

INSMED INC
Form 10-Q
May 10, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended

March 31, 2011

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia

(State or other jurisdiction of
incorporation or organization)

54-1972729

(I.R.S. employer identification no.)

11 Deer Park Drive, Suite 117
Monmouth Junction, NJ

(Address of principal executive offices)

08852
(Zip Code)

(732) 438-9434

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting Company (See the definitions of "large accelerated filer," "accelerated filer," and "small reporting

Edgar Filing: INSMED INC - Form 10-Q

Company” in Rule 12b-2 of the Exchange Act). Large accelerated filer [] Accelerated filer [] Non-accelerated filer
[] Small Reporting Company []

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes
[] No []

As of May 5, 2011, there were 24,828,101 shares of the registrant’s common stock, \$.01 par value, outstanding.

INSMED INCORPORATED

INDEX

PART I. FINANCIAL INFORMATION

<u>ITEM 1</u>	<u>Financial Statements (unaudited)</u>	<u>Consolidated Balance Sheets at March 31, 2011 and December 31, 2010</u>
		<u>Consolidated Statements of Operations for the three month periods ended March 31, 2011 and March 31, 2010</u>
		<u>Consolidated Statements of Cash Flows for the three month periods ended March 31, 2011 and March 31, 2010</u>
		<u>Notes to Consolidated Financial Statements</u>
		<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>
<u>ITEM 2</u>	-	
<u>ITEM 3</u>	-	<u>Quantitative and Qualitative Disclosures about Market Risk</u>
<u>ITEM 4</u>	-	<u>Controls and Procedures</u>

PART II. OTHER INFORMATION

<u>ITEM 1</u>	-	<u>Legal Proceedings</u>
<u>ITEM 1A</u>	-	<u>Risk Factors</u>
<u>ITEM 2</u>	-	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>
<u>ITEM 3</u>	-	<u>Defaults Upon Senior Securities</u>
<u>ITEM 4</u>	-	<u>(Removed and Reserved)</u>
<u>ITEM 5</u>	-	<u>Other Information</u>
<u>ITEM 6</u>	-	<u>Exhibits</u>

SIGNATURE

CERTIFICATIONS

In this Form 10-Q, we use the words the "Company," "Insmmed," "Insmmed Incorporated," "we," "us" and "our" to refer to Insmmed Incorporated, a Virginia corporation.

PART I
FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

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

See accompanying notes to unaudited consolidated financial statements

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

See accompanying notes to unaudited consolidated financial statements

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)	\$-

See accompanying notes to unaudited consolidated financial statements

INSMED INCORPORATED

NOTES TO UNAUDITED

CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business and Background

On December 1, 2010, we completed a business combination with Transave, Inc., or Transave, a privately-held, New Jersey-based pharmaceutical Company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Under the terms of the merger agreement, Insmmed paid off all of Transave's \$7.8 million debt, issued approximately 0.3 million shares of Insmmed common stock, approximately 9.1 million shares of Insmmed Series B Conditional Convertible Preferred Stock and cash consideration of \$561,280 in exchange for all of the outstanding capital stock of Transave. On March 1, 2011 at a special meeting of our shareholders, all of our shares of Series B Conditional Convertible Preferred Stock were converted into shares of our Common Stock, on a one for one basis. Also at this meeting, our shareholders approved a one for ten reverse stock split of our common stock, which became effective on March 2, 2011 (see note 5). This reverse stock split is reflected in the shares outstanding and earnings per share calculations throughout this 10-Q.

We are a pharmaceutical company and following the December 1, 2010 merger, have expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung and provides for potential improvements to the conventional inhalation methods of delivering drugs to the pulmonary system. These potential advantages include improvements in efficacy, safety and patient convenience. Our primary focus is orphan markets with high unmet medical needs which present a significant opportunity, as their challenge and complexity best fit our knowledge, know-how and expertise.

Our strategy is to utilize our patented advanced liposomal technology to develop safe and effective medicines that improve upon standards of care for those orphan respiratory diseases in which patient needs are currently unmet. Our initial primary target indications are Pseudomonas lung infections in cystic fibrosis ("CF") patients and non-tuberculous mycobacteria ("NTM") lung infection patients.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The consolidated balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2010 filed with the Securities

and Exchange Commission on March 16, 2011.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Transave, LLC, Insmmed Therapeutic Proteins, Insmmed Pharmaceuticals, Incorporated and Celtrix Pharmaceuticals, Incorporated. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition

Revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectability is assured. License fees are recognized as revenue when the milestones are achieved and payments are due. .

Beneficial Conversion Charge

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, we are required to record a beneficial conversion charge ("BCC") in accordance with Accounting Standards Codification ("ASC") 470-20. This BCC is measured as the difference between the fair value of the securities at the time of issue, \$6.10 in this case, and the fair value of the common stock at the commitment date, which was \$7.10. 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. The BCC is recorded as a non-cash charge to earnings. A BCC of \$9.2 million was recognized at the time of the Series B Conditional Convertible Stock conversions and represents a \$1.00 discount on the fair value of our common stock purchased by the convertible note holders. See Note 5 for further information about the beneficial conversion feature.

