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Insmmed Announces First Quarter 2011 Financial Results

Insmmed Announces First Quarter 2011 Financial Results

MONMOUTH JUNCTION, N.J., May 10, 2011 [PRNewswire](#)/ -- Insmmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today reported results for the first quarter ended March 31, 2011.

Key Recent Highlights:

- Received Food and Drug Administration (FDA) clearance of Investigational New Drug (IND) Application to conduct a primary efficacy study for ARIKACE® (liposomal amikacin for inhalation) in non-tuberculous mycobacterial (NTM) lung disease
- Filed for orphan drug status with FDA for ARIKACE® to treat NTM lung infections
- Received acceptance of abstract for oral presentation of six cycles of data from the open-label study of ARIKACE® in the treatment of cystic fibrosis (CF) patients with Pseudomonas lung infections, at the European Cystic Fibrosis Conference in Hamburg, Germany in June
- Executed a one-for-10 reverse stock split and regained compliance with Nasdaq's minimum bid price rule
- Relocated corporate headquarters from Richmond, VA to Monmouth Junction, NJ

"The first several months of the year have produced multiple successes for Insmmed," said Timothy Whitten, Insmmed's President and CEO. "In particular, we have reached several key milestones related to our development plan for ARIKACE®, including, most recently, the clearance of ARIKACE® to proceed to a primary efficacy study based on our NTM IND filing, and the submission in the U.S. of the ARIKACE® NTM orphan drug designation. We continue to ramp up our ARIKACE® clinical trial and drug manufacturing activity and remain on schedule to begin enrollment of our Phase 3 clinical trials for ARIKACE® in patients who have NTM lung infections and in CF patients who have Pseudomonas lung infections, in the second half of this year. In addition, we have regained compliance with Nasdaq's minimum bid price rule and we remain on solid financial ground, with a strong overall cash balance of \$104.9 million, which will continue to drive our development of ARIKACE®."

Financial Results:

For the first quarter of 2011, Insmmed posted a net loss attributable to common stockholders of \$16.1 million, or \$0.85 per share – basic and diluted, compared to net income of 0.1 million, or \$0.01 per share – basic and diluted, for the three months ended March 31, 2010. The net loss attributable to common stockholders in 2011 includes the conversion of the Series B Conditional Convertible Preferred Stock, and a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of \$9.2 million. When issuing debt or equity securities that are convertible into common stock at a discount from the fair value of the common stock at the date the debt or equity financing is committed, a company is required to record a beneficial conversion feature ("BCF") charge in accordance with Accounting Standards Codification 470-20. This BCF of \$9.2 million reduced net income available to holders of our common shares and, in turn, reduced our earnings per common share on a basic and diluted basis, by \$0.48. The charge represents the \$1.00 difference between the conversion price of the preferred stock of \$7.10 per share and its carrying value of \$6.10 per share. The carrying value of the preferred stock was based on its fair value at issuance, which was estimated using the common stock price reduced for a lack of marketability between the issuance date and the anticipated date of conversion.

Revenues were \$1.6 million, as compared to \$1.9 million for the quarter ended March 31, 2010. The reduction in revenue was primarily attributable to \$0.6 million in lower cost recovery from our IPLEX™ Expanded Access Program in Europe, which was partially offset by \$0.3 million in licensing fees received during the most recent quarter. The reduced IPLEX™ cost recovery was due to the smaller number of patients being supplied IPLEX™, while the license fee related to the initial payment for the licensing of patent technology to Eleison for our CISPLATIN Lipid Complex.

Research and development (R&D) expenses were \$5.8 million for the first quarter, compared to \$0.6 million in the first quarter of 2010. The \$5.1 million increase resulted from the addition of ARIKACE® related R&D expenses associated with the preparation of our Phase 3 clinical trials in CF and NTM. Selling, general and administrative expenses were \$3.2 million for the first quarter of 2011, compared to \$1.5 million for the same period in 2010. This increase was primarily due to the increased finance, legal and consulting fees related to the business combination with Transave, Inc. on December 1, 2010, as well as the associated proxy preparation costs for conversion of the preferred stock into common stock and reverse stock split consummated on March 2, 2011.

As of March 31, 2011, Insmmed had total cash, cash equivalents, short-term investments, and certificate of deposits on hand totaling \$104.9 million, consisting of \$102.7 million in cash and short-term investments and \$2.2 million in a certificate of deposit, as compared to \$110.2 million of cash on hand as of December 31, 2010. The \$5.3 million decrease in total cash was primarily due to the reported net loss of \$6.9 million and a partial offset of \$1.6 million due to an increase in payables.

Conference Call

To participate in today's live conference call at 8:30 AM ET, please dial 800-510-9691 (U.S. callers) or 617-614-3453 (international), and provide passcode 84658447. A live webcast of the call will also be available at: <http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=3981570>. 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 May 10th, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 65400341.

