Insmed Reports Third Quarter 2014 Financial Results

Conference Call Begins Today at 8:30 a.m. Eastern Time

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Insmed Incorporated (Nasdaq:INSM) today reported financial results for the three and nine months ended September 30, 2014.

Highlights of the third quarter of 2014 include:

- Reported its U.S. regulatory strategy to initiate one global phase 3 confirmatory study of ARIKAYCE™, or liposomal amikacin for inhalation, for patients with nontuberculous mycobacterial (NTM) lung infections who failed prior standard of care treatment;
- Announced plans to file a Market Authorization Application (MAA) by year-end 2014 with the European Medicines Agency (EMA) for ARIKAYCE for the treatment of two orphan lung diseases: NTM lung infections and Pseudomonas aeruginosa lung infections in patients with cystic fibrosis (CF);
- Strengthened the Company's balance sheet with an underwritten public offering, which provided net proceeds of approximately $108.0 million; and
- Introduced INS-1009 (inhaled treprostinil), the Company's novel inhalation formulation of a proven prostacyclin for the treatment of pulmonary arterial hypertension (PAH), with the presentation of several pre-clinical studies at the European Respiratory Society meeting.

"We are pleased with the recent regulatory clarity for our NTM program in both Europe and the U.S. We continue to advance our regulatory filing and our preparations for commercialization in Europe, while simultaneously moving forward with our global phase 3 study in NTM patients who failed prior standard-of-care treatment. We expect to initiate this global NTM study in early 2015 and to complete enrollment within one year. We anticipate having preliminary top-line clinical results in mid-2016. We were also pleased to introduce INS-1009 for the novel treatment of PAH, as it expands our pipeline and underscores our commitment to new treatments for orphan lung diseases," said Will Lewis, President and Chief Executive Officer of Insmed.

Third Quarter Financial Results

For the third quarter of 2014, Insmed posted a net loss of $24.0 million, or ($0.54) per share, compared with a net loss of $17.3 million, or ($0.46) per share, for the third quarter of 2013. The increase in net loss was primarily due to increases in personnel costs, manufacturing expenses and pre-commercial activities.

Research and development expense for the third quarter of 2014 increased to $15.2 million from $12.1 million in the third quarter of 2013. The increase in research and development expense was primarily due to higher compensation and personnel-related expenses and the build-out of additional third-party manufacturing capacity.

General and administrative expense for the third quarter of 2014 was $8.2 million compared with $4.7 million in the third quarter of 2013. The increase in general and administrative expense primarily resulted from greater personnel costs due to an increase in headcount and an increase in pre-commercial activities.

Balance Sheet Highlights and Cash Guidance

As of September 30, 2014, Insmed had cash and cash equivalents of $167.3 million and working capital of $149.6 million, both of which reflect an underwritten public offering in August, which generated $108.0 million of net proceeds to the Company. Excluding depreciation and non-cash stock compensation expense, the Company's cash operating expenses for the three months ended September 30, 2014 was $19.7 million. In addition, during the third quarter of 2014 the Company paid $2.9 million for capital expenditures primarily related to the build out of its office and laboratory facilities in Bridgewater, New Jersey.

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 ARIKAYCE commercialization. As a result, Insmed estimates that its cash operating expenses for the fourth quarter of 2014 will be in the range of $22 million to $26 million. In addition, the Company expects to pay approximately $2 million related to the completion of the build out of its office and laboratory facilities in New Jersey. The Company expects current cash balances will be sufficient to fund operations into 2016.

Conference Call

Insmed management will host a 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 855-803-5993 (domestic) or 706-634-5454 (international) and referencing conference ID number 22672003. 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 12, 2014, by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 22672003. 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 ARIKAYCE, or liposomal amikacin for inhalation, for at least two identified orphan patient populations: patients with nontuberculous 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 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 endedDecember 31, 2013 and its subsequent quarterly reports 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, share and per share data)

	As of September 30, 2014 (Unaudited)	As of December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 167,311	$ 113,894
Prepaid expenses and other current assets	3,532	2,269
Total current assets	170,843	116,163
In-process research and development	58,200	58,200
Fixed assets, net	5,982	1,812
Other assets	418	323
Total assets	$ 235,443	$ 176,498
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 8,867	$ 5,929
Accrued expenses	3,547	3,905
Accrued compensation	3,032	2,839
Accrued lease expense, current	317	307
Deferred rent	321	129
Capital lease obligations, current	16	64
Current portion of long term debt	5,178	3,283
Total current liabilities	21,278	16,456
Accrued lease expense, long-term	185	380
Debt, long-term	14,713	16,338
Total liabilities	36,176	33,174
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 49,605,544 and 39,137,679 issued and outstanding shares at September 30, 2014 and December 31, 2013, respectively	496	391
Additional paid-in capital	651,904	534,554
Accumulated deficit	(453,133)	(391,621)
Total shareholders' equity	199,267	143,324
Total liabilities and shareholders' equity	$ 235,443	$ 176,498

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

	Three Months ended September 30,		Nine Months ended September 30,	
	2014	2013	2014	2013
Other revenue	$ -	$ -	$ -	$ 11,500
Operating expenses:				
Research and development	15,200	12,095	41,493	34,654
General and administrative	8,204	4,747	22,806	16,267
Total operating expenses	23,404	16,842	64,299	50,921
Operating loss	(23,404)	(16,842)	(64,299)	(39,421)
Investment income	12	40	41	141
Interest expense	(594)	(525)	(1,795)	(1,802)
Other (expense) / income, net	(4)	-	152	2
Loss before income taxes	(23,990)	(17,327)	(65,901)	(41,080)
Benefit from income taxes	-	-	(4,389)	(1,221)
Net loss and comprehensive loss	$ (23,990)	$ (17,327)	$ (61,512)	$ (39,859)
Basic and diluted net loss per share	$ (0.54)	$ (0.46)	$ (1.50)	$ (1.19)
Weighted average basic and diluted common shares outstanding	44,082	37,389	40,882	33,577

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