Net (Loss) Income Per Share

Basic net (loss) income per share is computed based upon the weighted average number of common shares outstanding during the year. The following table sets forth the reconciliation of the weighted average number of common shares used to compute basic net (loss) income per common share to those used to compute diluted net loss income per common share for the three months ended March 31, 2011 and 2010 (in thousands):

	Three Months Ended March 31,	
	2011	2010
Weighted average number of shares - basic	18,814	13,021
Add dilutive effect of shares - restricted stock units and options	-	34
Weighted average number of shares - diluted	18,814	13,055

Edgar Filing: INSMED INC - Form 10-Q

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of March 31, 2011 and 2010, as they would be anti-dilutive (in thousands):

	Three Months Ended March 31,	
	2011	2010
Shares underlying warrants to purchase outstanding common stock	158	158
Shares underlying options to purchase outstanding common stock	392	242
Shares underlying restricted stock units	445	19

Comprehensive Loss

Comprehensive (loss) income consists of net (loss) income plus unrealized gains and losses on short-term investments. Comprehensive (loss) income for the three months ended March 31, 2011 and 2010 consists of the following (in thousands):

	Three Months Ended March 31,	
	2011	2010
Net (loss) income	\$(6,894)	\$118
Unrealized (loss) gain on short-term investments	(179)	330
Total comprehensive (loss) income	\$(7,073)	\$448

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2009-13, Multiple-Deliverable Revenue Arrangements. The new standard changes the requirements for establishing separate units of accounting in a multiple element arrangement and requires the allocation of arrangement consideration to each deliverable based on the relative selling price. The selling price for each deliverable is based on vendor-specific objective evidence (“VSOE”) if available, third-party evidence (“TPE”) if VSOE is not available, or estimated selling price if neither VSOE or TPE is available. ASU No. 2009-13 is effective for revenue arrangements entered into in fiscal years beginning on or after June 15, 2010. We adopted ASU No. 2009-13 effective January 1, 2011 and it did not have a material impact on our consolidated financial statements.

In January 2010, the FASB issued (ASU No. 2010-06, Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements (ASU 2010-06), which amends the existing fair value measurement and disclosure guidance currently included in Accounting Standards Codification (ASC) Topic 820, Fair Value Measurements and Disclosures, to require additional disclosures regarding fair value measurements. Specifically, ASU No. 2010-06 requires entities to disclose the amounts of significant transfers between Level 1 and Level 2 of the fair value hierarchy and the reasons for these transfers, the reasons for any transfer in or out of Level 3 and information in the reconciliation of recurring Level 3 measurements about purchases, sales, issuances and settlements on a gross basis. In addition, ASU No. 2010-06 also clarifies the requirement for entities to disclose information about both the valuation techniques and inputs used in estimating Level 2 and Level 3 fair value measurements. The adoption of ASU No. 2010-06 did not impact our consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, Revenue Recognition—Milestone Method (Topic 605): Milestone Method of Revenue Recognition, a consensus of the FASB Emerging Issues Task Force, which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. ASU No. 2010-17 is effective for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. We adopted ASU No. 2010-17 effective January 1, 2011 and it did not have a material impact on our consolidated financial statements.

3. Risks and Uncertainties

For the period from inception to March 31, 2011, the Company has incurred recurring operating losses and has accumulated a deficit of \$241.4 million. During the three months ended March 31, 2011, the Company recognized a net loss of \$6.9 million. Our net cash used in operations for the three months ended March 31, 2011 was \$5.1 million.

Even though we believe we currently have sufficient funds to meet our financial needs for the year of 2011, our business strategy in the future may require us to raise additional capital either through licensing, debt or equity sales. In the future, we may require additional funds for the continued development of our potential product candidates or to pursue the license of complementary technologies. There can be no assurance that adequate funds will be available when we need them or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or technology or cease operations.

4. Convertible Debt and Stockholders' Equity

Convertible Debt

On March 15, 2005, we entered into several purchase agreements with a group of institutional investors, pursuant to which we issued and sold to such investors certain 5.5% convertible notes in the aggregate principal amount of \$35,000,000, which convert into a certain number of shares of our common stock (the "2005 Notes") as well as warrants to purchase our common stock (the "2005 Warrants"). On March 1, 2010 our final payments to the holders of the remaining 2005 Notes were paid. The 2005 Warrants expired on March 15, 2010.

Common and Preferred Stock

On December 1, 2010, we entered into the Agreement and Plan of Merger (the "Merger Agreement") with Transave. Under the terms of the Merger Agreement, the Transave stockholders received an aggregate of 2,593,882 newly issued shares of the common stock, par value \$0.01 per share, of the Company and 9,174,589 shares of newly created Series B Conditional Convertible Preferred Stock, par value \$0.01 per share, of the Company. They also received an aggregate of approximately \$561,280 in cash. Collectively, the shares of the Company's common stock and the Company's preferred stock (on an as converted basis) issued in connection with the merger represent approximately 47% of the capital stock of the Company on a fully diluted basis.

On March 1, 2011, we held a special meeting of our shareholders to consider proposals relating to the conversion of our Series B Conditional Convertible Preferred Stock and a one for ten reverse stock split of the common stock. At the special meeting of shareholders, the shareholders approved all of the proposals.

As a result of the approval of the conversion of the Series B Conditional Convertible Preferred Stock, the 91,745,892 shares of the Series B Conditional Convertible Preferred Stock outstanding (on a pre-reverse stock-split basis) were automatically and immediately converted into 91,745,892 shares of our common stock. In addition, we filed Articles of Amendment to our Articles of Incorporation, as amended, to effect a one for ten reverse stock split of our common stock. The Amendment became effective on March 2, 2011. As a result of the Amendment, each holder of 10 shares of common stock immediately prior to the effectiveness of the reverse stock split became the holder of one share of our common stock. Shareholders received a cash payment in lieu of any fractional shares of common stock they are entitled to receive. Below is a table detailing the conversion of the preferred shares and the reverse stock split.