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 high 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.insmmed.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 positions, results of operations, the results of clinical trials, the development of our products, and the 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 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, we may experience delays in our product development or clinical trials, 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, 2010. 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.

INSMED INCORPORATED

Consolidated Balance Sheets (Unaudited)

(in thousands, except share and per share data)

| | March 31, 2011 | December 31, 2010 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 22,100 | \$ 10,743 |
| Short-term investments | 80,624 | 97,306 |
| Accounts receivable, net | 169 | 471 |
| Prepaid expenses | 169 | 277 |
| Total current assets | 103,062 | 108,797 |
| Certificate of deposit | 2,176 | 2,176 |
| In-process research and development | 77,900 | 77,900 |
| Goodwill | 6,290 | 6,290 |
| Fixed assets, net | 1,042 | 1,102 |
| Total assets | \$ 190,470 | \$ 196,265 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 3,082 | \$ 1,450 |
| Accrued expenses | 915 | 1,256 |
| Deferred rent | 150 | 150 |
| Capital lease obligations, current | 72 | 81 |
| Deferred revenue | 244 | 402 |
| Total current liabilities | 4,463 | 3,339 |
| Restricted stock units compensation liability | 132 | - |
| Capital lease obligations, long-term | 71 | 83 |
| Total liabilities | 4,666 | 3,422 |
| Stockholders' equity: | | |
| Common stock; \$.01 par value; authorized shares | | |
| 500,000,000; issued and outstanding shares, 24,828,101 in 2011 and 15,653,734 in 2010 | 248 | 1,565 |
| Preferred stock; \$.01 par value; authorized shares | | |
| 200,000,000; issued and outstanding shares, zero in 2011 and 9,174,589 in 2010 | - | 918 |
| Additional paid-in capital | 426,146 | 423,877 |
| Accumulated deficit | (241,404) | (234,510) |
| Accumulated other comprehensive income: | | |
| Unrealized gain on investments | 814 | 993 |
| | 185,804 | 192,843 |
| Total liabilities and stockholders' equity | \$ 190,470 | \$ 196,265 |

INSMED INCORPORATED

Consolidated Statements of Operations (Unaudited)

(in thousands, except per share data)

Three Months Ended

| | March 31, 2011 | 2010 |
|---|-------------------|---------|
| License fees | \$ 250 | \$ 2 |
| Other expanded access program income, net | 1,351 | 1,927 |
| Total revenues | 1,601 | 1,929 |
| Operating expenses: | | |
| Research and development | 5,760 | 642 |
| Selling, general and administrative | 3,256 | 1,538 |
| Total operating expenses | 9,016 | 2,180 |
| Operating loss | (7,415) | (251) |
| Investment income | 527 | 397 |
| Interest expense | (4) | (28) |
| Income (loss) before taxes | (6,892) | 118 |
| Income tax expense | 2 | - |
| Net (loss) income | (6,894) | 118 |
| Less: accretion of beneficial conversion feature | (9,175) | - |
| Net (loss) income attributable to common stockholders | \$ (16,069) | \$ 118 |
| Basic and diluted net (loss) income attributable to common stockholders per common share | \$ (0.85) | \$ 0.01 |
| Weighted average basic common shares outstanding | 18,814 | 13,021 |
| Weighted average diluted common shares outstanding | 18,814 | 13,055 |

INSMED INCORPORATED

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

| | Three Months Ended March 31, 2011 | 2010 |
|---|---|--------|
| Operating activities | | |
| Net (loss) income | \$ (6,894) | \$ 118 |
| Adjustments to reconcile net (loss) income to net cash | | |
| (used in) provided by operating activities: | | |
| Depreciation and amortization | 75 | 25 |
| Stock based compensation expense | 167 | 65 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 302 | 56 |
| Prepaid expenses | 108 | 77 |
| Accounts payable | 1,632 | 121 |
| Accrued expenses | (341) | (309) |
| Deferred revenue | (158) | 79 |
| Interest payable | - | (1) |
| Net cash (used in) provided by operating activities | (5,109) | 231 |
| Investing activities | | |
| Purchase of fixed assets | (14) | - |

| | | |
|---|------------|-----------|
| Sales of short-term investments | 16,588 | 26,393 |
| Purchases of short-term investments | (87) | (19,769) |
| Net cash provided by investing activities | 16,487 | 6,624 |
| Financing activities | | |
| Payments on capital lease obligations | (21) | - |
| Repayment of convertible notes | - | (231) |
| Net cash used in financing activities | (21) | (231) |
| Increase in cash and cash equivalents | 11,357 | 6,624 |
| Cash and cash equivalents at beginning of period | 10,743 | 12,740 |
| Cash and cash equivalents at end of period | \$ 22,100 | \$ 19,364 |
| Supplemental disclosures of non-cash investing and financing activities | | |
| Unrealized (loss) gain on investments | \$ (179) | \$ 330 |
| Accretion of beneficial conversion feature | \$ (9,175) | \$ - |

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