# Insmed Reports Fourth Quarter and Full Year 2012 Financial Results

MONMOUTH JUNCTION, NJ -- (Marketwire) -- 03/18/13 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing and commercializing inhaled therapies for patients battling serious lung diseases that are often life-threatening, reported financial results for the three and twelve months ended December 31, 2012.

Highlights of the fourth quarter and recent weeks include:

- Completed enrollment of the Phase 3 study of ARIKACE®, or liposomal amikacin for inhalation, in patients with cystic fibrosis (CF) who have Pseudomonas aeruginosa lung infections and remain on schedule to report top-line results in mid-2013
- Concluded the nine-month dosing phase of a dog inhalation toxicity study of ARIKACE and submitted an unaudited interim report to the US Food and Drug Administration (FDA) stating that the macrophage response was similar to that seen in our previous three-month dosing study in dogs and that there was no evidence of neoplasia, squamous metaplasia or proliferative changes
- Strengthened the cash position by drawing down the remaining $10 million under a loan and security agreement entered into in June 2012
- Recruited Matt Pauls as Chief Commercial Officer. Mr. Pauls, who will join the Company on April 1, 2013, brings to Insmed more than 20 years of experience in the pharmaceutical industry, including senior-level leadership roles in global marketing, sales, reimbursement, new product launches and commercial operations at leading pharmaceutical companies including Shire Pharmaceuticals, Bristol-Myers Squibb and Johnson and Johnson

"During the past six months, we laid the foundation for Insmed's transition to a commercial enterprise," noted Will Lewis, President and Chief Executive Officer of Insmed. "Our focus for 2013 will be to advance our regulatory filings with the data readouts from our two lead clinical trials, expand our leadership team, build out our supply chain and advance our commercial strategy to bring our inhaled therapies to patients suffering with serious lung diseases in these orphan indications."

Fourth Quarter Financial Results

For the fourth quarter of 2012 Insmed posted a net loss attributable to common stockholders of $15.5 million, or $0.49 per share, compared with a net loss of $8.2 million, or $0.33 per share, for the fourth quarter of 2011.

Research and development expense for the fourth quarter of 2012 increased to $12.2 million from $6.8 million for the fourth quarter of 2011. The increase was due to the active clinical development programs for ARIKACE in CF patients with Pseudomonas lung infections and in NTM patients during the fourth quarter of 2012.

General and administrative expense for the fourth quarter of 2012 was $3.6 million, compared with $3.5 million in the fourth quarter of 2011. The fourth quarter 2012 expenses included $1.0 million of severance expenses related to the departure of certain executives and employees. The fourth quarter 2011 expenses included $1.2 million in charges related to the discontinued use of the Company's Richmond, Virginia facility.

2012 Financial Results

For 2012 Insmed posted a net loss attributable to common stockholders of $41.4 million, or $1.56 per share, compared with a net loss of $68.8 million, or $2.95 per share, for 2011. The net loss attributable to common stockholders for 2012 included $2.9 million in severance costs related to the termination of certain executives and employees. The net loss attributable to common stockholders for 2011 included a $26.0 million non-cash impairment loss for the write-down of the carrying amounts of the Company's in-process research and development and goodwill intangible assets, a $9.2 million non-cash charge for the beneficial conversion feature of the previously outstanding Series B Preferred Stock issued in the Transave merger and $1.2 million in expenses relating to the discontinued use of the Company's Richmond, Virginia facility.

Research and development expense for 2012 increased to $29.8 million from $28.6 million for 2011. The net increase of $1.2 million was primarily due to increases in manufacturing expenses, as the Company increased production of ARIKACE for use in clinical studies, and compensation and compensation-related expenses. These increases were mostly offset by lower clinical development expenses during 2012, compared with 2011.

General and administrative expense for 2012 increased to $12.7 million from $11.5 million in 2011. The 2012 results included $2.2 million in severance expenses related to the departure of several executives and employees. The 2011 results included $1.2 million in charges related to the discontinued use of the Company's Richmond, Virginia facility.

Balance Sheet Highlights and Cash Guidance

As of December 31, 2012, Insmed had cash and cash equivalents of $92.9 million, compared with $78.4 million as of December 31, 2011. The increase in cash resulted from financing activities during 2012, which included proceeds from a $20.0 million debt financing and proceeds of $25.7 million from a common stock offering. These financings were partially offset by the use of $31.0 million in the Company's operations. As of December 31, 2012, working capital was $75.7 million, excluding a $2.2 million certificate of deposit that matures in July 2013.

The Company estimates its 2013 cash requirements to fund operations will be in the range of $45 million to $55 million. The Company expects that it will be able to fund operations into 2014 with its existing cash balances as of December 31, 2013.

Conference Call

Insmed management will host an investment community conference call today beginning at 8:30 a.m. Eastern time. Shareholders and other interested parties may participate in the call by dialing 800-299-9630 (domestic) or 617-786-2904 (international) and entering passcode 99541272. The call will also be broadcast live on the Internet at www.insmed.com, www.streetevents.com and www.earnings.com.

A replay of the conference call will be accessible two hours after its completion through March 24, 2013, by dialing 888-286-8010 (domestic) or 617-801-6888 (international) and entering passcode 88911892. The call will also be archived for 90 days at www.insmed.com, www.streetevents.com and www.earnings.com.

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases through the development and commercialization of inhalation therapies in orphan patient populations with critical unmet needs. Insmed's lead candidate, ARIKACE® or liposomal amikacin for inhalation, is engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of treatment for at least two identified orphan patient populations: cystic fibrosis (CF) patients with Pseudomonas aeruginosa lung infections and patients with nontuberculous mycobacteria lung infections (NTM). Insmed's Phase 3 registrational study of ARIKACE in Europe and Canada completed enrollment and the Company expects top-line clinical results in mid-2013. Insmed's U.S. Phase 2 clinical trial in patients with NTM is well underway with clinical results expected in late 2013. For more information, please visit www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements that are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Words, and variations of words, such as "intend," "expect," "will," "anticipate," "believe," "continue," "propose" and similar expressions are intended to identify forward-looking statements. Investors are cautioned that such statements in this release, including statements relating to the status, results and timing of results of preclinical studies and clinical trials and preclinical and clinical data and the anticipated benefits of Insmed's products, constitute forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, without limitation, failure or delay of U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting our product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to our product candidates, unexpected regulatory actions, delays or requests, the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations, inability to successfully develop our product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, 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, 2012 . Investors are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this news release. We undertake no obligation to update these forward-looking statements to reflect events or circumstances or changes in our expectations.