Common stock shares outstanding February 28, 2011	156,537,341
Preferred series B stock converted into common stock on March 1, 2011	91,745,892

Total shares outstanding prior to reverse stock split	248,283,233
1 for 10 reverse stock split	1:10
Approximate number of common shares outstanding March 2, 2011	24,828,323

As a result of the conversion of the Series B Conditional Convertible Preferred Stock, we recorded a non-cash charge for the beneficial conversion feature of the Series B Preferred Stock in the amount of \$9.2 million, which 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 acquisition date (or issuance date) and the anticipated date of conversion.

5. Stock Based Compensation

Stock Warrants

There was no stock warrant activity for the three months ended March 31, 2011. As of March 31, 2011 we had 157,554 warrants outstanding with a weighted average price of \$11 and an expiration date of May 2012.

Stock Options

As of March 31, 2011, we had two equity compensation plans under which we were granting stock options and shares of non-vested stock. We are currently granting stock-based awards from our Amended and Restated 2000 Stock Incentive Plan (the "2000 Plan") and our Amended and Restated 2000 Employee Stock Purchase Plan (the "2000 ESPP"). Both the 2000 Plan and the 2000 ESPP are administered by the Compensation Committee of the Board of Directors and the Board of Directors (the "Board").

The 2000 Plan was originally adopted by the Board and approved by our shareholders in 2000. Its original ten-year term was extended to March 15, 2015 when the 2000 Plan was last amended. Under the terms of the 2000 Plan, we are authorized to grant a variety of incentive awards based on our common stock, including stock options (both incentive options and non-qualified options), performance shares and other stock awards. The 2000 Plan currently provides for the issuance of a maximum of 925,000 shares of common stock which have all been utilized. At the 2011 annual meeting of shareholders scheduled to be held on May 18, 2011, the Company seeks shareholder approval for additional shares to be set aside for current and future use. These shares are reserved for awards to all participants in the 2000 Plan, including non-employee directors.

The 2000 ESPP was adopted by the Board on April 5, 2000 and approved by our shareholders on the same date. It was amended by the Board to increase the number of shares available for issuance, and such amendment was approved by our shareholders on May 11, 2005. The 2000 ESPP was subsequently amended and restated by action of the Board on October 4, 2006 and the amendment and restatement was approved by our shareholders on December 14, 2006. Under the terms of the 2000 ESPP, eligible employees have the opportunity to purchase our common stock at a discount. An option gives its holder the right to purchase shares of our common stock, up to a maximum value of \$25,000 per year. The 2000 ESPP provides for the issuance of a maximum of 150,000 shares of our common stock to participating employees.

A summary of stock option activity for the three months ended March 31, 2011 is as follows:

Number of Shares	Weighted Average	Weighted Average	Aggregate Intrinsic
---------------------	---------------------	---------------------	------------------------

Edgar Filing: INSMED INC - Form 10-Q

		Exercise Price	Remaining Contractual Life in Years	Value
Options outstanding at December 31, 2010	214,275	\$18.43		
Granted	198,400	5.90		
Exercised	-	-		
Cancelled	(20,599)	60.43		
Options outstanding at March 31, 2011	392,076	9.88	5.59	\$184,565
Vested and expected to vest at March 31, 2011	319,918	10.78	4.63	\$123,231
Exercisable at March 31, 2011	193,676	13.96	1.24	\$15,925

The Company calculates the fair value of stock options based upon the Black-Scholes-Merton valuation model. The following table summarizes the fair value and assumptions used in determining the fair value of stock options issued during the three months ended March 31, 2011.

Assumptions Used:

Volatility factors of expected market price of stock	129%
Risk-free interest rate	2%
Dividend yield	N/A
Expected option term (in years)	6

The volatility factor was estimated based on the Company's historical volatility. The expected life was determined using the simplified method as described in ASC Topic 718, Accounting for Stock Compensation, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant. Forfeitures are based on a historical percentage of actual option forfeitures since the business combination on December 1, 2010.

The Company recognized stock-based compensation expense related to stock options of approximately \$35,235 and \$22,822 for the three months ended March 31, 2011 and 2010, respectively. This expense was included in "Selling, general and administrative" expenses and "Research and development" expenses in the consolidated statement of operations. As of March 31, 2011, there was \$0.6 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.84 years.

Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we began granting Restricted Stock ("RS") and Restricted Stock Units ("RSU's") to eligible employees, including our executives. Each RS and RSU represents a right to receive one share of our common stock upon the completion of a specific period of continued service or our achievement of certain performance metrics. Shares of RS are valued at the market price of our common stock on the date of grant and RSU's are valued based on the market price on the date of settlement. RSU's are classified as liabilities, as they may be settled with a cash payment for each unit vested, equal to the fair market value of our common stock on the vesting date if there are insufficient shares available in the pool. We recognize noncash compensation expense for the fair values of these RS and RSU's on a straight-line basis over the requisite service period of these awards, which is generally three years.

A summary of RS and RSU's activity for the three months ended March 31, 2011 is as follows:

Number of Awards	Weighted-Average
Restricted Stock	Grant Price
Units	

Outstanding at December 31, 2010	-	
Granted	444,655	\$ 5.84
Vested	-	
Outstanding at March 31, 2011	444,655	\$ 5.84

The Company recognized stock-based compensation expense related to RSU's of approximately \$132,208 and \$42,178 for the three months ended March 31, 2011 and 2010, respectively. This expense was included in the "Selling, general and administrative" expenses and "Research and development" expenses in the consolidated statement of operations. As of March 31, 2011, there was \$1.8 million of unrecognized compensation expense related to unvested RSU's, which is expected to be recognized over a weighted average period of 2.71 years.

