Insmed Reports First Quarter 2015 Financial Results

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on developing orphan treatments for rare pulmonary diseases, today reported financial results for the quarter ended March 31, 2015.

First quarter and recent highlights include:

- Validation of the company's Marketing Authorization Application (MAA) for ARIKAYCE™ by the European Medicines Agency (EMA).
- Advancement of the company's phase 3 global 212 study of patients with treatment-resistant nontuberculous mycobacteria (NTM), lung infections with the opening of multiple clinical trial sites.
- Acceptance of six abstracts for poster presentation at the American Thoracic Society (ATS) 2015 International Conference taking place in Denver from May 15 - 20.
- Additions to the senior leadership team including the appointments of Eugene Sullivan, MD, chief medical and scientific officer and Don Nociolo, vice president of technical operations.
- Completion of a public offering of 11.5 million shares of common stock that generated net proceeds of approximately $223 million.

"2015 is a year of key deliverables for Insmed and we remain on track to deliver our five stated corporate objectives, which include the advancement of ARIKAYCE and the development of INS1009," said Will Lewis, president and chief executive officer of Insmed. "Our global registration program for ARIKAYCE is making important progress with an increasing number of sites actively recruiting patients in the 212 study. We are also advancing our newest program, INS1009, an inhaled prodrug formulation of treprostinil for pulmonary arterial hypertension, and we look forward to providing additional updates on this promising clinical candidate as the year progresses."

First Quarter 2015 Financial Results

For the first quarter of 2015, Insmed posted a net loss of $27.4 million, or ($0.55) per share, compared with a net loss of $14.3 million, or ($0.36) per share, for the first quarter of 2014. The company's financial results for the first quarter of 2014 were positively impacted by a $4.4 million income tax benefit that resulted from the sale of a portion of its New Jersey Net Operating Losses under New Jersey's Technology Business Tax Certificate Transfer Program.

Research and development expenses were $17.2 million for the first quarter of 2015 as compared with $11.4 million in the first quarter of 2014. The increase in research and development expenses was primarily due to the advancement of the company's clinical development program for ARIKAYCE, the build-out of additional third-party manufacturing capacity, and an increase in internal expenses.

General and administrative expenses for the first quarter of 2015 were $9.5 million as compared with $6.7 million in the first quarter of 2014. The increase in general and administrative expenses was primarily related to an increase in personnel-related expenses, which included a $1.5 million increase in non-cash stock-based compensation expense related to performance-based stock options that vested upon EMA's validation of the ARIKAYCE MAA, as well as pre-commercial activities related to Europe.

Balance Sheet Highlights and Cash Guidance

As of March 31, 2015, the company's cash and cash equivalents totaled $134.6 million. The company's cash balance does not include the net proceeds from its public offering of 11.5 million shares of common stock that generated net proceeds of approximately $223 million in April 2015. Excluding depreciation and non-cash stock compensation expense, the company's cash operating expenses for the quarter ended March 31, 2015 were $21.8 million. Insmed ended the first quarter of 2015 with $25.0 million in short-term debt and working capital of $99.1 million.

In 2015, the company is investing in the following activities: (i) clinical development of ARIKAYCE, (ii) third-party manufacturing capacity, (iii) regulatory and pre-commercial initiatives for ARIKAYCE, and (iv) filing an Investigational New Drug Application and initiating a phase 1 clinical study of INS1009. As a result, Insmed estimates that its cash operating expenses for the first half of 2015 will be in the range of $46 million to $56 million. The company estimates that its cash operating expenses for the second half of 2015 will be $48 million to $58 million.

About ARIKAYCE

ARIKAYCE is a form of the antibiotic amikacin, which is enclosed in nanocapsules of lipid called liposomes. This advanced pulmonary liposome technology prolongs the release of amikacin in the lungs while minimizing systemic exposure. The treatment uses biocompatible lipids endogenous to the lung that are formulated into small (0.3 micron), charge-neutral liposomes. ARIKAYCE is administered once-daily using an optimized, investigational eFlow® Nebulizer System manufactured by PARI Pharma GmbH, a novel, highly efficient and portable aerosol delivery system.

About eFlow® Technology and PARI Pharma

ARIKAYCE is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKAYCE. The optimized device uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared with other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow Technology is not an ultrasonic nebulizer technology and is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments.

