INSMED INC
Form 10-Q
May 08, 2012

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2012

OR

o 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	54-1972729
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
9 Deer Park Drive, Suite C Monmouth Junction, NJ	08852
(Address of principal executive offices)	(Zip Code)

(732) 997-4600
(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 x No o

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 x No o

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

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

As of May 4, 2012, there were 24,874,852 shares of the registrant’s common stock, $.01 par value, outstanding.

INSMED INCORPORATED

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1	Financial Statements (unaudited)		
		Consolidated Balance Sheets at March 31, 2012 and December 31, 2011	3
		Consolidated Statements of Comprehensive Operations for the three month periods ended March 31, 2012 and March 31, 2011	4
		Consolidated Statements of Cash Flows for the three month periods ended March 31, 2012 and March 31, 2011	5
		Notes to Consolidated Financial Statements	6
ITEM 2		Management's Discussion and Analysis of Financial Condition and Results of Operations	16
ITEM 3		Quantitative and Qualitative Disclosures about Market Risk	22
ITEM 4		Controls and Procedures	22

PART II. OTHER INFORMATION

ITEM 1	Legal Proceedings	23
ITEM 1A	Risk Factors	24
ITEM 2	Unregistered Sales of Equity Securities and Use of Proceeds	24
ITEM 3	Defaults Upon Senior Securities	24
ITEM 4	Mine Safety Disclosures (Not Applicable)	24
ITEM 5	Other Information	24
ITEM 6	Exhibits	25
SIGNATURE		26
CERTIFICATIONS		28

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

Index

PART I
FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED
Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	March 31, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$22,043	$14,848
Short-term investments	48,739	61,424
Accounts receivable	-	757
Prepaid expenses and other current assets	178	370
Total current assets	70,960	77,399
Certificate of deposit	2,091	2,085
In-process research and development	58,200	58,200
Deposits	135	212
Fixed assets, net	1,867	1,937
Total assets	$133,253	$139,833
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,879	$2,334
Accrued expenses	193	800
Accrued compensation	510	795
Accrued lease expense, current	285	278
Deferred rent	154	156
Capital lease obligations, current	115	114
Total current liabilities	4,136	4,477
Accrued lease expense, long-term	852	923
Capital lease obligations, long-term	131	166
Total liabilities	5,119	5,566
Stockholders' equity:		
Common stock; $.01 par value; authorized shares 500,000,000; issued and outstanding shares, 24,874,852 in 2012 and 24,833,301 in 2011	249	248
Additional paid-in capital	428,237	427,743
Accumulated deficit	(301,018)	(294,174)
Accumulated other comprehensive income:		
Unrealized gain on investments	666	450
Total stockholders' equity	128,134	134,267
Total liabilities and stockholders' equity	$133,253	$139,833

See accompanying notes to audited consolidated financial statements

Index

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

	Three Months Ended March 31,	
	2012	2011
License fees	$-	$250
Other expanded access program income, net	-	1,351
Total revenues	-	1,601
Operating expenses:		
Research and development	4,487	5,760
General and administrative	2,777	3,256
Total operating expenses	7,264	9,016
Operating loss	(7,264)	(7,415)
Investment income	418	527
Interest expense	(2)	(4)
Gain on sale of asset, net	5	-
Loss before income taxes	(6,843)	(6,892)
Income tax expense	2	2
Net loss	(6,845)	(6,894)
Accretion of beneficial conversion charge	-	(9,175)
Net loss attributable to common stockholders	$(6,845)	$(16,069)
Basic and diluted net loss attributable to common stockholders per common share	$(0.28)	$(0.85)
Comprehensive loss	$(6,629)	$(7,073)
Weighted average basic and diluted common shares outstanding	24,860	18,814