A total of approximately 1 million shares of common stock were reserved for issuance at March 31, 2011 in connection with restricted stock, stock options, stock warrants, and the employee stock purchase plan.

6. Investments and Fair Value Measurements

We categorize financial assets and liabilities measured and reported at fair value in the financial statements on a recurring basis based upon the level of judgments associated with the inputs used to measure their fair value. Hierarchical levels, which are directly related to the amount of subjectivity associated with the inputs used to determine the fair value of financial assets and liabilities are as follows:

- Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 – Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.
- Level 3 – Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Each major category of financial assets and liabilities measured at fair value on a recurring basis are categorized in the tables below based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

Financial instruments in Level 1 generally include U.S. treasuries and mutual funds listed in active markets. Financial instruments in Level 2 generally include municipal bonds listed in secondary markets.

Assets and liabilities measured at fair value as of March 31, 2011 and December 31, 2010 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Quoted Prices in Inactive Markets for Identical Assets (Level 2)	Significant Unobservable Inputs (Level 3)
Total			

As of March 31, 2011:

Assets:

Edgar Filing: INSMED INC - Form 10-Q

Cash and Cash Equivalents	\$22,100	\$22,100	\$-	\$-
Corporate bonds	6,705	6,705	-	-
U.S. Treasury securities	504	504	-	-
Mutual Funds	54,508	54,508	-	-
Government agency bonds	18,907	-	18,907	-
Certificate of deposit (a)	2,176	2,176	-	-
	\$104,900	\$85,993	\$18,907	\$-

As of December 31, 2010:

Assets:

Cash and Cash Equivalents	\$10,743	\$10,743	\$-	\$-
Corporate bonds	10,228	10,228	-	-
U.S. Treasury securities	505	505	-	-
Mutual Funds	54,311	54,311	-	-
Government agency bonds	32,262	-	32,262	-
Certificate of deposit (a)	2,176	2,176	-	-
	\$110,225	\$77,963	\$32,262	\$-

(a) - Certificate of deposit matures in July 2013.

We recognize transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no significant transfers into/out of level 1, level 2 or level 3 during the three months ended March 31, 2011 and 2010.

As of March 31, 2011, we held 5 securities which were in an unrealized loss position with a total estimated fair value of \$8.2 million and gross unrealized losses of approximately \$0.01 million. We also recorded \$0.2 million of gross unrealized loss. The net unrealized gain of \$0.8 million is reported in accumulated other comprehensive income in the stockholder's equity section of our balance sheet. Of the 5 securities, none had been in a continuous unrealized loss position for greater than one year. Unrealized gains and losses for the three months ended March 31, 2011 is as follows (in thousands):

	Amortized Cost	March 31, 2011		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. Treasury securities	\$495	\$9	\$-	\$504
Corporate bonds	6,659	46	-	6,705
Mutual Funds	53,743	765	-	54,508
Government agency bonds	18,913	50	(56)	18,907
	\$79,810	\$870	\$(56)	\$80,624

As of March 31, 2010, we held 7 securities which were in an unrealized loss position with a total estimated fair value of \$12.4 million and gross unrealized losses of approximately \$32,614. Of the 7 securities, none had been in a continuous unrealized loss position for greater than one year. Unrealized gains and losses for the three months ended March 31, 2010 is as follows (in thousands):

	Amortized Cost			Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. Treasury securities	\$10,491	\$4	\$-	\$10,495
Mutual Funds	52,565	740	-	53,305
Government agency bonds	39,316	64	(33)	39,347

\$102,372 \$808 \$(33) \$103,147

We review the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making our determination, we consider a number of factors, including: (1) the significance of the decline, (2) whether the securities were rated below investment grade, (3) how long the securities have been in an unrealized loss position, and (4) our ability and intent to retain the investment for a sufficient period of time for it to recover. We have concluded that none of the available-for-sale securities with unrealized losses at March 31, 2011 has experience an other-than-temporary impairment.

7. Commitments and Contingencies

Commitments

On February 11, 2011 we entered into a master services agreement with Chiltern International Inc, a pharmaceutical development services provider. Under the terms of the Agreement, Chiltern will provide project management, clinical monitoring, data management and related services to us in connection with the conduct of Phase 3 clinical studies of ARIKACE for treatment of CF and NTM. We may terminate the agreement or any work order at any time for any reason and without cause upon 30 days' prior written notice.

Legal Proceedings

Cacchillo vs. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo ("Plaintiff") in the United States District Court for the Northern District of New York (Court) seeking monetary damages and a court order requiring Insmmed to support her compassionate use application to the FDA and if approved, to provide her with IPLEX. Plaintiff was a participant in the phase II clinical trial of IPLEX sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy ("MMD"). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, we decided not to proceed to a phase III trial.

In the complaint, Plaintiff alleges (i) violation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEX, (ii) fraudulent inducement to enter the phase II clinical trial with the false promise to support Plaintiff's compassionate use application to the FDA, (iii) negligent representation that we would support Plaintiff's compassionate use application, (iv) intentional infliction of emotional distress by refusing to support Plaintiff's compassionate use application after providing IPLEX, (v) violation of an assumed duty of care to Plaintiff, (vi) breach of fiduciary duty to Plaintiff, (vii) negligence and (viii) unjust enrichment. Plaintiff seeks compensatory and punitive monetary damages and sought injunction relief as noted above.

