Insmed Reports Third Quarter 2013 Financial Results

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 11/05/13 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing an inhaled anti-infective to treat patients battling serious lung diseases in orphan indications that are often life-threatening, today reported financial results for the three and nine months ended September 30, 2013.

Highlights of the third quarter of 2013 and subsequent weeks include:

- Completed patient enrollment in the Phase 2 clinical trial of ARIKACE®, or liposomal amikacin for inhalation, for patients with recalcitrant nontuberculous mycobacteria (NTM) lung disease in the U.S. and Canada;
- Commenced the Scientific Advice Working Party (SAWP) process with European Medicines Agency (EMA) for clarity on the path forward for ARIKACE to treat NTM lung disease in Europe;
- Strengthened the Company's intellectual property position with the addition of another European patent allowance;
- Completed an underwritten public offering of 6.9 million shares of common stock, including the underwriters' exercise in full of their over-allotment option of 900,000 shares, which provided net proceeds to the Company of approximately $67.0 million.

"During the third quarter we made significant progress advancing ARIKACE closer to our goal of treating patients with NTM lung disease. With no approved treatments for this indication, completion of enrollment in our U.S. and Canadian Phase 2 study is a significant milestone in bringing ARIKACE to patients with NTM lung disease who are in great need of an effective treatment option," stated Will Lewis, President and Chief Executive Officer of Insmed. "We remain on track to report top-line NTM data and to initiate a dialogue with the FDA in the first quarter of 2014. In addition we are mapping a path forward for ARIKACE to treat NTM lung disease in Europe through the SAWP process and expect to engage in communications with the EMA during the fourth quarter of 2013."

"We continue work to build Insmed into a world-class biopharmaceutical company. Importantly, our successful financing in July with top-tier institutional investors provides us with the financial resources to advance ARIKACE for NTM lung disease and Pseudomonas aeruginosa lung infections in cystic fibrosis (CF) patients to important data readouts and regulatory filings, and to build our infrastructure to support clinical and commercial objectives," concluded Mr. Lewis.

Third Quarter Financial Results

For the third quarter of 2013, Insmed reported a net loss of $17.3 million, or $0.46 per share, compared with a net loss of $9.4 million, or $0.38 per share, for the third quarter of 2012.

Research and development expenses for the third quarter of 2013 increased to $12.1 million from $5.7 million for the third quarter of 2012, primarily due to higher costs for clinical trial activities associated with the Company's Phase 3 clinical trial and two-year open-label extension study in CF patients with Pseudomonas aeruginosa lung infections in Europe and Canada, its Phase 2 clinical trial in patients with NTM lung disease in the U.S. and Canada, and costs related to process improvements made to manufacturing processes. Also contributing to the increase were higher internal expenses including compensation and related expenses due to greater headcount.

General and administrative expenses for the third quarter of 2013 increased to $4.7 million from $3.6 million for the third quarter of 2012. The increase was primarily due to pre-commercial market research and related costs.

Balance Sheet Highlights and Cash Guidance

As of September 30, 2013, Insmed had cash, cash equivalents totaling $128.0 million, compared with $92.9 million as of December 31, 2012. The $35.1 million net increase was due principally to $67.0 million of net proceeds we received from an underwritten public offering of our common stock we completed during July 2013. The Company utilized $32.6 million of cash to fund operations in the first nine months of 2013. As of September 30, 2013, working capital was $109.9 million.

The Company plans to fund further clinical development of ARIKACE, invest in third-party manufacturing capacity and fund its efforts to obtain regulatory approvals and prepare for commercialization. As a result, Insmed estimates that its cash requirements to fund operations for the fourth quarter of 2013 will be in the range of $15 million to $17 million. The Company believes that its cash balance as of September 30, 2013, will be sufficient to fund its operations through 2014.

Conference Call

Insmed management will host an investment community conference call to discuss these results and answer questions today beginning at 8:30 a.m. Eastern time. Shareholders and other interested parties may participate in the call by dialing 888-803-5993 (domestic) or 706-634-5454 (international) and referencing conference ID number 90792237. The call will also be broadcast live on the Company's website at www.insmed.com.