See accompanying notes to audited consolidated financial statements

Index

INSMED INCORPORATED
Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2012	2011
Operating activities		
Net loss	$(6,845)	$(6,894)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	136	75
Stock based compensation expense	495	167
Gain on sale of asset, net	(5)	-
Changes in operating assets and liabilities:		
Accounts receivable	757	302
Prepaid expenses and other assets	263	108
Accounts payable	545	1,632
Accrued expenses	(609)	(46)
Accrued lease expenses	(64)	-
Accrued compensation	(285)	(295)
Deferred revenue	-	(158)
Net cash used in operating activities	(5,612)	(5,109)
Investing activities		
Purchase of fixed assets	(66)	(14)
Sales of short-term investments	12,907	16,588
Purchases of short-term investments	-	(87)
Net cash provided by investing activities	12,841	16,487
Financing activities		
Payments on capital lease obligations	(34)	(21)
Net cash used in financing activities	(34)	(21)
Increase in cash and cash equivalents	7,195	11,357
Cash and cash equivalents at beginning of period	14,848	10,743
Cash and cash equivalents at end of period	$22,043	$22,100
Supplemental disclosures of cash flow information		
Cash paid for interest	$2	$-
Cash paid for taxes, net	$2	$-
Supplemental disclosures of non-cash investing and financing activities		
Unrealized gain (loss) on investments	$216	$(179)
Accretion of beneficial conversion charge	$-	$(9,175)

See accompanying notes to audited consolidated financial statements

Index

INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business and Background

Insmed® Incorporated is a development-stage biopharmaceutical company with expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We develop innovative inhaled treatments for serious lung infections. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung, and we believe it 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 on orphan markets with high unmet medical needs, which we believe presents 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 aeruginosa (which we refer to as Pseudomonas) lung infections in cystic fibrosis (CF) patients and patients with non-tuberculous mycobacteria (NTM) lung infections.

On December 1, 2010, we completed a business combination, which we refer to as the merger, with Transave, Inc., or Transave, a privately-held, NJ-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our integration with Transave was completed in 2011, including the relocation of our corporate headquarters to Monmouth Junction, New Jersey, and cessation of operations at Richmond, Virginia, location as of December 31, 2011. On March 2, 2011, we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this 10-Q give retroactive effect to the reverse stock split for all periods presented.

After giving effect to the merger, former Transave stockholders had approximately a 46.7% equity interest in the combined Company (on an as-converted, fully diluted basis), and legacy Insmed Incorporated shareholders had a 53.3% equity interest. The shares retained by us pursuant to the merger agreement with Transave (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Conditional Convertible Preferred Stock, or Series B Preferred Stock, and the one-for-ten reverse stock split of our common stock) will be delivered on June 1, 2012 to certain former Transave stockholders, subject to reduction for any claims and indemnification payments that are pending in accordance with the terms of the merger agreement.

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 (GAAP) 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The consolidated balance sheet at December 31, 2011 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by GAAP 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, 2011 filed with the Securities and Exchange Commission on March 13, 2012.

Index

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Transave, LLC, Insmed Therapeutic Proteins, Insmed 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 GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of revenue and expenses reported for each periods presented are effected by estimates and assumptions, which are used for, but not limited to, the accounting for revenue recognition, stock-based compensation, income taxes, loss contingencies and accounting for research and development costs. Actual results could differ from those estimates.

Identified Intangible Assets

As part of the merger, we recorded in-process research and development identified intangible assets. Identifiable intangible assets are measured at their respective fair values as of the acquisition date and are not amortized until commercialization. Once commercialization occurs, these intangible assets will be amortized over their estimated useful lives. While we believe the fair values assigned to our acquired intangible assets are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition date, unanticipated events or circumstances may occur that require us to review the assets for impairment. Events or circumstances that may require an impairment assessment include negative clinical trial results, the non-approval of a new drug application (NDA) by the U.S. Food and Drug Administration, or the FDA, material delays in our development program or a sustained decline in market capitalization.

Indefinite-lived intangible assets are not subject to periodic amortization. Rather, indefinite-lived intangibles are reviewed for impairment by applying a fair value based test on an annual basis or more frequently if events or circumstances indicate impairment may have occurred. Events or circumstances that may require an interim impairment assessment are consistent with those described above. The Company has elected to perform its annual impairment test as of October 1 of each year.

Revenue Recognition and Collaboration Agreements

Historically, revenue from our Expanded Access Program in Italy is recognized when the drugs have been provided to program patients and collectability is assured. Revenue from collaborations is recognized as license fees when milestones are achieved and payments are due. The Company analyzes each element of an agreement to determine if it shall be accounted for as a separate element or single unit of accounting. If an element shall be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for that element are applied to determine when revenue shall be recognized. If an element shall not be treated separately for revenue recognition purposes, the revenue recognition principles most appropriate for the bundled group of elements are applied to determine when revenue shall be recognized. Payments received in excess of revenues recognized are recorded as deferred revenue until such time as the revenue recognition criteria have been met. We no longer manufacture IPLEX and the cost recovery revenues from our IPLEX EAP in Europe ceased in December 2011, when our IPLEX inventory was fully depleted.

