 2011 from $10.3 million for the year ended December 31, 2010. The $1.9 millionincrease was due largely to the Richmond office closure costs and headcount increases associated with the administrative support for the development of ARIKACE, which were partially offset by the non-recurring business combination costs which were incurred in 2010.

As of December 31, 2011, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling $78.4 million, consisting of $76.3 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 $31.8 million decrease in total cash was primarily due to the net cash used in operating activities of $30.2 million during the 2011 fiscal year.

Conference Call

To participate in today's live conference call at 8:30 AM ET, please dial 800-798-2864 (U.S. callers) or 617-614-6206 (international), and provide passcode 48373405. A live webcast of the call will also be available at: http://www.media-server.com/m/p/xfhdp2ne. 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 10:30 AM ET on March 13th, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 11615475.

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, 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. 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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