



[Home](#) / [Investors](#) / [Press Releases](#)

Insmmed Announces Financial Results for Third Quarter and Nine-Months Ended September 30, 2008

Insmmed Announces Financial Results for Third Quarter and Nine-Months Ended September 30, 2008

RICHMOND, VA. October 30, 2008 - Insmmed Inc. (Nasdaq CM: INSM), a developer of follow-on biologics and biopharmaceuticals, today reported results for the third quarter and nine-months ended September 30, 2008.

Recent Company Highlights

- Follow-on Biologics Program
 - Received approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency to initiate a Phase I clinical study for the Company's second follow-on biologic ("FOB") product candidate, INS-20. Insmmed's INS-20 is a pegylated recombinant form of human G-CSF, and an FOB of the FDA-approved product Neulasta®, which had U.S. sales of approximately \$2.4 billion in 2007.
- IPLEX™;

< >Received \$3.0 million in cost recovery revenue in the third quarter related to the expanded access program ("EAP") for IPLEX™. The EAP in Italy to treat patients with Amyotrophic Lateral Sclerosis ("ALS"), also known as Lou Gehrig's Disease, currently includes 23 physicians and over 100 subjects have enrolled; Announced the presentation of clinical study results with Premacure demonstrating IPLEX™ increased serum IGF-I levels into the normal range in significantly premature infants. Premacure is developing IPLEX™ as a potential treatment for Retinopathy of Prematurity ("ROP") via a Material Transfer Agreement with Insmmed. Based in part on the results of this study, Premacure intends to initiate a phase II multicenter trial in the ROP indication during the fourth quarter.

"We continue to execute on our business plan and efficiently advance each of our key clinical programs," said Dr. Geoffrey Allan, President and CEO of Insmmed. "Our second FOB candidate, INS-20, has entered the clinic, and demonstrates further that we have the potential to be an initial entrant into the emerging U.S. FOB marketplace. In addition, we are working closely with RBC Capital Markets, our financial advisor, to aggressively pursue our strategic options for partnering and funding."

Revenues for the third quarter ended September 30, 2008 were \$4.1 million, up from \$1.4 million for the corresponding period in 2007. The increase was primarily attributable to a \$1.6 million increase in cost recovery revenue from our EAP to treat patients with ALS in Italy and the grant receipt of \$1.0 million from the Muscular Dystrophy Association supporting the IPLEX™ Phase 2 Myotonic Muscular Dystrophy ("MMD") trial.

The net loss for the third quarter of 2008 was \$2.2 million or \$0.02 per share, compared with a net loss of \$3.9 million or \$0.03 per share in the third quarter of 2007. This \$1.7 million reduction was primarily attributable to the \$2.7 million increase in revenues, which was offset by a \$438,000 increase in total expenses, a \$434,000 increase in net interest expense and the realization of a \$54,000 non-cash loss on investments.

The \$438,000 increase in total expenses was due to a \$395,000 increase in research and development ("R&D expenses") and a \$43,000 decrease in selling, general and administrative expenses ("SG&A Expenses").

The higher R&D Expenses were due largely to increased clinical trial activity in the current quarter compared to last year as our phase 2 IPLEX™ MMD trial continues to progress. SG&A Expenses were consistent quarter over quarter. Interest income for the current quarter of \$78,000 was \$292,000 lower than the corresponding quarter of 2007 due to a combination of the lower interest rate environment and a lower average cash balance. Interest expense of \$301,000 was \$142,000 higher than the same quarter in 2007 due to an increase in the debt discount amortization resulting from the quarterly payment of our 2005 convertible notes, which began in March 2008. The loss on investments arises from the write-down of our investment in Napo. This investment, which was funded by a milestone payment from Napo, was recorded as part of our agreement with Napo in 2007.

For the nine months ended September 30, 2008, revenues totaled \$8.8 million, up from \$5.3 million in the first nine months of 2007. Consistent with the third quarter results, the increase was primarily attributable to a \$4.5 million improvement in cost

recovery from our EAP to treat patients with ALS in Italy and the grant receipt of \$1.0 million from the Muscular Dystrophy Association supporting the IPLEX™ MMD trial. This was partially offset by the absence of license income from Napo and the revenues lost from our withdrawal of IPLEX™ in the short stature market pursuant to the terms of our settlement agreement with Genentech Inc. and Tercica Inc., entered into in 2007.

The net loss for the nine months ended September 30, 2008 was \$11.7 million, or \$0.10 per share, compared to \$16.7 million, or \$0.15 per share, for the first nine months of 2007. Year-over-year, R&D Expenses increased to \$15.8 million for the first nine months of 2008, from \$14.4 million during the same period last year, reflecting an overall increase in clinical trial activity for our FOB and IPLEX™ programs. SG&A Expenses fell to \$3.7 million for the first nine months of 2008 from \$7.4 million a year earlier 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 first nine months of 2008 of \$453,000 was a reduction from the \$895,000 earned in the same period of 2007. Interest expense increased to \$983,000 in the most recent nine month period from \$465,000 during the corresponding period of 2007. The same factors effecting the third quarter interest movements impacted the year to date figures. The \$500,000 loss on investments represents the full write down of the Napo investment during the first nine months of 2008.

As of September 30, 2008, we had total cash, cash equivalents and short-term investments on hand of \$5.8 million, compared to \$16.5 million on hand as of December 31, 2007. The \$10.7 million decrease in cash, cash equivalents and short-term investments primarily reflects the use of \$9.1 million for operating activities and a \$1.7 million principal repayment of our 2005 convertible notes, which began on March 1, 2008.

Conference Call

To participate in today's 8:30 AM ET live conference call, please dial 866-831-6270 (U.S. callers) or 617-213-8858 (international callers), and provide passcode 95924014. A live webcast of the call will also be available at: <http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=2000938> 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 888-286-8010 (U.S. callers) or 617-801-6888 (international callers), using passcode 69712597.

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 product candidates may fail in the clinic or may not be successfully marketed or manufactured, the FOB market in the United States may be slow to develop or never develop, government regulation of the FOB market (in foreign countries and possibly in the United States) could be onerous or slow in developing or never develop, we may lack financial resources to complete development of product candidates or to fund the ongoing operations of the Company, 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 FOB market may be unsuccessful, we may be unable to secure an appropriate business partner for our follow-on biologics business, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 and 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.

Investor Relations Contact:


Brian Ritchie - FD
212-850-5683
brian.ritchie@fd.com

Corporate Communications Contact:

John Procter - Gibraltar Associates

202-879-5808

jprocter@gibraltar-llc.com

Additional assets available online:  [Photos](#) (4)