On October 7, 2010, Plaintiff filed a motion for a preliminary injunction that would require us to provide a written statement supporting the "compassionate use" of IPLEX for Plaintiff and directing us to provide IPLEX to Plaintiff at cost in the event that the compassionate use application were granted by the FDA. On October 13, 2010, we filed an opposition to Plaintiff's motion for the preliminary injunction and on October 15, 2010, an oral argument was held before the Court on the Plaintiff's motion.

On October 22, 2010, the Court denied Plaintiff's motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court's denial of her motion for a preliminary injunction to the United States Court of Appeals for the Second Circuit. The matter was argued before the Court of Appeals on March 15, 2011, and on March 23, 2011, the Court affirmed the trial court's order denying the Plaintiff's motion for a preliminary injunction.

Plaintiff's claim for monetary damages remains outstanding. We believe that the allegations contained in the complaint are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

Mackinson et al. v. Insmmed

On February 24, 2011, an action was filed against us, our subsidiary Transave, LLC, Transave, our directors and the former directors of Transave, captioned Mackinson et al. v. Insmmed Incorporated et al., C.A. No. 6216, as a purported class action seeking a quasi-appraisal remedy for alleged violations of Delaware's appraisal statute and the fiduciary duty of disclosure in connection with the merger consummated pursuant to that certain Agreement and Plan of Merger, dated as of December 1, 2010, by and among Insmmed Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders' agent. We intend to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

From time to time, we are a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of our business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on our consolidated financial position, results of operations or cash flows.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

Statements contained herein, including without limitation, "Management's Discussion and Analysis of Financial Condition and Results of Operations," contain certain projections, estimates and other forward-looking statements. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential" expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Forward-looking statements include, but are not limited to: our success in developing ARIKACE; our estimates regarding our existing supply of IPLEX; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; our clinical development of product candidates, clinical trials and our ability to obtain and maintain regulatory approval for our product candidates; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract collaborators with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate collaborations, license agreements and other collaborative efforts, including those relating to the development and commercialization of our product candidates; sources of revenues and anticipated revenues, including contributions from corporate collaborations, license agreements and other collaborative efforts for the development and commercialization of products; our ability to create an effective direct sales and marketing infrastructure for products we elect to market and sell directly; the rate and degree of market acceptance of our product candidates; the timing and amount of reimbursement for our product candidates; the success of other competing therapies that may become available; and the manufacturing capacity for our product candidates.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements. Any forward-looking statement should be considered in light of factors discussed in Part II, Item 1A "Risk Factors" and elsewhere in this report. We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes thereto in our Annual Report on Form 10-K, for the year ended December 31, 2010.

Overview

On December 1, 2010, we completed a business combination with Transave, Inc., or Transave, a privately-held, New Jersey-based pharmaceutical company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Under the terms of the merger agreement, Insmmed paid off all of Transave's \$7.8 million debt, issued approximately 2.6 million shares of Insmmed common stock, approximately 9.2 million shares of Insmmed Series B Conditional Convertible Preferred Stock and cash consideration

of \$561,280 in exchange for all of the outstanding capital stock of Transave. Of the 9.2 million shares of Series B Conditional Convertible Preferred Stock, 1.76 million shares were retained by us as security for any indemnification payments required pursuant to the merger agreement. On March 1, 2011 at a special meeting of our shareholders, all of our shares of Series B Conditional Convertible Preferred Stock were converted into shares of our common stock, on a one for one basis. At this meeting, our shareholders also approved a one for ten reverse stock split of our common stock on March 2, 2011. The reverse stock split is reflected in the shares outstanding and earnings per share calculations throughout this Quarterly Report on Form 10-Q.

After giving effect to the merger and following conversion of the preferred stock into common stock, former Transave stockholders have approximately a 47% equity interest in the combined Company, and legacy Insmmed Incorporated shareholders have a 53% interest on a fully diluted, as exercised, basis. The shares retained by us pursuant to the merger agreement (approximately 1.76 million shares of common stock) will be delivered on June 12, 2012, subject to reduction for any indemnification payments being made under the merger agreement.

We are a pharmaceutical company and following the business combination on December 1, 2010, have expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung and provides for potential improvements to the conventional inhalation methods of delivering drug to the pulmonary system. These potential advantages include improvements in efficacy, safety and patient convenience. Our primary focus is orphan markets with high unmet medical needs which present a significant opportunity, as their challenge and complexity best fit our knowledge, know-how and expertise.

Our Company's strategy is to utilize our patented advanced liposomal technology to develop safe and effective medicines that improve upon standards of care for those orphan respiratory diseases in which patient needs are currently unmet. Our initial primary target indications are Pseudomonas lung infections in cystic fibrosis ("CF") patients and non-tuberculous mycobacteria ("NTM") lung infections.

Key Components of Our Statement of Operations

Revenues

Our revenue consists of secondary revenue streams for IPLEXTM Expanded Access Program ("EAP") in Europe for the treatment of Amyotrophic Lateral Sclerosis ("ALS"), and royalty revenue for the licensing of patent technology for CISPLATIN Lipid Complex. We no longer manufacturer IPLEX and the cost recovery revenues from our IPLEX EAP in Europe will be eliminated by approximately the third quarter of 2011, when our current IPLEX inventory is depleted.

