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Insmed Reports First Quarter Financial Results

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 05/07/13 -- Insmed Incorporated (NASDAQ: INSM), ("Insmed" or the "Company"), 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 months ended March 31, 2013.

Highlights of the first quarter of 2013 and recent weeks included:

- Phase 3 update. Completed the patient treatment period of the Company's registrational Phase 3 clinical trial of ARIKACE®, the Company's liposomal amikacin for inhalation, to treat cystic fibrosis (CF) patients with Pseudomonas lung infections in Europe and Canada and remain on track to report top-line clinical results from the trial in mid-2013.
- Orphan Drug Designation. Received orphan drug designation from the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development for the treatment of infections caused by non-tuberculous mycobacteria (NTM) for ARIKACE.
- Cash Payment expected from Premacure. Reported that Premacure AB, recently acquired by Shire plc, elected to obtain all of the Company's rights to receive revenues for former product candidate, IGF-1, under the May 2012 Premacure License Agreement. Insmed expects to receive \$11.5 million in May 2013 in exchange for any future royalties from Premacure, and Premacure will assume Insmed's royalty obligations to other parties.
- Appointed Matt Pauls as Chief Commercial Officer. Mr. Pauls has more than 20 years of experience in the pharmaceutical industry, including senior-level leadership roles in global marketing, sales, reimbursement, new product launches and commercial operations at leading pharmaceutical companies.
- Appointed Peter Clarke as Vice President of Manufacturing. Mr. Clarke has nearly 30 years of experience in biopharmaceutical manufacturing at both startup and established pharmaceutical companies in Europe and the United States.

"We continue to advance Insmed's transformation into a commercial entity. During the first quarter we made significant progress in executing our hiring plan, advancing our manufacturing strategy and carrying out our clinical trials and regulatory filing preparation for ARIKACE," stated Will Lewis, President and Chief Executive Officer of Insmed.

"We remain on track to report top-line clinical results from our Phase 3 trial in CF mid-year and our Phase 2 trial in NTM before the end of the year. Collectively, these data sets bring us closer to our goal to commercialize a potentially life-saving treatment for patients suffering from these orphan lung diseases."

First Quarter Financial Results

For the first quarter of 2013, Insmed posted a net loss of \$13.7 million, or \$0.43 per share, compared with a net loss of \$6.8 million, or \$0.28 per share, for the first quarter of 2012.

Research and development expense in the first quarter increased to \$10.3 million from \$4.7 million in the first quarter of 2012, primarily due to a \$4.6 million increase in external costs for clinical trial activities associated with the Company's Phase 3 CF clinical trial and two-year extension study in Europe and Canada, and its Phase 2 NTM clinical trial in the United States.

General and administrative expense for the first quarter of 2013 increased to \$4.0 million from \$2.5 million in the first quarter of 2012 primarily due to a \$1.0 million increase in professional fees related to the review, accounting and reporting of certain equity awards previously granted to employees and directors that, at the time of the grants, were in excess of annual per-person sub-limits included in the Company's 2000 Stock Incentive Plan. The Company also incurred an additional \$0.3 million of non-cash stock compensation expense resulting from re-measuring at fair value these equity awards.

During the first quarter the Company received \$1.2 million in cash from the sale of a portion of its New Jersey State net operating losses (NOLs) under the State of New Jersey's Technology Business Tax Certificate Transfer Program (the Program). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits for cash.

Balance Sheet Highlights and Cash Guidance

As of March 31, 2013, Insmed had cash, cash equivalents and a certificate of deposit totaling \$81.6 million, compared with \$92.9 million as of December 31, 2012. As of March 31, 2013, working capital was \$60.6 million, excluding a \$2.2 million certificate of deposit that matures in July 2013.

As disclosed in the Company's Form 8-K filed on April 30, 2013, the Company expects to receive \$11.5 million in May 2013 from Premacure as a result of Premacure's exercise of an option to obtain a fully paid license to develop, manufacture and commercialize IGF-1, with its natural binding protein, IGFBP-3, for the prevention and treatment of complications of preterm birth.

The Company estimates that its full year 2013 cash requirements to fund operations will be in the range of \$45 million to \$55 million. The Company expects current cash balances will be sufficient to fund operations into 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 56371335. 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 May 21, 2013, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 56371335. The call will also be archived for 90 days on the Company's website at www.insmed.com.

About Insmed

Insmmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases. Insmmed 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. Insmmed's Phase 3 registrational study of ARIKACE in CF patients in Europe and Canada has completed and the Company expects top-line clinical results in mid-2013. Insmmed's Phase 2 clinical trial in patients with NTM is under way in the United States and Canada, with clinical results expected in late 2013. For more information, please visit <http://www.insmed.com>.

Forward-Looking Statements

This release contains forward-looking statements that are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. 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 results of preclinical studies and clinical trials and preclinical and clinical data and the anticipated benefits of Insmmed's products, and to the Company's cash position and financing 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 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, 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. 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)

	March 31, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 79,434	\$ 90,782
Certificate of deposit	2,173	2,153
Prepaid expenses and other current assets	1,418	643
Total current assets	83,025	93,578
In-process research and development	58,200	58,200
Other assets	110	117
Fixed assets, net	1,681	1,666
Total assets	\$ 143,016	\$ 153,561
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 8,184	\$ 7,060
Accrued expenses	5,329	2,933
Accrued compensation	1,359	2,207
Accrued lease expense, current	298	295
Deferred rent	144	149
Capital lease obligations, current	83	96
Current portion of long term debt	4,875	3,007
Total current liabilities	20,272	15,747
Accrued lease expense, long-term	580	647
Capital lease obligations, long-term	48	64
Debt, long-term	14,511	16,221
Total liabilities	35,411	32,679
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 31,571,926 and 31,488,204 issued and outstanding shares at March 31, 2013 and December 31, 2012, respectively	316	315
Additional paid-in capital	455,725	455,325
Warrant to purchase 329,932 shares of common stock for \$2.94 per share at March 31,		

2013 and December 31, 2012	790	790
Accumulated deficit	(349,226)	(335,548)
Total shareholders' equity	107,605	120,882
Total liabilities and shareholders' equity	\$ 143,016	\$ 153,561

INSMED INCORPORATED

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

	Three Months Ended March 31,	
	2013	2012
Revenues	\$ -	\$ -
Operating expenses:		
Research and development	10,334	4,739
General and administrative	3,975	2,525
Total operating expenses	14,309	7,264
Operating loss	(14,309)	(7,264)
Investment income	51	418
Interest expense	(643)	(2)
Gain on sale of assets, net	2	5
Loss before income taxes	(14,899)	(6,843)
Provision (benefit) for income taxes	(1,221)	2
Net loss	\$ (13,678)	\$ (6,845)
Basic and diluted net loss per share	\$ (0.43)	\$ (0.28)
Weighted average basic and diluted common shares outstanding	31,554	24,860
Net loss	\$ (13,678)	\$ (6,845)
Comprehensive loss:		
Unrealized gains on investments, net of taxes	-	216
Comprehensive loss	\$ (13,678)	\$ (6,629)

Investor Relations Contacts:

LHA
Anne Marie Fields
Senior Vice President
212-838-3777
afields@lhai.com

Bruce Voss
Managing Director
310-691-7100
bvoss@lhai.com