Index

Research and Development

Research and development costs are expensed as incurred except for purchased in-process research and development (see Identified Intangible Assets policy above and Note 4). 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 primarily depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol.

Stock-Based Compensation

Stock-based compensation transactions are accounted for using a fair-value-based method to recognize non-cash compensation expense; this expense is recognized ratably over the requisite service period, which generally equals the vesting period of options, and is adjusted for expected forfeitures.

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 and the fair value of the common stock at the commitment date. The BCC is recorded as a non-cash charge to earnings. 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 weighted average number of common shares used to compute basic net loss per common share equaled the same number of shares used to compute diluted net loss per common share for the three months ended March 31, 2012 and 2011.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding as of March 31, 2012 and 2011, as they would be anti-dilutive (in thousands):

	Three Months Ended March 31,	
	2012	2011
Shares underlying warrants to purchase outstanding common stock	158	158
Shares underlying options to purchase outstanding common stock	845	392
Shares underlying restricted stock units	494	445

Accumulated Other Comprehensive Income

Accumulated 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, 2012 consists of the

following (in thousands):

Index

		Unrealized gain (loss) on short-term investments
Beginning Balance at December 31, 2011	$	450
Current-period other comprehensive income		216
Ending Balance at March 31, 2012	$	666

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. The new guidance limits the highest-and-best-use measure to nonfinancial assets, permits certain financial assets and liabilities with offsetting positions in market or counterparty credit risks to be measured at a net basis, and provides guidance on the applicability of premiums and discounts. Additionally, the new guidance expands the disclosures on Level 3 inputs by requiring quantitative disclosure of the unobservable inputs and assumptions, as well as description of the valuation processes and the sensitivity of the fair value to changes in unobservable inputs. We adopted ASU 2011-04 effective January 1, 2012 and it did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, Presentation of Comprehensive Income, which requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of equity. In December 2011, the FASB issued ASU 2011-12, Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU 2011-05. ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income. All other requirements of ASU 2011-05 are not affected by ASU 2011-12. ASU 2011-05 and 2011-12 are effective for years beginning after December 15, 2011. We adopted ASU 2011-05 and ASU 2011-12 effective January 1, 2012 and it did not have a material impact on our consolidated financial statements.

In September 2011, the FASB issued ASU 2011-08, Intangibles — Goodwill and Other, which amends current guidance to allow a company to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. The amendment also revises previous guidance by expanding upon the examples of events and circumstances that an entity should consider between annual impairment tests in determining whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We adopted ASU 2011-08 effective January 1, 2012 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, 2012, the Company has incurred recurring operating losses and has accumulated a deficit of $301.0 million. During the three months ended March 31, 2012, the Company recognized a net loss of $6.8 million. Our net cash used in operations for the three months ended March 31, 2012 was $5.6 million.

Index

Even though we believe we currently have sufficient funds to meet our financial needs for fiscal year of 2012, 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. Identified Intangible Assets

In the third quarter of 2011, the FDA placed a clinical hold on our phase 3 U.S. clinical trials for ARIKACE in CF patients with Pseudomonas lung infections and for patients with NTM lung infections.

In January 2012, the FDA lifted the clinical hold on ARIKACE in patients with NTM lung infections. In February 2012, we announced that we would be initiating the ARIKACE NTM trial as a phase 2 trial, as well as the previously planned phase 3 trial for ARIKACE in the CF indication in Europe. In April 2012, the Company announced the first patient dosed in the European phase 3 clinical study which is called Clinical Evaluation of ARikace™ (CLEAR – 108). The Company also intends to conduct CLEAR - 108 in Canada. We expect to begin enrolling patients in the phase 2 clinical trial for NTM in mid-2012 and we also initiated a nine-month dog inhalation toxicity study in April of 2012.

In May 2012, The FDA lifted the clinical hold on ARIKACE in U.S. for the treatment of CF patients with Pseudomonas lung infections.

As a result of these events, the Company believes there are no indicators of impairment of in-process research and development intangible assets as of March 31, 2012.

