Insmed Announces Financial Results for Third Quarter and Nine-Months Ended September 30, 2012

MONMOUTH JUNCTION, N.J., Nov. 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 third quarter and nine-months ended September 30, 2012.

Key Recent Highlights

- Appointed Will Lewis, Co-Founder and former President and Chief Financial Officer of Aegerion Pharmaceuticals, Inc. (NASDAQ: AEGR), to the position of President and Chief Executive Officer, and Andrew Drechsler, former Chief Financial Officer of VaxInnate Corporation, to the position of Chief Financial Officer
- Significantly enhanced financial position through $25.7 million registered direct offering of common stock and $20 million loan agreement with Hercules Technology Growth Capital
- Granted second composition of matter patent for ARIKACE® by U.S. Patent and Trademark Office, providing exclusivity for ARIKACE throughmid-August 2028
- Phase 3 study (CLEAR-108) of ARIKACE in patients with cystic fibrosis who have Pseudomonas aeruginosa lung infections continues to enroll and remains on schedule for top-line results in mid-2013
- Phase 2 trial (TARGET-NTM) of ARIKACE in patients with non-tuberculous mycobacteria lung infections continues to enroll and remains on schedule for top-line results by end of 2013

"The significant progress and strategic changes made by Insmed in the third quarter have positioned us at the threshold of several significant potential value-creating milestones," said Will Lewis, President and CEO of Insmed. "With another $25.7 million in capital added and the expected reporting of late-stage clinical data next year, we have quickly aligned the Company for the successful commercial launch of ARIKACE in the U.S. and Europe, following receipt of the required regulatory approvals."

Financial Results

Quarter Ended September 30, 2012

For the third quarter of 2012, Insmed posted a net loss attributable to common stockholders of $9.4 million, or $0.38 per common share — basic and diluted, as compared to a net loss of $34.6 million, or $1.39 per common share — basic and diluted, for the three months ended September 30, 2011. The $25.2 million improvement in net loss was primarily due to a non-cash impairment charge of $26.0 million in the third quarter of 2011 relating to a write-down of in-process research and development and goodwill. This reduction in expenses in the third quarter of 2012 was offset by a $0.4 million decline in IPLEX® discontinued product revenue, a $0.2 million reduction in investment income and a $0.2 million increase in interest expense.

Insmed did not record any revenues for the three months ended September 30, 2012, as compared to $0.4 million in revenues reported for the three months ended September 30, 2011. The $0.4 million decrease was due to the elimination of discontinued product revenue.

Research and development (R&D) expenses decreased to $5.5 million in the three months ended September 30, 2012, from $6.9 million for the three months ended September 30, 2011. The decrease of $1.4 million in 2012 is primarily attributable to a reduction of $2.3 million in development costs associated with initiating two ARIKACE-related clinical trials, as compared to the same period in 2011, when the clinical program was initially being planned. This reduction was partially offset by an increase of $0.4 million in manufacturing costs associated primarily with initiating a non-clinical study and the build-up of clinical trial drug supply for the ongoing Phase 3 (CLEAR-108) and Phase 2 (TARGET-NTM) clinical studies, a $0.4 million increase in regulatory and quality assurance costs driven by the purchase of comparator drugs used in Insmed's clinical study and a $0.1 million increase in compensation-related expenses, as headcount increased to support the ongoing trials.

General and administrative expenses increased $1.3 million to $3.8 million in the three months ended September 30, 2012 from $2.5 million for the three months ended September 30, 2011due primarily to employee separation costs recorded in the third quarter of 2012.

Investment income for the third quarter of 2012 of $0.2 million was $0.2 million lower than the corresponding period in 2011 due to the lower cash balance available for investment. Interest expense was $0.2 million higher than the third quarter of 2011 due to payments associated with the recent debt financing.