A replay of the conference call will be accessible two hours after its completion through November 11, 2013, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 90792237. The call will also be archived for 90 days on the Company's website at www.insmed.com.

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases. Insmed is

focused on the development and commercialization of ARIKACE®, or liposomal amikacin for inhalation, for at least two identified orphan patient populations: cystic fibrosis patients with Pseudomonas aeruginosa lung infections and patients with nontuberculous mycobacteria lung disease. For more information, visit www.insmed.com.

Forward-looking Statements

This release contains forward-looking statements. 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 the status, results and timing of clinical trials and clinical data, the anticipated benefits of Insmed's products, the anticipated timing of regulatory submissions, and the ability to obtain required regulatory approvals, bring products to market and successfully commercialize products and Insmed's cash needs constitute forward-looking statements that 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 European, Canadian, U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting the Company's product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to the Company's product candidates, unexpected regulatory actions, delays or requests, the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations, the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in Company's prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies, the inability to successfully develop the Company's product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, changes in the Company's financing requirements or ability raise additional capital, and other risks and challenges detailed in the Company's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2012 and subsequent filings. Investors are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this news release. The Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances or changes in its expectations.

-Tables to Follow -

INSMED INCORPORATED

Consolidated Balance Sheets
(in thousands, except par value, share and per share data)

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 128,025	$ 90,782
Certificate of deposit	-	2,153
Prepaid expenses and other current assets	1,720	643
Total current assets	129,745	93,578
In-process research and development	58,200	58,200
Other assets	101	117
Fixed assets, net	1,904	1,666
Total assets	$ 189,950	$ 153,561
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 4,661	$ 7,060
Accrued expenses	5,652	2,933
Accrued compensation	1,953	2,207
Accrued lease expense, current	303	295
Deferred rent	134	149
Capital lease obligations, current	64	96
Current portion of long term debt	7,055	3,007
Total current liabilities	19,822	15,747
Accrued lease expense, long-term	449	647
Capital lease obligations, long-term	16	64
Debt, long-term	12,538	16,221
Total liabilities	32,825	32,679
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 39,100,899 and 31,488,204 issued and outstanding shares at September 30, 2013 and December 31, 2012, respectively	391	315
Additional paid-in capital	532,141	455,325
Warrant to purchase common stock	-	790

Accumulated deficit	(375,407)	(335,548)
Total shareholders' equity	157,125	120,882
Total liabilities and shareholders' equity	$ 189,950	$ 153,561

See accompanying notes to consolidated financial statements

INSMED INCORPORATED
Consolidated Statements of Comprehensive Loss
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Other revenue	$ -	$ -	$ 11,500	$ -
Operating expenses:				
Research and development	12,095	5,706	34,654	18,190
General and administrative	4,747	3,647	16,267	8,410
Total operating expenses	16,842	9,353	50,921	26,600
Operating loss	(16,842)	(9,353)	(39,421)	(26,600)
Investment income	40	193	141	901
Interest expense	(525)	(222)	(1,802)	(225)
Gain on sale of assets, net	-	-	2	5
Loss before income taxes	(17,327)	(9,382)	(41,080)	(25,919)
Provision (benefit) for income taxes	-	-	(1,221)	4
Net loss	$ (17,327)	$ (9,382)	$ (39,859)	$ (25,923)
Basic and diluted net loss per share	$ (0.46)	$ (0.38)	$ (1.19)	$ (1.04)
Weighted average basic and diluted common shares outstanding	37,389	25,013	33,577	24,916
Net loss	$ (17,327)	$ (9,382)	$ (39,859)	$ (25,923)
Comprehensive loss:				
Unrealized (loss) gain on short-term investments, net of taxes	-	199	-	385
Comprehensive loss	$ (17,327)	$ (9,183)	$ (39,859)	$ (25,538)

See accompanying notes to consolidated financial statements

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