5. Stockholders' Equity

Common and Preferred Stock

On December 1, 2010, we entered into the Agreement and Plan of Merger, or the merger agreement, with Transave. Under the terms of the merger agreement, the Transave stockholders received an aggregate of 2.6 million newly issued shares of the common stock of the Company and 9.2 million shares of newly created Series B Preferred Stock of the Company. They also received an aggregate of approximately $0.6 million in cash. Collectively, the shares of the Company's common stock and the Company's Series B 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 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 those proposals.

As a result of the approval of the conversion of the Series B Preferred Stock, the 91.7 million shares of the Series B Preferred Stock outstanding (on a pre-reverse stock-split basis) were automatically and immediately converted into 91.7 million shares of our common stock. In addition, we filed Articles of Amendment to our Articles of Incorporation, as amended, to affect 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 ten 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. The following table summarizes the conversion of the preferred shares and the reverse stock split.

Index

Common stock shares outstanding February 28, 2011	156,537
Preferred series B stock converted into common stock on March 1, 2011	91,746
Total shares outstanding prior to reverse stock split	248,283
1 for 10 reverse stock split	1:10
Approximate number of common shares outstanding March 2, 2011	24,828

As a result of the conversion of the Series B 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 Series B Preferred Stock of $7.10 per share and its carrying value of $6.10 per share. The carrying value of the Series B 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.

6. Stock Based Compensation

Stock Warrants

There was no stock warrant activity for the three months ended March 31, 2012. As of March 31, 2012, we had 0.2 million warrants outstanding with a weighted average price of $11 and an expiration date of May 2012.

Stock Options

As of March 31, 2012, 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 30, 2015, when the 2000 Plan was amended in May 2005 after approved by our shareholders. As of March 31, 2012, the 2000 Plan provides for the issuance of a maximum of 3.9 million shares of common stock. 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. The 2000 ESPP which, following the appropriate shareholder approval was subsequently amended in 2005 and 2006, provides for the issuance of a maximum of 150,000 shares of our common stock to participating employees. The Company did not offer employees the right purchase Common Stock under the ESPP during the first quarter of 2012.

The following table summarizes stock option activity for the three months ended March 31, 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value

Options outstanding at December 31, 2011	891,751	$5.15		
Granted	3,000	4.05		
Exercised	-	-		
Forfeited	(17,190)	3.03		
Cancelled	(33,000)	19.01		
Options outstanding at March 31, 2012	844,561	4.64	8.44	$330,246
Vested and expected to vest at March 31, 2012	781,684	4.75	8.36	$297,884
Exercisable at March 31, 2012	142,351	9.61	3.61	$-

Index

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, 2012.

Volatility	104.6	%
Risk-free interest rate	1.0	%
Dividend yield	0.0	%
Expected option term (in years)	6.25	

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 $0.15 million and $0.04 million for the three months ended March 31, 2012 and 2011, respectively. General and administrative expenses include $0.10 million and $0.03 million and research and development expenses include $0.05 million and $0.01 million of stock-based compensation expense in the consolidated statement of operations for the three months ended March 31, 2012 and 2011, respectively. As of March 31, 2012, there was $1.98 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.54 years.

Restricted Stock and Restricted Stock Units

In May 2008, under the 2000 Plan, we began granting Restricted Stock ("RS") and Restricted Stock Units ("RSUs") 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 RSUs are valued based on the market price on the date of settlement. We recognize noncash compensation expense for the fair values of these RS and RSUs on a straight-line basis over the requisite service period of these awards, which is generally three years.

No RS was issued during the three months ended March 31, 2012. A summary of RSU activity for the three months ended March 31, 2012 is as follows:

	Number of RSU's	Weighted Average Grant Price
Outstanding at December 31, 2011	487,025	$6.37
Granted	56,684	3.44
Released	(43,819)	5.98
Forfeited	(5,730)	6.16
Outstanding at March 31, 2012	494,160	$6.07
Expected to Vest	458,873	$6.05

The Company recognized stock-based compensation expense related to RSU's of approximately $0.3 million and $0.1 million for the three months ended March 31, 2012 and 2011, respectively. General and administrative expenses include $0.3 million and $0.1 million and research and development expenses include less than $0.1 million and $0.1 million of stock-based compensation expense in the consolidated statement of operations for the three months ended March 31, 2012 and 2011, respectively. As of March 31, 2012, there was $2.6 million of unrecognized compensation expense related to unvested RSU's, which is expected to be recognized over a weighted average period of 1.77 years.