About Nontuberculous Mycobacteria (NTM)

Nontuberculous mycobacteria (NTM) are organisms found in the soil and water that can cause serious lung disease in susceptible individuals, for which there are currently limited effective treatments and no approved therapies. The prevalence of NTM disease is reported to be

increasing, and according to reports from the American Thoracic Society is believed to be greater than that of tuberculosis in the U.S. According to the National Center for Biotechnology Information, epidemiological studies show that presence of NTM infection is increasing in developing countries, perhaps because of the implementation of tap water. Women with characteristic phenotype are believed to be at higher risk of acquiring NTM infection along with patients with defects on cystic fibrosis transmembrane conductance regulators.

NTM lung disease is often a chronic condition that can lead to progressive inflammation and lung damage, and is characterized by bronchiectasis and cavitary disease. NTM infections often require lengthy hospital stays for medical management. Treatment usually involves multi-drug regimens that can be poorly tolerated and have limited effectiveness, especially in patients with severe disease or in those who have failed prior treatment attempts. According to a company-sponsored patient chart study conducted by Clarity Pharma Research, approximately 50,000 patients suffering from NTM lung disease visited physician offices in the U.S. during 2011.

About INS1009

INS1009, the company's inhaled treprostinil prodrug for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs. Insmed has applied its product design, drug development and sustained-release formulation expertise to advance INS1009 with the goal of addressing current limitations of inhaled prostacyclin therapies in the treatment of PAH. INS1009 is expected to be delivered once-daily via inhalation. It is designed to provide consistent, effective drug levels and may also reduce the acute systemic effects of current treatment options.

About Pulmonary Arterial Hypertension (PAH)

Pulmonary arterial hypertension, or PAH, is a chronic, life-threatening form of pulmonary hypertension that is characterized by abnormally high blood pressure in the arteries between the heart and lungs. Pulmonary arteries carry blood from the heart to the lungs, where it picks up oxygen to be delivered throughout the body. In PAH, the pulmonary arteries constrict abnormally. This forces the heart to pump harder to maintain adequate blood flow, which causes blood pressure within the lungs to rise. Common early symptoms include shortness of breath, fatigue, weakness, chest pain and syncope (fainting), particularly during physical activity. PAH worsens over time and is life-threatening because the pressure in a patient's pulmonary arteries rises to dangerously high levels, which strains the heart and may lead to heart failure. The one-year mortality rate among patients with PAH is 15% despite currently available treatments. The cause of some cases of PAH is unknown and there is no cure. PAH is considered an orphan disease, afflicting 30,000 to 40,000 people in the U.S. and 200,000 people globally.

There are several prescription medications approved by the U.S. Food and Drug Administration (FDA) to treat the symptoms of PAH and patients typically are treated with combination therapy including endothelin receptor antagonists, PDE-5 inhibitors and prostacyclin agonists. With annual sales exceeding $1 billion, prostacyclins are the preferred choice for treating late-stage disease. Prostacyclin formulations used to treat PAH include oral, intravenous, subcutaneous and inhaled formulations. All existing prostacyclin compounds have the limitation of a short half-life in the body and require multiple dosing sessions per day for inhaled and oral formulations, or the invasiveness of continuous infusion for injectable formulations.

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. Insmed is also focused on the development of INS1009, the company's inhaled treprostinil prodrug for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs.

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 offering, the intended use of proceeds, 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, market conditions, 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, 2014 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 March 31, 2015 (Unaudited)	As of December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$134,554	$159,226
Prepaid expenses and other current assets	5,689	5,488

Total current assets	140,243	164,714
In-process research and development	58,200	58,200
Fixed assets, net	7,292	7,534
Other assets	417	416
Total assets	$206,152	$230,864
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$7,860	$9,249
Accrued expenses	5,976	5,321
Accrued compensation	1,584	4,317
Other current liabilities	716	743
Current portion of long term debt	24,989	-
Total current liabilities	41,125	19,630
Other long-term assets	162	141
Debt, long-term	-	24,856
Total liabilities	41,287	44,627
Shareholders' equity:		
Common stock	500	498
Additional paid-in capital	662,514	656,519
Accumulated deficit	(498,149)	(470,780)
Total shareholders' equity	164,865	186,237
Total liabilities and shareholders' equity	$206,152	$230,864

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

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenues	$ --	$ --
Operating expenses:		
Research and development	17,164	11,351
General and administrative	9,542	6,728
Total operating expenses	26,706	18,079
Operating loss	(26,706)	(18,079)
Investment income	23	17
Interest expense	(722)	(606)
Other income (expense), net	36	(19)
Loss before income taxes	(27,369)	(18,687)
Benefit from income taxes	-	(4,389)
Net loss and comprehensive loss	($27,369)	($14,298)
Basic and diluted net loss per share	($0.55)	($0.36)
Weighted average basic and diluted common shares outstanding	49,957	39,240

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