Insmed Reports 2013 Fourth Quarter and Full Year Financial Results

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MONMOUTH JUNCTION, NJ -- (Marketwired) -- 03/06/14 -- Insmed Incorporated (NASDAQ: INSM) today reported financial results for the three and twelve months ended December 31, 2013. The Company will not hold a quarterly conference call to discuss these results given the proximity to the scheduled announcement in late March of top-line results from its phase 2 clinical trial with ARIKAYCE® to treat nontuberculous mycobacteria (NTM) lung infections. The Company plans to hold a conference call at that time.

Highlights of the fourth quarter of 2013 and subsequent two months include:

- Reported positive interim data from the two-year, open-label extension study of ARIKAYCE, or liposomal amikacin for inhalation, 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;
- Received Orphan Medical Product Designation in the European Union for ARIKAYCE to treat lung infections caused by NTM;
- Secured another European patent allowance, thereby strengthening the Company's intellectual property position;
- Appointed David W.J. McGirr to its Board of Directors. Mr. McGirr is the former Chief Financial Officer of Cubist Pharmaceuticals, Inc.; and
- Appointed Peggy Berry as Vice President of Regulatory Affairs. Ms. Berry has more than 25 years of experience in the pharmaceutical industry and began her career at the U.S. Food and Drug Administration. Ms. Berry has secured ten drug approvals during her career. She will be reporting to Will Lewis, President and Chief Executive Officer (CEO).

"2013 was a transformational year, one in which we laid the foundation to build Insmed into a leading biopharmaceutical company operating at the intersection of orphan, pulmonary and infectious diseases," stated Will Lewis, President and CEO of Insmed. "Most significantly, we advanced the ARIKAYCE clinical programs to treat NTM lung disease as well as Pseudomonas aeruginosa in CF patients. We also expanded our leadership team with talented executives in key regulatory and commercial roles. Our collective talents are focused on advancing the regulatory strategy and filings for ARIKAYCE for the treatment of NTM lung infections and CF patients with Pseudomonas."

"In the near term we plan to report top-line results from our phase 2 clinical trial of ARIKAYCE to treat NTM lung infections. Following the release of these data, we expect to have discussions with regulatory authorities in the U.S. and Europe regarding a path forward to filing for approval. In the interim, we have initiated a comprehensive education campaign to raise awareness of NTM and to increase accurate and early diagnosis," added Mr. Lewis. "It is our goal to be the leader in this globally uncontested orphan disease market."

Fourth Quarter Financial Results

For the fourth quarter of 2013, Insmed reported a net loss attributable to common stockholders of $16.2 million, or $0.41 per share, compared with a net loss attributable to common stockholders of $15.5 million, or $0.49 per share, for the fourth quarter of 2012.

Research and development expenses for the fourth quarter of 2013 were $9.6 million as compared to $12.2 million for the fourth quarter of 2012. Fourth quarter 2013 research development expenses were primarily comprised of costs for clinical trial activities associated with the Company's phase 2 trial in patients with NTM lung disease in the U.S. and Canada and two-year open-label extension study in CF patients with Pseudomonas aeruginosa lung infections in Europe and Canada, and costs related to manufacturing process improvements.

General and administrative expenses for the fourth quarter of 2013 increased to $6.0 million from $3.6 million for the fourth quarter of 2012. The increase was primarily due to an increase of $1.0 million of pre-commercial market research and related costs and a $1.2 million increase in compensation expense (including a $0.3 million increase in non-cash stock compensation expense).

Full Year Financial Results

For 2013 Insmed posted a net loss attributable to common stockholders of $56.1 million, or $1.60 per share, compared with a net loss attributable to common stockholders of $41.4 million, or $1.56 per share, for 2012. The greater loss is primarily due to an increase in both research and development expenses and general and administrative expenses.

