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Insmed Announces Fourth Quarter and Full-Year 2010 Financial Results

RICHMOND, Va., March 10, 2011 [/PRNewswire/](#) -- Insmed Inc. (Nasdaq CM: INSM), a biopharmaceutical company, today reported results for the fourth quarter and full-year ended December 31, 2010.

Key Recent Highlights:

- Filed Investigational New Drug (IND) Application in February 2011 with the FDA to begin a phase 3 clinical trial for ARIKACE™ (liposomal amikacin for inhalation) in non-TB Mycobacteria (NTM) lung infections.
- Successfully concluded 72 week phase 2b open-label study for ARIKACE for pseudomonas lung infections in cystic fibrosis (CF) patients.
- Received positive opinion from European Medicines Agency (EMA) on Company's Pediatric Investigation Plan for ARIKACE in the CF indication.
- Gained shareholder approval for conversion of preferred stock into common stock and 1:10 reverse stock split.

"Following the closure of our transformative business combination in December 2010, we have been aggressively moving forward with the development plan for ARIKACE, our phase 3 compound for pseudomonas lung infections for CF patients, and NTM lung infections," said Timothy Whitten, Insmed's President & CEO. "We are well underway with the initial preparations and necessary work around these trials and continue to expect to begin accruing patients to the phase 3 trials in both indications in the second half of 2011, with results expected in the first half of 2013."

Financial Results

On March 1, 2011, at a special meeting, our shareholders approved a one for 10 reverse stock split of our common stock, which became effective at 5:00 pm EST on March 2, 2011. This reverse stock split is reflected in the shares outstanding and earnings per share calculations below.

Revenues for the fourth quarter ended December 31, 2010 were \$1.3 million, as compared to \$2.5 million for the corresponding period in 2009. The \$1.2 million decrease resulted from \$0.6 million in lower cost recovery from our IPLEX™ Expanded Access Program (EAP) in Europe, \$0.5 million of IPLEX grant revenue which was recognized in the fourth quarter of 2009 and \$0.1 million in lower royalties during the most recent period. The reduction in the IPLEX cost recovery was due to the Company's decision in July 2009 to cease supplying the drug to new patients in order to preserve the remaining IPLEX inventory for patients currently receiving the drug. The \$0.5 million reduction in grant revenue related to a grant received in the fourth quarter of 2009 from the Muscular Dystrophy Association (MDA) for the previously completed IPLEX Phase 2 Myotonic Muscular Dystrophy trial. The reduced royalty was due to the expiration of a TGF- beta royalty in 2010.

In the fourth quarter of 2010, the Company posted a net loss of \$5.8 million, or \$0.42 per share, as compared to a net profit of \$2.3 million, or \$0.18 per share, in the fourth quarter of 2009. The \$8.1 million variance arose from a \$5.5 million increase in total expenses, the elimination of a \$2.0 million tax refund which occurred in 2009 and a \$1.2 million reduction in revenue. These were partially offset by a \$0.6 million improvement in investment income.

The \$5.5 million increase in total expenses resulted from a \$1.7 million increase in research and development expenses (R&D Expenses) and a \$3.8 million increase in selling, general and administrative expenses (SG&A Expenses). The higher R&D Expenses were due primarily to the addition of ARIKACE-related R&D Expenses in December 2010, while the increase in SG&A Expenses resulted from increased external finance, legal and consulting expenses related to the business combination, and the addition of ARIKACE-related support costs for December 2010.

The \$2.0 million tax impact resulted from the utilization of Net Operating Losses in the fourth quarter of 2009, which reduced the amount of taxes paid on the gain on sale of Insmed's follow-on biologics (FOB) assets to Merck in March 2009. The lower interest expense was due to the reduction of the debt discount amortization associated with the Company's 2005 convertible notes which were fully paid off in 2010.

For the year-ended December 31, 2010, revenues totalled \$6.9 million, as compared to \$10.4 million for the year-ended December 31, 2009. The reduction was primarily due to a year-over-year decrease of \$2.3 million in cost recovery from Insmed's IPLEX EAP in Europe, a \$1.0 million reduction in grant revenue related to the 2009 receipt of a \$1.0 million grant from the MDA and \$0.1 million in reduced royalties. The causes of the fourth quarter revenue variance were also responsible for the full-year differences in revenue between 2010 and 2009.

