Insmed Reports Second Quarter 2014 Financial Results

BRIDGEWATER, N.J. (August 6, 2014) - Insmed Incorporated (Nasdaq: INSM) today reported financial results for the three and six months ended June 30, 2014.

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

- Announced plans to file a Market Authorization Application (MAA) with the European Medicines Agency (EMA) for ARIKAYCE™, or liposomal amikacin for inhalation, for the treatment of two orphan lung diseases: nontuberculous mycobacterial (NTM) lung infections in treatment refractory patients and Pseudomonas aeruginosa lung infections in patients with cystic fibrosis (CF);
- Announced plans to initiate two global Phase 3 clinical trials of ARIKAYCE in NTM; one for the broad NTM patient population and one confirmatory study for treatment refractory patients with NTM lung infections;
- Received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for ARIKAYCE to treat NTM lung infections; and
- Appointed David R. Brennan, former Chief Executive Officer of AstraZeneca plc, to the Insmed Board of Directors.

"With the recent regulatory clarity, we are moving forward with preparation for commercialization in Europe while simultaneously advancing our two global NTM studies," said Will Lewis, President and Chief Executive Officer of Insmed. "Given these positive developments, we are pleased with the progress we are making toward our goal of bringing this potentially front line therapy to the benefit of the thousands of NTM and CF patients."

Second Quarter Financial Results
For the second quarter of 2014, Insmed posted a net loss of $23.2 million, or ($0.59) per share, compared with a net loss of $8.9 million, or ($0.28) per share, for the second quarter of 2013. The increase in net loss was primarily due to $11.5 million in Other revenue received during the 2013 quarter related to a one-time payment for the sale of the Company's right to receive future royalties under its license agreement with Premacure (now Shire plc), as well as to higher expenses in the 2014 quarter.

Research and development expense in the 2014 second quarter increased to $14.9 million from $12.2 million in the second quarter of 2013. The increase in research and development expense was primarily due to the build-out of additional third-party manufacturing capacity and higher compensation and personnel-related expenses. These increases were partially 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 second quarter of 2014 was $7.9 million compared with $7.5 million in the second quarter of 2013. The increase in general and administrative expense primarily resulted from an increase in pre-commercial activities and higher personnel costs due to an increase in headcount. These increases were largely offset by a $1.4 million decrease in non-cash stock compensation expense in the second quarter of 2014, compared with the prior year's second quarter.

Balance Sheet Highlights and Cash Guidance
As of June 30, 2014, Insmed had cash and cash equivalents of $82.7 million and working capital of $64.9 million. Excluding depreciation and non-cash stock compensation expense, the Company's cash operating expenses for the three months ended June 30, 2014 was $19.7 million and includes expenditures of $2.1 million related to the build out of additional and redundant third party manufacturing capacity.

During the second half 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 ARIKAYCE commercialization. As a result, Insmed estimates that its cash operating expenses for the second half of 2014 will be in the range of $42 million to $47 million, which includes additional expenditures of $6 million to $8 million for third-party manufacturing capacity. In addition, in the second half of 2014 the Company expects to invest $2.5 million to $3.5 million in new capital expenditures and pay current liabilities of $2.5 million related to the Company's new office and laboratory facilities in Bridgewater, N.J. The Company expects current cash balances will be sufficient to fund operations into 2015.

Senior Leadership Team Update
Matthew Pauls, Chief Commercial Officer (CCO), will be leaving Insmed in August 2014 to become the Chief Executive Officer of a biopharmaceutical company based in Sweden and the U.S. Insmed plans to initiate a search to identify a new CCO.

Lilia Arvizu, PhD, recently joined Insmed in the newly created role of Vice President of Global Medical Affairs. Dr. Arvizu is responsible for medical education, medical communication and oversight of grants, investigator initiated studies and the medical science liaison personnel. Dr. Arvizu has more than 15 years of medical affairs experience at companies focused on orphan diseases and broader therapeutic indications.

Gina Eagle, MD, was recently promoted to Vice President of Clinical Development. Dr. Eagle is responsible for designing and overseeing the clinical trials and development of the Company's product candidates. Dr. Eagle spent 6 years practicing medicine and has more than 9 years of experience in clinical development in the pharmaceutical industry.

Kevin McDermott was recently promoted to Vice President of Global Market Access. Mr. McDermott is responsible for developing pricing strategies, creating a strong pharmacoeconomic foundation, and securing market access worldwide. Mr. McDermott has more than 14 years of senior leadership in market access.

"We welcome Lilia and look forward to sharing her passion and expertise in medical affairs. We also congratulate Gina and Kevin on their recent promotions," stated Mr. Lewis. "In addition, we wish Matt continued success in his new role as CEO, and we appreciate his contributions to Insmed over the last year."

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 ended December 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 June 30, 2014 (unaudited)	As of December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 82,697	$ 113,894
Prepaid expenses and other current assets	4,015	2,269
Total current assets	86,712	116,163
In-process research and development	58,200	58,200
Fixed assets, net	4,778	1,812
Other assets	420	323
Total assets	$ 150,110	$ 176,498
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 11,407	$ 5,929
Accrued expenses	4,546	3,905
Accrued compensation	2,071	2,839
Accrued lease expense, current	314	307
Deferred rent	167	129
Capital lease obligations, current	32	64
Current portion of long term debt	3,281	3,283
Total current liabilities	21,818	16,456
Accrued lease expense, long-term	250	380
Debt, long-term	16,494	16,338
Total liabilities	38,562	33,174
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 39,276,389 and 39,137,679 issued and outstanding shares at June 30, 2014 and December 31, 2013, respectively.	393	391
Additional paid-in capital	540,298	534,554
Accumulated deficit	(429,143)	(391,621)
Total shareholders' equity	111,548	143,324

Total liabilities and shareholders' equity	$ 150,110	$ 176,498

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

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Other revenue	$ -	$ 11,500	$ -	$ 11,500
Operating expenses:				
Research and development	14,942	12,225	26,293	22,559
General and administrative	7,874	7,544	14,602	11,520
Total operating expenses	22,816	19,769	40,895	34,079
Operating loss	(22,816)	(8,269)	(40,895)	(22,579)
Investment income	12	50	29	101
Interest expense	(595)	(635)	(1,201)	(1,277)
Other income, net	175	-	156	2
Loss before income taxes	(23,224)	(8,854)	(41,911)	(23,753)
Benefit from income taxes	-	-	(4,389)	(1,221)
Net loss and comprehensive loss	$ (23,224)	$ (8,854)	$ (37,522)	$ (22,532)
Basic and diluted net loss per share	$ (0.59)	$ (0.28)	$ (0.96)	$ (0.71)
Weighted average basic and diluted common shares outstanding	39,273	31,754	39,256	31,654

LHA
Anne Marie Fields, 212-838-3777
Senior Vice President
afields@lhai.com
or
Bruce Voss, 310-691-7100
Managing Director
bvoss@lhai.com