Insmed Announces Fourth Quarter and Full-Year 2008 Financial Results

RICHMOND, Va., March 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics (FOB) and biopharmaceuticals, today reported results for the quarter and full-year ended December 31, 2008.

Company Highlights

- Follow-on Biologics Program
  - Insmed entered into a definitive agreement with Merck & Co., Inc. whereby Merck, through an affiliate, will purchase all assets related to Insmed's follow-on biologics platform.
    - Insmed to receive a total of $130 million for the assets. After fees, taxes and other costs related to the transaction, Insmed expects net proceeds of approximately $123 million as a result of this agreement.
    - Insmed will receive initial payments of up to $10 million for Insmed's lead follow-on biologic candidates and the remaining balance upon closing of the transaction, which continues to be targeted for March 31, 2009.

- IPLEX(TM)
  - Completed the Phase 2 trial of IPLEX(TM) in Myotonic Muscular Dystrophy (MMD), and expect preliminary data in the second quarter of 2009;
  - Completed an external assessment of the total market for MMD treatments that indicated that the market for MMD could be as high as between $800 million and $1.4 billion;
  - Generated $10.5 million in cost recovery revenue from the IPLEX(TM) expanded access program (EAP) for Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's disease) in Italy during 2008. The EAP now includes 110 patients enrolled and 23 physicians;
  - Gained royalty-free worldwide rights for IPLEX(TM) in connection with potential EAP ALS programs outside of Italy;
  - The European Medicines Agency (EMEA) granted Premacure AB orphan designation for Insmed's IPLEX(TM) for the prevention of retinopathy of prematurity (ROP) in neonates of less than 32 weeks of gestational age. Premacure AB intends to initiate a phase 2 multicenter trial for IPLEX(TM) in the ROP indication during the second quarter of 2009.

"The sale of our FOB assets to Merck represents a watershed moment for Insmed," said Dr. Geoffrey Allan, Ph.D., President and CEO Insmed. "This agreement demonstrates Insmed's world-class clinical capabilities, and provides us with a substantial cash infusion that positions us well for future growth. In the short-term, we expect to be cash neutral for the balance of 2009 as we continue moving ahead with our IPLEX(TM) programs for MMD and ALS. In addition, we intend to pursue a comprehensive and thoughtful analysis to determine the most appropriate use of the proceeds we will receive from Merck. Our objective, though, is to utilize this capital to grow our business, and create additional shareholder value, as we have done through the transaction with Merck."

Financial Results for Fourth Quarter and Full-year 2008

Revenues for the fourth quarter ended December 31, 2008 were $2.9 million, up from $2.1 for the corresponding period in 2007. The increase was mainly attributable to an $846,000 increase in cost recovery revenue from our EAP to treat patients with ALS in Italy.

The net loss for the fourth quarter of 2008 was $4.0 million or $0.03 per share, compared with a net loss of $3.3 million or $0.03 per share in the fourth quarter of 2007.

R&D expenses increased to $5.4 million from $4.6 million, reflecting an increase in clinical trial activity for our FOB and IPLEX(TM) programs. SG&A Expenses increased to $1.3 million from $0.9 million, due primarily to higher IPLEX(TM) distribution costs and increased legal costs associated with the Merck transaction.

Interest income in the fourth quarter of 2008 fell to $47,000 from $264,000 in same period of 2007. This was due to the combination of a lower average cash balance on hand and lower interest rates during the most recent quarter. Interest expense increased slightly to $273,000 in the most recent period from $217,000 during the corresponding period of 2007.

Revenues for the full-year 2008 totaled $11.7 million, up from $7.6 million in the corresponding period of 2007. This increase was primarily due to a $5.1 million improvement in cost recovery from the EAP to treat patients with ALS in Italy and the grant receipt of $1.0 million from the Muscular Dystrophy Association supporting the IPLEX(TM) MMD trial. This was partially offset by the absence of license income from Napo and the revenues lost from our withdrawal of IPLEX(TM) in the short stature market pursuant to the terms of our settlement agreement with Genentech Inc. and Tercica Inc., entered into in March 2007.

The net loss for the 12 months ended December 31, 2008 was $15.7 million or $0.13 per share, compared to $20.0 million or $0.17 per share for the 12 months ended December 31, 2007. R&D Expenses increased to $21.0 million from $19.2 million, reflecting the higher activity as our clinical trials in the FOB and IPLEX(TM) areas advanced. SG&A Expenses fell to $5.1 million from $8.2 million, due to the elimination of litigation expenses following the March 2007 settlement and the removal of commercial expenses associated with our business restructuring plan.

Interest income for the full-year 2008 was $0.5 million, compared to $1.2 million for the full-year 2007. This decrease was mainly due to lower interest rates and a lower average cash balance for the full-year 2008 as compared to the full-year 2007. Interest expense for the 12 months ended December 31, 2008 was $1.3 million, compared to $682,000 for the corresponding period of 2007. This higher interest expense was due to an increase in the debt discount amortization resulting from the quarterly payments of our 2005 convertible notes, which began in March 2008. The $500,000 loss on investments represents the full write down on the prior year Napo investment during 2008.

As of December 31, 2008, we had total cash, cash equivalents and short-term investments on hand of $2.4 million, compared to $16.5 million on hand as of December 31, 2007. The $14.1 million decrease in cash, cash equivalents and short-term investments mainly reflected the use of $12.0 million for operating activities and $2.2 million for principal and interest repayment of our 2005 convertible notes, which began on March 1, 2008.

Conference Call

To participate in today's live 8:30 AM ET conference call, please dial 866-700-5192 (U.S. callers) or 617-213-8833 (international), and provide passcode 10018019. A live webcast of the call will also be available at http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=2106073. 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 12:30 PM ET on March 11th at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 38324430.

About Insmed

Insmed Inc. is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. For more information, please visit 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 planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, 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. The risks and uncertainties include, without limitation, risks that closing conditions under our agreement with Merck & Co., Inc. may not be met, product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete

development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our continuing efforts to grow the business and develop IPLEX(TM) may be unsuccessful, the actual market for MMD may not actually match up with our external assessment, our common stock could be delisted from the Nasdaq Capital Market 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, 2007. Readers 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.