Nine Months Ended September 30, 2012

Net loss attributable to common stockholders for the nine months ended September 30, 2012 was $25.9 million, or $1.04 per common share — basic and diluted, compared to a net loss of $60.7 million, or $2.66 per common share — basic and diluted, for the nine months ended September 30, 2011. The $34.8 million reduction in the net loss period on period was primarily due to the combination of the previously mentioned $26.0 million non-cash impairment charge incurred in the third quarter of 2011 and 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 in the 2011 period and, in turn, increased our loss per common share on a basic and diluted basis in the 2011 period by $0.40. The beneficial conversion 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 other operating expenses of $3.3 million in the nine months ended September 30, 2012 was fully offset by a revenue reduction of $3.0 million, a decline in investment income of $0.5 million and an increase in interest expense of $0.2 million.

Insmed did not record any revenues for the nine months ended September 30, 2012. Insmed reported $3.0 million in revenues for the nine months ended September 30, 2011. The $3.0 million decrease was due to the inclusion of $2.7 million of product revenue and the receipt of $0.3 million in license fees for our discontinued CISPLATIN lipid complex program in the nine months ended September 30, 2011, as compared to no revenues or license fees from this program in the current year.

R&D expenses decreased to $17.6 million in the nine months ended September 30, 2012 from $21.4 million for the nine months ended September 30, 2011. The decrease of $3.8 million is again primarily attributable to a reduction of $4.5 million in development costs and $0.9 million for regulatory and quality assurance costs associated with initiating two ARIKACE related clinical trials, as compared to when the clinical program was initially being planned in the same period in 2011. These reductions were partially offset by an increase of $1.5 million in manufacturing costs in the nine months ended September 30, 2012 associated with initiating a non-clinical study and building drug supply for the ongoing CLEAR-108 and TARGET-NTM clinical trials.

General and administrative expenses increased by $0.6 million to $9.0 million in the nine months ended September 30, 2012. The increase was due largely to the $1.2 million employee separation costs incurred in the third quarter of 2012, offset in part by the absence of finance, legal and consulting fees which were incurred in the nine months ended September 30, 2011 in relation to post Transave merger matters and the March 2011 reverse stock split transaction.

Investment income decreased to $0.9 million in the nine months ended September 30, 2012, from $1.4 million in the nine months ended September 30, 2011. The decrease is a result of the lower overall average cash and short-term investments balance for the current year to date period, as compared to the year to date period ended September 30, 2011.

Liquidity Position

As of September 30, 2012, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totalling $91.9 million, consisting of $89.7 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 $13.5 million increase in total cash was due primarily to the $35.4 million of net proceeds received in relation to the third quarter financing activities. These financing activities consisted of $9.7 from debt and $25.7 million from the sale of common stock, which was partially offset by $22.1 million used in operating activities.

Conference Call

To participate in today's live conference call, please dial 800-573-4754 (U.S. callers) or 617-224-4325 (international), and provide passcode 53958411. A live webcast of the call will also be available at http://www.media-server.com/m/p/86at7fkj. 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 37999986.

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious orphan lung diseases through the development and commercialization of novel, targeted inhalation therapies in orphan patient populations with critical unmet needs. Insmed's lead candidate, ARIKACE®, 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 patient populations: cystic fibrosis (CF) patients with Pseudomonas lung infections and patients with nontuberculous mycobacteria lung infections (NTM). Following positive phase 2 results in CF patients, Insmed's phase 3 registrational study of ARIKACE (CLEAR-108) in Europe and Canada is well underway, as is the U.S. Phase 2 trial in NTM (TARGET-NTM). The Company expects to report clinical results from both the CF Phase 3 and NTM Phase 2 studies in 2013 and currently is preparing for regulatory filings and for commercialization, if and when regulatory approvals are obtained. 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. 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 our financial position, our estimates regarding our capital requirements, our expected cash position 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 in the forward-looking statements. Such risks and uncertainties include, without limitation, failure or delay of U.S. Food and Drug Administrationand other regulatory reviews and approvals, competitive developments affecting our product development, delays in product development or clinical trials, patent disputes involving currently developing products, unexpected regulatory actions, delays or requests, the failure of future clinical trials, inability to successfully develop our product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changed 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, 2011 and our Quarterly Report on Form 10-Q for the quarter ended September 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 update these forward-looking statements to reflect events or circumstances or changes in expectations.

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