Research and development expenses for 2013 increased to $44.3 million from $29.8 million for 2012. The increase was primarily due to the increased activities related to our phase 3 clinical study in CF patients and related two-year, open-label safety study in Europe and Canada, and our phase 2 NTM clinical study in the United States. We initiated the phase 3 CF study and phase 2 NTM study in the second quarter of 2012 and initiated the two-year CF extension study in October 2012.

General and administrative expenses for 2013 increased to $22.2 million from $12.7 million in 2012. The increase was due primarily to a $5.5 million increase in compensation expense (including an increase of $3.9 million in non-cash stock-based compensation expense), a $1.8 million increase in professional fees, including a $1.4 million increase in legal fees related to the investigation, accounting and reporting of excess equity awards and $2.9 million for consulting expenses, mainly for market research and other related costs. The 2012 results

included $2.2 million in severance expenses related to the departure of several executives and employees.

Balance Sheet Highlights and Cash Guidance

As of December 31, 2013, Insmed had cash, cash equivalents and short-term investments of $113.9 million, compared with $92.9 million as of December 31, 2012. The increase was primarily due to $67.0 million of net proceeds from an underwritten public offering of common stock completed in July 2013. The Company utilized $46.7 million of cash to fund operations during 2013. Excluding the one-time $11.5 million cash payment the Company received from Premacure (now Shire) in May 2013, net cash used in operating activities for 2013 would have been $58.2 million. As of December 31, 2013, working capital was $99.7 million.

During 2014 the Company plans to continue to fund further clinical development of ARIKAYCE, invest in third-party manufacturing capacity, support efforts to obtain regulatory approvals, and prepare for commercialization. Insmed estimates that its cash requirements to fund operations for the first quarter of 2014 will be in the range of $15.0 million to $17.0 million. The Company expects to provide additional 2014 cash guidance when it releases first quarter 2014 financial results.

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 nontuberculous mycobacteria lung disease and cystic fibrosis patients with Pseudomonas aeruginosa 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, 2013 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)

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 113,894	$ 90,782
Certificate of deposit	-	2,153
Prepaid expenses and other current assets	2,269	643
Total current assets	116,163	93,578
In-process research and development	58,200	58,200
Other assets	323	117
Fixed assets, net	1,812	1,666
Total assets	$ 176,498	$ 153,561
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 5,929	$ 7,060
Accrued expenses	3,905	2,933
Accrued compensation	2,839	2,207
Accrued lease expense, current	307	295
Deferred rent	129	149
Capital lease obligations, current	64	96
Current portion of long term debt	3,283	3,007
Total current liabilities	16,456	15,747

Accrued lease expense, long-term	380	647
Capital lease obligations, long-term	-	64
Debt, long-term	16,338	16,221
Total liabilities	33,174	32,679
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 39,137,679 and 31,488,204 issued and outstanding shares at December 31, 2013 and December 31, 2012, respectively	391	315
Additional paid-in capital	534,554	455,325
Warrant to purchase common stock	-	790
Accumulated deficit	(391,621)	(335,548)
Total shareholders' equity	143,324	120,882
Total liabilities and shareholders' equity	$ 176,498	$ 153,561

INSMED INCORPORATED
Consolidated Income Statement
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2013	2012	2013	2012
Other revenue	$ -	$ -	$ 11,500	$ -
Operating expenses:				
Research and development	9,625	12,228	44,279	29,781
General and administrative	5,969	3,605	22,236	12,657
Total operating expenses	15,594	15,833	66,515	42,438
Operating loss	(15,594)	(15,833)	(55,015)	(42,438)
Investment income	25	921	166	1,822
Interest expense	(610)	(539)	(2,412)	(763)
Other, net	(35)	-	(33)	5
Loss before income taxes	(16,214)	(15,451)	(57,294)	(41,374)
Provision (benefit) for income taxes	-	-	(1,221)	-
Net loss	$ (16,214)	$ (15,451)	$ (56,073)	$ (41,374)
Basic and diluted net loss per share	$ (0.41)	$ (0.49)	$ (1.60)	$ (1.56)
Weighted average basic and diluted common shares outstanding	39,116	31,373	34,980	26,545

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