

Home / Investors/ News Releases

Insmed CEO Issues Statement on White House FY09 Budget and FDA Statements on Follow-On Biologics

RICHMOND, Va., Feb 05, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM) CEO Geoffrey Allan issued the following statement today following the White House FY09 Budget and Food and Drug Administration statements on developing an approval pathway for follow-on biologics:

"Insmed is very pleased to see that the White House recognizes the importance of establishing a follow-on biologics approval pathway to deliver safe and more affordable medicines to Americans.

"We are also pleased by news of the Food and Drug Administration's preparation of a proposal to assist the Congress in moving forward with legislation to establish an approval pathway for follow-on biologics.

"We hope that the attention this important issue has received from both the White House and FDA will move Congress to adopt follow-on biologics legislation so patients can receive safe and affordable access to generic versions of these life-saving biotech drugs."

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. Insmed has a state-of-the- art, FDA-approved biologic commercial manufacturing facility in Boulder, Colorado and a Corporate office in Richmond, Virginia. 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 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 entrance into the follow on biologics market may be unsuccessful, our common stock could be delisted from the Nasdag Global Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.