Research and Development Expenses

Research and development expenses consist primarily of salaries and related expenses, cost to develop and manufacture drug candidates, patent protection costs, amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Our expenses related to clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with third party organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

Since we began operations in late 1999, we have devoted substantially all of our resources to the research and development of a number of product candidates. Until the sale of our Follow on Biologics (“FOB”) platform on March 31, 2009, our research and development efforts were principally focused on pursuing a dual path strategy involving entry into the FOB arena and advancing our proprietary protein platform into niche markets with unmet needs. Following the business combination on December 1, 2010 our focus is now principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our initial priority is to conduct Phase 3 studies with patient accrual expected to begin in the second half of 2011 for ARIKACE in treating CF patients with Pseudomonas lung infections and patients with NTM lung infections

Historically all of our research and development expenditures related to our proprietary protein platform were interrelated as they are all associated with drugs that modulate IGF-1 activity in the human body. All of these products also share a substantial amount of our common fixed costs such as salaries, facility costs, utilities and maintenance. Given the small portion of research and development expenses that are historically related to products other than IPLEX we have determined that very limited benefits would be obtained from implementing cost tracking systems that would be necessary to allow for cost information on a product-by-product basis. Prospectively all of our currently planned research and development activities are expected to be incurred in the development of ARIKACE.

At present we expect research of ARIKACE in the CF and NTM indications to represent our main research and development effort for 2011.

Our clinical trials with our product candidates are subject to numerous risks and uncertainties that are outside of our control, including the possibility that necessary regulatory approvals may not be obtained. For example, the duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial, including, among others, the following:

- the number of patients that ultimately participate in the trial;
- the duration of patient follow-up that is determined to be appropriate in view of results;
 - the number of clinical sites included in the trials;
- the length of time required to enroll suitable patient subjects; and
 - the efficacy and safety profile of the product candidate.

Our clinical trials may also be subject to delays or rejections based on our inability to enroll patients at the rate that we expect or our inability to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our planned clinical trials.

Moreover, all of our product candidates and particularly those that are in the preclinical or early clinical trial stage must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. Some of these product candidates may never reach the clinical trial stage of research and development. As preclinical studies and clinical trials progress, we may determine that collaborative relationships will be necessary to help us further develop or to commercialize our product candidates, but such relationships may be difficult or impossible to arrange. Our projects or intended projects may also be subject to change from time to time as we evaluate our research and development priorities and available resources.

Any significant delays that occur or additional expenses that we incur may have a material adverse effect on our financial position and may require us to raise additional capital sooner or in larger amounts than is presently expected. In addition, as a result of the risks and uncertainties related to the development and approval of our product candidates and the additional uncertainties related to our ability to market and sell these products once approved for commercial

sale, we are unable to provide a meaningful prediction regarding the period in which material net cash inflows from any of these projects is expected to become available.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, market research and human resource functions, and professional fees for legal, including patent-related expenses, consulting, tax and accounting services. Our selling, general and administrative expenses also include facility and related costs not included in research and development expenses, insurance, depreciation and general corporate expenses. We expect that our selling, general and administrative expenses will increase with the continued development and commercialization of our product candidates.

Investment Income and Interest Expense

Investment income consists of interest and dividend income earned on our cash, cash equivalents and short-term investments. Short-term investments are available for sale and consist primarily of short-term municipal bonds, U.S. treasuries and mutual funds. Interest expense consists primarily of interest costs related to convertible notes that were fully repaid in March 2010.

Results of Operations

Three months ended March 31, 2011 compared to three months ended March 31, 2010

Net loss attributable to common stockholders for the three months ended March 31, 2011 was \$16.1 million, (or \$0.85 per common share – basic and diluted), compared to net income of 0.1 million, (or \$0.01 per common 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, which 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.

Revenue

Revenues for the three months ended March 31, 2011 totaled \$1.6 million, as compared to \$1.9 million for the three months ended March 31, 2010. The \$0.3 million decrease was primarily due to a year-over-year decrease of 0.6 million in cost recovery from our IPLEX EAP in Europe, offset by \$0.3 million in license fees received in 2011 for the licensing of patent technology for CISPLATIN Lipid Complex.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2011 and 2010 were comprised of the following:

	Three Months Ended March 31,		Increase (Decrease)	
	2011	2010		
	(in thousands)			
Clinical development	\$2,034	\$179	\$1,855	1036 %

Edgar Filing: INSMED INC - Form 10-Q

Clinical manufacturing	1,076	-	1,076	N/A	
Preclinical development	1,004	-	1,004	N/A	
Regulatory and quality assurance	178	144	34	24	%
Compensation and related	1,468	319	1,149	360	%
	\$5,760	\$642	\$5,118	797	%

Research and development expenses increased to \$5.8 million in the three months ended March 31, 2011 from \$0.6 million for the three months ended March 31, 2010. The increase of \$5.1 million in 2011 is attributable to full scale research and development of ARIKACE including the preparation for initiation of Phase 3 studies and the manufacturing of supply to support the studies. Clinical development expenses increased \$1.9 million for the first three months of 2011 compared to 2010, a result of the planning effort for the two Phase 3 CF studies and one Phase 3 NTM study during the quarter. The \$1.1 million increase in clinical manufacturing expenses from 2011 to 2010 is attributable to the manufacturing of ARIKACE for use in Phase 3 studies. The preclinical development expense increase of \$1.0 million in the first quarter of 2011 compared to 2010 is attributable to the final major milestone payment in the quarter for a carcinogenicity animal study associated with the Phase 2 CF program. Higher compensation and related expenses were attributable to increased headcount and average per salary headcount associated with the development of ARIKACE. Overall research and development headcount increased from approximately 8 as of March 2010 to 28 as of March 2011. In addition a greater number of highly compensated employees constitute the research and development department as we research and develop ARIKACE.

