Insmed Reports First Quarter 2014 Financial Results

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 05/08/14 -- Insmed Incorporated (NASDAQ: INSM) today reported financial results for the three months ended March 31, 2014.

Highlights of the first quarter of 2014 and recent weeks include:

- Announced top-line clinical results from a phase 2 clinical study of ARIKAYCE™, or liposomal amikacin for inhalation, for the treatment of patients with treatment-resistant nontuberculous mycobacterial (NTM) lung infections;
- Applied for Breakthrough Therapy Designation in the United States for ARIKAYCE to treat NTM lung infections;
- Reported positive interim data from the two-year, open-label extension study of ARIKAYCE to treat Pseudomonas aeruginosa infections in cystic fibrosis (CF) patients, which demonstrated long-term safety and durability of effect at 12 months;
- Entered into a contract manufacturing agreement with Therapure Biopharma Inc. for the manufacture of ARIKAYCE; and
- Received Orphan Medical Product Designation in the European Union for ARIKAYCE to treat lung infections caused by NTM.

"We remain on track to discuss our recent clinical results with the U.S. Food and Drug Administration and the European Medicines Agency to determine next steps for ARIKAYCE," said Will Lewis, President and Chief Executive Officer of Insmed. "We look forward to the presentations of ARIKAYCE data at the American Thoracic Society's Annual Meeting later this month. The presentation of the NTM data will include data from the three month, open label portion of the study."

First Quarter Financial Results

For the first quarter of 2014, Insmed posted a net loss of $14.3 million, or ($0.36) per share, compared with a net loss of $13.7 million, or ($0.43) per share, for the first quarter of 2013. The 2014 and 2013 results include a benefit from income taxes resulting from the sale of a portion of the Company's New Jersey State Net Operating Losses under the State of New Jersey's Technology Business Tax Certificate Transfer Program for cash of $4.4 million and $1.2 million in the first quarter of 2014 and 2013, respectively.

Research and development expense in the 2014 first quarter increased to $11.4 million from $10.3 million in the first quarter of 2013. The increase in research and development expenses primarily resulted from an increase in internal expenses, specifically compensation and personnel related expenses, including higher non-cash stock compensation expense, and an increase in manufacturing expenses as a result of the completion of certain process improvement projects at the Company's third party manufacturing partner and the manufacture of ARIKAYCE for clinical supply. These increases were offset by a decrease in external clinical expenses which was primarily related to the completion of the Company's phase 3 pivotal study in CF patients in 2013.

General and administrative expense for the first quarter of 2014 was $6.7 million compared with $4.0 million in the first quarter of 2013. The increase in general and administrative expenses primarily resulted from an increase in pre-commercial activities, an increase in personnel costs due to an increase in headcount, and an increase in non-cash stock compensation expense.

Balance Sheet Highlights and Cash Guidance

As of March 31, 2014, Insmed had cash and cash equivalents of $101.3 million and working capital of $86.2 million. The Company's cash operating expenses were $15.6 million in the first quarter of 2014.

During the second quarter of 2014, the Company plans to continue to fund further clinical development of ARIKAYCE, increase its investment in third-party manufacturing capacity, support efforts to obtain regulatory approvals and prepare for commercialization. As a result, Insmed estimates that its second quarter 2014 cash-based operating expenses will be in the range of $18 million to $20 million. In addition, the Company will make $3 million to $5 million in capital expenditures related to the build-out of the Company's new headquarters in Bridgewater, NJ. The Company will relocate its operations to the Bridgewater facility during 2014 as the lease for its current operating facility expires in December 2014. The Company expects current cash balances will be sufficient to fund operations into 2015. The Company plans to provide additional cash guidance in the third quarter once additional discussions with the regulatory authorities have taken place.

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 ARIKAYCE, or liposomal amikacin for inhalation, for at least two identified orphan patient populations: patients with non-tuberculous mycobacteria (NTM) lung infections and cystic fibrosis (CF) patients with Pseudomonas aeruginosa lung infections. For more information, please visit http://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 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, the ability to obtain Breakthrough Therapy Designation for ARIKAYCE in the U.S.,

the inability to make product candidates commercially successful, changes in anticipated expenses, changes in the Company's financing requirements or ability to 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, 2013 and its most recent quarterly report on Form 10-Q. 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.

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

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 101,251	$ 113,894
Prepaid expenses and other current assets	4,958	2,269
Total current assets	106,209	116,163
In-process research and development	58,200	58,200
Other assets	234	323
Fixed assets, net	1,977	1,812
Total assets	$ 166,620	$ 176,498
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 9,818	$ 5,929
Accrued expenses	3,143	3,905
Accrued compensation	1,371	2,839
Accrued lease expense, current	310	307
Deferred rent	121	129
Capital lease obligations, current	48	64
Current portion of long term debt	5,187	3,283
Total current liabilities	19,998	16,456
Accrued lease expense, long-term	315	380
Debt, long-term	14,569	16,338
Total liabilities	34,882	33,174
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 39,268,885 and 39,137,679 issued and outstanding shares at March 31, 2014 and December 31, 2013, respectively.	393	391
Additional paid-in capital	537,264	534,554
Accumulated deficit	(405,919)	(391,621)
Total shareholders' equity	131,738	143,324
Total liabilities and shareholders' equity	$ 166,620	$ 176,498

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

	Three Months ended March 31, 2014	2013
Revenues	$ -	$ -
Operating expenses:		
Research and development	11,351	10,334
General and administrative	6,728	3,975
Total operating expenses	18,079	14,309
Operating loss	(18,079)	(14,309)

Investment income	17	51
Interest expense	(606)	(643)
Other, net	(19)	2
Loss before income taxes	(18,687)	(14,899)
(Benefit) from income taxes	(4,389)	(1,221)
Net loss and comprehensive loss	$ (14,298)	$ (13,678)
Basic and diluted net loss per share	$ (0.36)	$ (0.43)
Weighted average basic and diluted common shares outstanding	39,240	31,554

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