Insmed Reports Second Quarter Financial Results

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 08/06/13 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing and commercializing an inhaled anti-infective to treat patients battling serious lung diseases that are often life-threatening, reported financial results for the three and six months ended June 30, 2013.

Highlights of the second quarter of 2013 and recent weeks include:

- Achieved the Primary Endpoint in a Registrational Phase 3 Clinical Trial of ARIKACE® to treat Cystic Fibrosis (CF) Patients with Pseudomonas aeruginosa infections (Pa). The European and Canadian Phase 3 clinical trial of once-daily ARIKACE (liposomal amikacin for inhalation) achieved its primary endpoint of non-inferiority to twice-daily TOBI®(tobramycin inhalation solution) for relative change in forced expiratory volume in one second (FEV1) from baseline to end of study. Secondary endpoints showed comparability of once-daily ARIKACE compared with twice-daily TOBI consistent with the primary endpoint of the study.
- Granted Qualified Infectious Disease Product (QIDP) and Fast Track Designations for ARIKACE in Nontuberculous Mycobacteria (NTM) Lung Infections. The U.S. Food and Drug Administration (FDA) granted ARIKACE QIDP and Fast Track designations for the treatment of NTM.
- Completed an Underwritten Public Offering. Insmed completed an underwritten public offering of 6.9 million shares of common stock, which reflects 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.
- Received Notice of Allowance for Key European Composition-of-Matter Patent for ARIKACE. The European Patent Office notified Insmed that it intends to grant a key European composition of matter patent for ARIKACE. Once granted, the patent will provide protection for novel anti-infective formulations comprising an aminoglycoside and Insmed'sliposomal delivery technology, and methods for making the formulations. Amikacin is one of the aminoglycosides covered by the patent. The patent also includes claims relating to the use of the aminoglycoside/lipid formulations for treating pulmonary infections, including those caused by Pa and certain mycobacterial infections, among others.
- Appointed Christine Pellizzari as General Counsel and Secretary. In July, Ms. Pellizzari joined Insmed with nearly 20 years of experience at development- and commercial-stage biopharmaceutical companies, including senior-level legal and strategic leadership roles at Aegerion Pharmaceuticals and Dendrite, Inc.

"Throughout the second quarter and in recent weeks we made significant progress in a number of areas critical to our goal of becoming a patient-centric biopharmaceutical company. We reported positive clinical data and regulatory developments, fortified our patent portfolio, enhanced our management team and strengthened our balance sheet. We are focused on preparing our regulatory filing for ARIKACE in Europe and Canada to treat Pseudomonas aeruginosa infections in patients with CF, and pursuing a dialogue with the FDA regarding the U.S. regulatory pathway for ARIKACE to treat NTM," said Will Lewis, President and Chief Executive Officer of Insmed.

"With positive Phase 3 data for our CF indication and our QIDP and Fast Track designations for our NTM indication, we are actively moving forward with our strategy to bring once-daily ARIKACE to patients suffering from these orphan lung diseases in two indications in two geographies in two years," concluded Mr. Lewis.

Second Quarter Financial Results

For the second quarter of 2013, Insmed reported a net loss of $8.9 million, or $0.28 per share, compared with a net loss of $9.7 million, or $0.39 per share, for the second quarter of 2012. The decrease in net loss is primarily due to $11.5 million in revenue recorded during the second quarter of 2013 that related to a one-time payment for the sale of the Company's right to receive future royalties under its license agreement with Premacure AB (now Shire plc). This one-time revenue was partially offset by higher research and development and general and administrative expenses.

Research and development expenses in the second quarter of 2013 increased to $12.2 million from $7.7 million in the second 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 lung infections in Europe and Canada, and its Phase 2 clinical trial in patients with NTM lung infections in the United States.

General and administrative expenses for the second quarter of 2013 increased to $7.5 million from $2.2 million in the second quarter of 2012. The increase was primarily due to higher compensation expense, which included $2.6 million in non-cash stock-based compensation expense, and $1.0 million in market research and other related costs.

Balance Sheet Highlights and Cash Guidance

As of June 30, 2013, Insmed had cash, cash equivalents and a certificate of deposit totaling $76.8 million, compared with $92.9 million as of December 31, 2012. Excluding the one-time payment of $11.5 million from Shire, the Company utilized $27.8 million of cash to fund operations in the first six months of 2013. As of June 30, 2013, working capital was $58.3 million, excluding a $2.2 million certificate of deposit.

On July 22, 2013, Insmed completed an underwritten public offering of 6,900,000 shares of the Company's common stock, including the underwriters' exercise in full of their over-allotment option of 900,000 shares, which generated $67.0 million of net proceeds to the Company.

The Company plans to fund further clinical development of ARIKACE, invest in third party manufacturing capacity and fund its efforts to obtain regulatory approvals. As a result, the Company estimates that its cash requirements to fund operations in second half of 2013 will be in the range of $28 million to $33 million. The Company believes that its cash balance of $76.8 million as of June 30, 2013, plus the proceeds from its recently completed public offering, 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 25882867. 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 August 12, 2013, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 25882867. 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 (CF) patients with Pseudomonas aeruginosa lung infections and patients with non-tuberculous mycobacteria (NTM) lung infections. 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)

	June 30, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 74,588	$ 90,782
Certificate of deposit	2,195	2,153
Prepaid expenses and other current assets	1,783	643
Total current assets	78,566	93,578
In-process research and development	58,200	58,200
Other assets	104	117
Fixed assets, net	1,855	1,666
Total assets	$ 138,725	$ 153,561
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 7,865	$ 7,060
Accrued expenses	3,188	2,933
Accrued compensation	1,889	2,207
Accrued lease expense, current	301	295
Deferred rent	139	149
Capital lease obligations, current	69	96
Current portion of long term debt	4,650	3,007
Total current liabilities	18,101	15,747
Accrued lease expense, long-term	514	647
Capital lease obligations, long-term	32	64
Debt, long-term	14,894	16,221
Total liabilities	33,541	32,679

Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 31,999,760 and 31,488,204 issued and outstanding shares at June 30, 2013 and December 31, 2012, respectively	320	315
Additional paid-in capital	462,944	455,325
Warrant to purchase common stock	-	790
Accumulated deficit	(358,080)	(335,548)
Total shareholders' equity	105,184	120,882
Total liabilities and shareholders' equity	$ 138,725	$ 153,561

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Other revenue	$ 11,500	$ -	$ 11,500	$ -
Operating expenses:				
Research and development	12,225	7,745	22,559	12,484
General and administrative	7,544	2,238	11,520	4,763
Total operating expenses	19,769	9,983	34,079	17,247
Operating loss	(8,269)	(9,983)	(22,579)	(17,247)
Investment income	50	290	101	708
Interest expense	(635)	(1)	(1,277)	(3)
Gain on sale of assets, net	-	-	2	5
Loss before income taxes	(8,854)	(9,694)	(23,753)	(16,537)
Provision (benefit) for income taxes	-	2	(1,221)	4
Net loss	$ (8,854)	$ (9,696)	$ (22,532)	$ (16,541)
Basic and diluted net loss per share	$ (0.28)	$ (0.39)	$ (0.71)	$ (0.67)
Weighted average basic and diluted common shares outstanding	31,754	24,875	31,654	24,867
Net loss	$ (8,854)	$ (9,696)	$ (22,532)	$ (16,541)
Comprehensive loss:				
Unrealized (loss) gain on short-term investments, net of taxes	-	(30)	-	186
Comprehensive loss	$ (8,854)	$ (9,726)	$ (22,532)	$ (16,355)

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