Selling General and Administrative Expenses

Selling, general and administrative expenses increased to \$3.3 million in the three months ended March 31, 2011 from \$1.5 million for the three months ended March 31, 2010. The \$1.7 million increase was due largely to the increased finance, legal and consulting fees related to the business combination with Transave on December 1, 2010 as well as the reverse stock split transaction on March 2, 2011.

Investment Income and Interest Expense

Investment income increased by \$0.1 million to \$0.5 million in the three months ended March 31, 2011 from \$0.4 million in the three months ended March 31, 2010. The increase is a result of improved returns on our short-term investments totaling \$102.7 million as of March 31, 2011. The reduction in interest expense for the first three months of 2011 as compared to the same period in 2010 was entirely due to the elimination of convertible notes, which were fully repaid in March 2010.

Liquidity and Capital Resources

Overview

There is considerable time and cost associated with developing a potential drug or pharmaceutical product to the point where FDA approval for sales is received. In our financial management, we have generally sought to raise the funds necessary for such development primarily through the issuance of equity securities in private and public placement transactions. However, we may pursue additional financing options, including entering into agreements with collaborative partners in order to provide milestone payments, license fees and equity investments.

We have funded our operations to date through public and private placements of debt and equity securities and the proceeds from the sale of our FOB platform to Merck & Co., Inc., or Merck. We will continue to incur losses to the extent we expand our research and development and do not expect material revenues for at least the next several years. Furthermore, revenues from our EAP in Italy associated with cost recovery will be eliminated by

approximately the third quarter of 2011, when our current IPLEX inventory, which has fully been expensed, is depleted. As of March 31, 2011, we had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of \$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 due to the funding of operations, primarily research and development activities. Our working capital was \$98.6 million as of March 31, 2011.

Even though we believe we currently have sufficient funds to meet our financial needs for the year of 2011, our business strategy in the future may require us to raise additional capital either through licensing, debt or equity sales. In the future, we may require additional funds for the continued development of our potential product candidates or to pursue the license of complementary technologies. There can be no assurance that adequate funds will be available when we need them or on favorable terms. If at any time we are unable to obtain sufficient additional funds, we will be required to delay, restrict or eliminate some or all of our research or development programs, dispose of assets or technology or cease operations.

We could, but presently have no plans to, enter into agreement with corporate partners in order to fund operations through milestone payments, license fees and equity investments.

Cash Flows

Net cash used in operating activities was \$5.1 million for the three months ended March 31, 2011 compared with \$0.2 million provided by operating activities in the three months ended March 31, 2010. Net cash used in operating activities in 2011 related primarily to a net loss of \$6.9 million from higher operating expenses, which included a \$5.1 million increase in research and development expenses and a \$1.7 million increase in selling, general and administrative expenses. Partially offsetting the higher operating expenses was a \$1.3 million increase in accounts payable and accrued expenses as of March 31, 2011.

Net cash provided by investing activities was \$16.5 million for the three months ended March 31, 2011 compared with \$6.6 million provided by investing activities for the three months ended March 31, 2010. Net cash provided by investing activities in 2011 and 2010 is a result of the sale of short-term investments.

Zero cash was used in or provided by financing activities for the three months ended March 31, 2011 compared with \$0.2 million used in financing activities for the three months ended March 31, 2010.

Contractual Obligations and Commitments

During the three months ended March 31, 2011, there were no material changes outside the ordinary course of our business to our contractual obligations and commitments disclosures as set forth in our Annual Report on Form 10-K for the year ended December 31, 2010, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations."

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, other than operating leases, that have or are reasonably likely to have a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that we believe is material to investors. In particular, we do not have any interest in entities referred to as variable interest entities, which include special purpose entities and structured finance entities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest excess cash in investment grade, interest-bearing securities and, at March 31, 2011, had approximately \$105 million invested in money market instruments, treasuries, municipal bonds, mutual funds and a certificate of deposit account. Such investments are subject to interest rate and credit risk and are not insured by the federal government. Our policy of investing in highly rated securities, whose liquidities are, at March 31, 2011, all less than two years minimizes such risks. In addition, while a hypothetical one percent per annum decrease in market interest rates would have reduced our interest income for the period, it would not have resulted in a loss of the principal and the decline in interest income would have been immaterial. Our purpose in making these investments is to generate investment income.

We currently do not transact any significant portion of our business in functional currencies other than the U.S. dollar. To the extent that we continue to transact our business using the U.S. dollar as our functional currency, we do not believe that the fluctuations in foreign currency exchange rates will have a material adverse effect on our results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of certain members of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, as of March 31, 2011, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Cacchillo vs. Insmmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the United States District Court for the Northern District of New York (Court) seeking money damages and a court order requiring Insmmed to support her compassionate use application to the FDA and if approved, to provide her with IPLEX. Plaintiff was a participant in the phase II clinical trial of IPLEX sponsored by us evaluating the effectiveness of the investigational drug in patients with type 1 myotonic muscular dystrophy (“MMD”). The data from this trial did not provide sufficient evidence that IPLEX was effective to treat MMD. As a result, we decided not to proceed to a phase III trial.

In the complaint, Plaintiff alleges (i) violation of constitutional due process and equal protection by depriving Plaintiff of continued access to IPLEX, (ii) fraudulent inducement to enter the phase II clinical trial with the false promise to support Plaintiff’s compassionate use application to the FDA, (iii) negligent representation that we would support Plaintiff’s compassionate use application, (iv) intentional infliction of emotional distress by refusing to support Plaintiff’s compassionate use application after providing IPLEX, (v) violation of an assumed duty of care to Plaintiff, (vi) breach of fiduciary duty to Plaintiff, (vii) negligence and (viii) unjust enrichment. Plaintiff seeks compensatory and punitive monetary damages and sought injunction relief as noted above.

