Insmed Announces Financial Results For Second Quarter And Six-months Ended June 30, 2012

MONMOUTH JUNCTION, N.J., Aug. 7, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company dedicated to the development of innovative inhaled pharmaceuticals for the treatment of serious lung infections, today reported results for the second quarter and six-months ended June 30, 2012.

Key Recent Highlights:

- Dosed first patient in April in CLEAR-108 phase 3 European and Canadian registration study of ARIKACE® in patients with cystic fibrosis who have Pseudomonas aeruginosa lung infections; approximately 65 of 80 planned sites activated and recruiting patients
- Dosed first patient in June in the U.S. TARGET-NTM phase 2 trial of ARIKACE in patients with non-tuberculous mycobacteria (NTM) lung infections
- Secured $20 million term loan from Hercules Technology Growth Capital, Inc.
- Granted second composition of matter patent for ARIKACE by U.S. Patent and Trademark Office

"We have successfully transitioned Insmed into a phase 3 development stage company, a significant milestone in our history," said Timothy Whitten, President and CEO of Insmed. "During the second quarter, Insmed made substantial progress in advancing ARIKACE in the clinic in our two priority orphan indications. We continue to expect top-line data from CLEAR-108 in mid-2013 and top-line results from the randomized part of TARGET-NTM in the fourth quarter of 2013. In addition, we recently secured a term loan from Hercules for up to $20 million, $10 million of which has been funded, that will extend our cash runway well into 2014 and provide the Company with further financial stability and flexibility."

Financial Results:

For the second quarter of 2012, Insmed posted a net loss attributable to common stockholders of $9.7 million, or $0.39 per common share — basic and diluted, as compared to a net loss of $10.0 million or $0.40 per common share — basic and diluted, for the three months ended June 30, 2011. The $0.3 million improvement in the net loss was due to a $1.5 million reduction in operating expenses, which was partially offset by a $1.0 million decline in IPLEX® revenue and a $0.2 million reduction in investment income.

Insmed did not record any revenues for the three months ended June 30, 2012 as compared to $1.0 million in revenues reported for the three months ended June 30, 2011. The $1.0 milliondecrease was due to the elimination of IPLEX EAP revenues following the depletion of IPLEX inventory in December 2011.

Research and development expenses decreased to $7.5 million in the three months ended June 30, 2012 from $8.7 million for the three months ended June 30, 2011. The decrease of $1.2 million in 2012 is primarily attributable to a reduction of $2.9 million in development costs associated with initiating two ARIKACE related clinical trials, as compared to the same period in 2011, when three trials were being planned. This includes the one-time start-up costs for each of the three trials in 2011, which were not duplicated in 2012. This reduction was partially offset by an increase of $1.8 million in manufacturing costs associated primarily with initiating the nine-month dog inhalation toxicity study and the build-up of clinical trial drug supply for the ongoing ARIKACE CLEAR-108 and TARGET-NTM clinical studies.

General and administrative expenses of $2.5 million for the three months ended June 30, 2012 were $0.2 million lower than the $2.7 million for the same quarter in 2011 due mainly to a reduction in external finance and legal fees.

Investment income for the second quarter of 2012 of $0.3 million was $0.2 million lower than the corresponding period in 2011 due to the lower cash balance available for investment.

Net loss attributable to common stockholders for the six months ended June 30, 2012 was $16.5 million (or $0.67 per common share — basic and diluted), compared to net loss of $26.1 million(or $1.19 per common share — basic and diluted), for the six months ended June 30, 2011. The $9.6 million reduction in the net loss period on period was primarily due to the $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 the net loss attributable to holders of our common shares and, in turn, reduced our loss 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 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 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. Additionally, a reduction in operating expenses of $3.2 million was partially offset by revenue reduction of $2.6 million and a decline in investment income of $0.3 million in the six months ended June 30, 2012.

Insmed did not record any revenues for the six months ended June 30, 2012. Insmed reported $2.6 million in revenues for the six months ended June 30, 2011. The $2.6 million decrease was due to the elimination of $2.3 million of IPLEX EAP revenues following the depletion of IPLEX inventory in December 2011 and the receipt of $0.3 million in license fees for our CISPLATIN lipid complex in 2011, as compared to zero in the current year.

Research and development expenses decreased to $12.0 million in the six months ended June 30, 2012 from $14.5 million for the six months ended June 30, 2011. The decrease of $2.5 million in the six months ended June 30, 2012 is again attributable primarily to a reduction of $3.5 million in development costs associated with initiating two ARIKACE related clinical trials, as compared to the same period in 2011, when three trials were being planned. This was also offset by an increase of $1.1 million in manufacturing costs in the six months ended June 30, 2012associated with initiating the nine-month dog inhalation toxicity study and building drug supply for the ongoing CLEAR-108 and TARGET-NTM clinical trials.

General and administrative expenses decreased to $5.2 million in the six months ended June 30, 2012 from $6.0 million for the six months ended June 30, 2011. The $0.8 million decrease was due largely to lower finance, legal and consulting fees incurred in the six months ended June 30, 2011 related to post Transave merger matters and the March 2011 reverse stock split transaction.

Investment income decreased to $0.7 million in the six months ended June 30, 2012 from $1.0 million in the six months ended June 30, 2011. The decrease is a result of the lower overall average cash and short-term investments balance for the current quarter as compared to the quarter ended June 30, 2011.

As of June 30, 2012, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totalling $75.2 million, consisting of $73.1 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 $3.2 million decrease in total cash was due primarily to the funding of operations, consisting primarily of research and development activities, totalling $12.9 million, which was primarily offset by the net $9.7 million of funding in June 2012 under the term loan with Hercules Technology Growth Capital.

Conference Call

To participate in today's live conference call, please dial 800-299-7089 (U.S. callers) or 617-801-9714 (international), and provide passcode 17092264. A live webcast of the call will also be available at http://www.media-server.com/m/p/uk852bf4. 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 11016101.

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to the development of innovative inhaled pharmaceuticals for the treatment of serious lung infections, with a particular focus on orphan diseases. Insmed's core expertise is the development of inhaled antibiotic therapy delivered via proprietary advanced liposomal pulmonary technology. For more information, please visit http://www.insmed.com.

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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, our estimates regarding our capital requirements and our needs for additional financing, our ability to access additional funds under the Hercules loan agreement, results of operations, the status, results and timing of results of pre-clinical studies and clinical trials and pre-clinical and clinical data described herein, the timing of and costs associated with pre-clinical studies and clinical trials, the development of our products, our estimates of the size of the potential markets for our product candidates, 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 U.S. Food and Drug Administration 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 June 30, 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.