Net loss for the 12-months ended December 31, 2010 was \$6.4 million, or \$0.49 per share, compared to a net income of \$118.4 million, or \$9.31 per share, for the corresponding 12-months of 2009. This \$124.8 million variance was due to the \$127.0 million after tax gain on the sale of the Company's FOB assets to Merck in 2009, combined with a \$3.5 million decrease in total revenues. These were partially offset by a \$4.0 million reduction in total expenses, a \$1.0 million increase in investment returns and a \$0.7 million decrease in interest expense.

The \$4.0 million decrease in total expenses was due to a \$4.4 million reduction in R&D Expenses, which was partially offset by a \$0.4 million increase in SG&A Expenses. The \$4.4 million reduction in R&D Expenses was due primarily to a decrease in manufacturing expenses following the sale of Insmed's FOB assets in March 2009, and was partially offset by the ARIKACE-related R&D Expenses incurred in December 2010. The \$0.4 million increase in SG&A Expenses was due largely to the increased finance, legal and consulting fees related to the strategic review and the business combination with Transave on December 1, 2010. The improved return on investments reflected the increased cash position and higher yield rates, while the lower interest expense was due to the elimination of the debt discount amortization.

As of December 31, 2010, Insmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of \$110.2

million, consisting of \$108.0 million in cash and short-term investments and \$2.2 million in a certificate of deposit, as compared to \$124.3 million of cash on hand as of December 31, 2009. The \$14.1 million decrease in total cash was due to the \$8.0 million full payment of Transave debt at the time of the merger, together with the payment of approximately \$6.1 million in costs primarily related to the strategic review during 2010 and the business combination with Transave.

Conference Call

To participate in today's live conference call, please dial 866-543-6405 (U.S. callers) or 617-213-8897 (international), and provide passcode 84436520. A live webcast of the call will also be available at: <http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=3766623>. Please allow extra time prior to the webcast to register, download and install any necessary audio software. The webcast will be archived for 30 days, and a telephone replay of the call will be available for seven days, beginning at 11:30 AM ET on March 10th 2011, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 46156189.

About Insmmed

Insmmed Incorporated is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases, and has a proprietary protein platform aimed at niche markets with unmet medical need. Insmmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. For more information, please visit <http://www.insmed.com>.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to our financial position, results of operations, the development of our products, and business strategies, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. Our results may also be affected by such factors as the receipt and timing of FDA and other regulatory approvals, if at all, competitive developments affecting our product development, delays in product development or clinical trials, and patent disputes involving currently developing products. The risks and uncertainties include, without limitation, we may be unsuccessful in developing our product candidates or receiving necessary regulatory approvals, our product candidates may not prove to be commercially successful, our expenses may be higher than anticipated and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2009. Investors are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

Contact:

Brian Ritchie - FD
212-850-5683
brian.ritchie@fd.com

Media Contact:

Irma Gomez-Dib - FD
212-850-5761
irma.gomez-dib@fd.com

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2010	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,743	\$ 12,740
Short-term investments	97,306	109,441
Income tax receivable	-	2,023
Accounts receivable, net	471	245
Prepaid expenses	277	159
Total current assets	108,797	124,608
Long-term assets:		
Certificate of deposit	2,176	2,085
In-process research and development	77,900	-
Goodwill	6,290	-
Fixed assets, net	1,102	2
Deferred financing costs, net	-	-
Total long-term assets	87,468	2,087
Total assets	\$ 196,265	\$ 126,695

Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	1,450	\$	312
Accrued project costs & other	139		1,150	
Payroll liabilities	1,117		580	
Interest payable	-		1	
Deferred rent	150		132	
Capital lease obligations, current	81		-	
Deferred revenue	402		398	
Convertible debt	-		231	
Debt discount	-		(23)	
Net convertible debt	-		208	
Total current liabilities	3,339		2,781	
Long-term liabilities:				
Capital lease obligations, long-term	83		-	
Total liabilities	3,422		2,781	
Stockholders' equity:				
Common stock; \$.01 par value; authorized shares 50,000,000; issued and outstanding shares, 15,653,734 in 2010 and 13,020,810 in 2009	1,565		1,302	
Preferred stock; \$.01 par value; authorized shares 20,000,000; issued and outstanding shares, 9,174,589 in 2010 and zero in 2009	918		-	
Additional paid-in capital	423,877		350,243	
Accumulated deficit	(234,510)		(228,076)	
Accumulated other comprehensive income:				
Unrealized gain on investments	993		445	
Net stockholders' equity	192,843		123,914	
Total liabilities and stockholders' equity	\$	196,265	\$	126,695

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

	Twelve Months Ended December 31,		
	2010	2009	2008
Royalties	\$ 4	\$ 129	\$ 144
Grant revenue	-	1,044	1,044
Other expanded access program income, net	6,917	9,200	10,511
Total revenues	6,921	10,373	11,699
Operating expenses:			
Research and development	4,757	9,207	21,047
Selling, general and administrative	10,256	9,840	5,063
Total expenses	15,013	19,047	26,110
Operating loss	(8,092)	(8,674)	(14,411)

Investment income	1,845	808	500
Realized loss on investment	-	-	(500)
Interest expense	(109)	(781)	(1,256)
Gain on sale of asset, net	-	127,474	-
Income (loss) before taxes	(6,356)	118,827	(15,667)
Income tax expense	78	477	-
Net (loss) income	\$ (6,434)	\$ 118,350	\$ (15,667)
Basic net (loss) income per share	\$ (0.49)	\$ 9.31	\$ (1.28)
Shares used in computing basic net (loss) income per share	13,250	12,712	12,213
Diluted net (loss) income per share	\$ (0.49)	\$ 9.31	\$ (1.28)
Shares used in computing diluted net (loss) income per share	13,250	12,727	12,213

INSMED INCORPORATED
Consolidated Statements of Cash Flows
(in thousands)

	Twelve Months Ended December 31,		
	2010	2009	2008
Operating activities			
Net income	\$ (6,434)	\$ 118,350	\$ (15,667)
Adjustments to reconcile net income to net cash			
(used in) provided by operating activities:			
Depreciation and amortization	54	707	1,043
Stock based compensation expense	366	2,542	850
Gain on sale of asset, net	-	(127,474)	-
Change in trading securities	-	-	143
Realized loss on investments	-	-	500
Changes in operating assets and liabilities:			
Accounts receivable	19	(123)	-
Income tax receivable	2,023	(2,023)	128
Prepaid expenses	(78)	-	-
Accounts payable	(2,750)	(85)	170
Accrued project costs & other	(1,144)	(965)	373
Payroll liabilities	201	214	433
Income tax liability	-	127	(178)
Deferred rent	18	(36)	53
Deferred revenue	4	96	57
Restricted stock unit liability	-	(113)	113
Asset retirement obligation	-	(2,217)	-
Interest payable	(1)	(12)	(10)
Net cash (used in) operating activities	(7,722)	(11,012)	(11,992)
Investing activities			
Cash consideration for merger	(6,733)	-	-
Cash received from asset sale	-	127,474	-
Sales of short-term	115,153	-	12,673

investments			
Purchases of short-term investments	(102,462)	(108,744)	-
Net cash provided by investing activities	5,958	18,730	12,673
Financing activities			
Proceeds from issuance of common stock	-	580	-
Payments on capital lease obligations	(6)	-	-
Repayment of convertible notes	(231)	(1,246)	(2,211)
Certificate of deposits	-	10	-
Warrants converted into shares	-	3,491	-
Other	4	42	121
Net cash provided by (used in) financing activities	(233)	2,877	(2,090)
Increase (decrease) in cash and cash equivalents	(1,997)	10,595	(1,409)
Cash and cash equivalents at beginning of period	12,740	2,145	3,554
Cash and cash equivalents at end of period	\$ 10,743	\$ 12,740	\$ 2,145
Supplemental information			
Cash paid for interest	\$ -	\$ 82	\$ 234
Cash paid for taxes	139	2,795	-