On October 7, 2010, Plaintiff filed a motion for a preliminary injunction that would require us to provide a written statement supporting the “compassionate use” of IPLEX for Plaintiff and directing us to provide IPLEX to Plaintiff at cost in the event that the compassionate use application were granted by the FDA. On October 13, 2010, we filed an opposition to Plaintiff’s motion for the preliminary injunction and on October 15, 2010, an oral argument was held before the Court on the Plaintiff’s motion.

On October 22, 2010, the Court denied Plaintiff’s motion for the preliminary injunction concluding that the Court lacked subject matter jurisdiction with respect to her claim for a preliminary injunction. Plaintiff appealed the Court’s denial of her motion for a preliminary injunction to the United States Court of Appeals for the Second Circuit. The matter was argued before the Court of Appeals on March 15, 2011, and on March 23, 2011, the Court affirmed the trial court’s order denying the Plaintiff’s motion for a preliminary injunction.

Plaintiff’s claim for monetary damages remains outstanding. We believe that the allegations contained in the complaint are without merit and we intend to continue to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if any, that might result from an adverse resolution of this action.

Mackinson et al. v. Insmmed

On February 24, 2011, an action was filed against us, our subsidiary Transave, LLC, Transave, our directors and the former directors of Transave, captioned Mackinson et al. v. Insmmed Incorporated et al., C.A. No. 6216, as a purported class action seeking a quasi-appraisal remedy for alleged violations of Delaware’s appraisal statute and the fiduciary duty of disclosure in connection with the merger consummated pursuant to that certain Agreement and Plan of Merger, dated as of December 1, 2010, by and among Insmmed Incorporated, River Acquisition Co., Transave, LLC, Transave and TVM V Life Science Ventures GmbH & Co. KG, in its capacity as stockholders’ agent. We intend to vigorously defend this action. It is not possible at this time to estimate the amount of loss or range of possible loss, if

any, that might result from an adverse resolution of this action.

From time to time, we are a party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of our business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on our consolidated financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. Except for the historical information in this report, the matters contained in this report include forward-looking statements that involve risks and uncertainties. The factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors, among others, may have a material adverse effect upon our business, results of operations and financial condition.

You should consider carefully the risk factors, together with all of the other information included in our Annual Report on Form 10-K for the year ended December 31, 2010. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. (Removed and Reserved)

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

- 3.1 Articles of Incorporation of Insmmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
- 3.2 Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
- 3.3

Edgar Filing: INSMED INC - Form 10-Q

Form of Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, creating a new series of Preferred Stock designated as Series A Junior Participating Preferred Stock (previously filed as Exhibit A to the Rights Agreement, dated as of May 16, 2001, between Insmmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001 and incorporated herein by reference)

- 3.4 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2002 and incorporated herein by reference)
 - 3.5 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
 - 3.6 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for one for ten reverse stock split (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 2, 2011, and incorporated herein by reference)
 - 3.7 Amendment to Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.2 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference)
 - 10.1 Master Services Agreement, effective as of February 11, 2011, between Chiltern International Inc. and Insmmed Incorporated.
 - 31.1 Certification of Timothy Whitten, Chief Executive Officer of Insmmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
 - 31.2 Certification of Kevin P. Tully, Executive vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
 - 32.1 Certification of Timothy Whitten, Chief Executive Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.
 - 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.
-

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSMED INCORPORATED
(Registrant)

Date: May 10, 2011

By:/s/ Kevin P. Tully
Name: Kevin P. Tully, C.G.A.,
Title: Executive Vice President and
Chief Financial Officer (Principal
Financial Officer and Principal
Accounting Officer)

EXHIBIT INDEX

Exhibit No. Description of Exhibit

- 3.1 Articles of Incorporation of Insmmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
- 3.2 Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
- 3.3 Form of Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, creating a new series of Preferred Stock designated as Series A Junior Participating Preferred Stock (previously filed as Exhibit A to the Rights Agreement, dated as of May 16, 2001, between Insmmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001 and incorporated herein by reference)
- 3.4 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmmed Incorporated's Annual Report on Form 10-K for the year ended December 31, 2002 and incorporated herein by reference)
- 3.5 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
- 3.6 Articles of Amendment to Insmmed Incorporated's Articles of Incorporation, as amended, for one for ten reverse stock split (previously filed as Exhibit 3.1 to Insmmed Incorporated's Current Report on Form 8-K filed on March 2, 2011, and incorporated herein by reference)
- 3.7 Amendment to Amended and Restated Bylaws of Insmmed Incorporated (previously filed as Exhibit 3.2 to Insmmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference)
- 10.1 Master Services Agreement, effective as of February 11, 2011, between Chiltern International Inc. and Insmmed Incorporated.[*]
- 31.1 Certification of Timothy Whitten, Chief Executive Officer of Insmmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
- 31.2 Certification of Kevin P. Tully, Executive vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2003.
- 32.1 Certification of Timothy Whitten, Chief Executive Officer of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.**

- 32.2 Certification of Kevin P. Tully, Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) of Insmmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.**

* [Confidential treatment has been requested for certain portions of this exhibit. The confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission.

**] This certification accompanies this Quarterly Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2003 and shall not be deemed filed by the Company for purposes of the Securities Exchange Act of 1934.