A total of approximately 2.1 million shares of common stock were reserved for issuance at March 31, 2012 in connection with restricted stock, stock options, stock warrants, and the employee stock purchase plan.

7. 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.

The following table presents assets and liabilities measured at fair value as of March 31, 2012 and December 31, 2011.

		Fair Value Measurements at Reporting Date Using		
	Total	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)
As of March 31, 2012:				
Assets:				
Cash and cash equivalents	$22,043	$ 22,043	$ -	$ -
Mutual funds	48,739	48,739	-	-
Certificate of deposit	2,091	2,091	-	-

	$72,873	$ 72,873	$ -	$ -
As of December 31, 2011:				
Assets:				
Cash and cash equivalents	$14,848	$ 14,848	$ -	$ -
Mutual funds	56,163	56,163	-	-
Government agency bonds	5,261	-	5,261	-
Certificate of deposit	2,085	2,085	-	-
	$78,357	$ 73,096	$ 5,261	$ -

Index

The Company's cash and cash equivalents permit daily redemption and the fair values of these investments are based upon the quoted prices in active markets provided by the holding financial institutions. Short-term investments such as U.S. treasury securities, mutual funds and government agency bonds are held to their maturities and are carried at cost, which approximates fair value. The cash equivalents consist of liquid investments with a maturity of three months or less and the short-term investments consist of instruments with maturities greater than three months and less than one year. The certificate of deposit matures in July, 2013.

The Company's in-process research and development asset was fair valued at the date of the merger using the income approach. This approach calculates fair value by estimating future cash flows attributable to the assets and then discounting these cash flows to a present value using a risk-adjusted discount rate. This approach requires significant management judgment with respect to future volume, revenue and expense growth rates, changes in working capital use, appropriate discount rates and other assumptions and estimates. The estimates and assumptions used were consistent with our business plans at the date of the merger.

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, 2012 and 2011.

As of March 31, 2012, we held one security which was in an unrealized loss position with a total estimated fair value of $5.5 million and gross unrealized losses of approximately $0.1 million. We also recorded $0.7 million of gross unrealized gains. The net unrealized gain of $0.7 million is reported in accumulated other comprehensive income in the stockholder's equity section of our balance sheet. This security had not been in a continuous unrealized loss position for greater than one year. The following table summarizes unrealized gains and losses for the three months ended March 31, 2012.

	March 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Mutual funds	$48,073	$735	$(69)	$48,739

As of March 31, 2011, we held five securities which were in an unrealized loss position with a total estimated fair value of $8.2 million and gross unrealized losses of approximately $0.1 million. We also recorded $0.9 million of gross unrealized gains. 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 five securities, none had been in a continuous unrealized loss position for greater than one year. The following table summarizes unrealized gains and losses for the three months ended March 31, 2011.

Index

	March 31, 2011			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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

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.

8. Commitments and Contingencies

Commitments

In January 2012, we signed a contract with our drug supply manufacturer for drug required for our dog toxicology study at a total cost of $1.4 million.

Legal Proceedings

Cacchillo v. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo (“Plaintiff”) in the U.S. District Court for the Northern District of New York (the “Court”), captioned Cacchillo v. Insmed, Inc., No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmed 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”). In the complaint, Plaintiff alleged (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) breach of contract, seeking monetary and non-monetary damages, (v) intentional infliction of emotional distress by refusing to support Plaintiff’s compassionate use application after providing IPLEX, (vi) violation of an assumed duty of care to Plaintiff, (vii) breach of fiduciary duty to Plaintiff, (viii) negligence and (ix) 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 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 U.S. Court of Appeals for the Second Circuit, which affirmed the trial court’s order denying the Plaintiff’s motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff's claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff's claim for monetary damages with respect to these claims remains outstanding. The parties are engaged in discovery. Trial is currently scheduled to begin in January 2013.

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.

Index

Pilkiewicz v. Transave LLC

On March 28, 2011, Frank G. Pilkiewicz and other former stockholders of Transave (collectively, the "Petitioners") filed an appraisal action against our subsidiary Transave, LLC in the Delaware Court of Chancery captioned Frank G. Pilkiewicz, et al. v. Transave, LLC, C.A. No. 6319-CS. On December 13, 2011, following the mailing of the revised notice of appraisal rights in accordance with the settlement terms of Mackinson et al. v. Insmed, an Amended Petition for Appraisal of Stock was filed by the Petitioners.

The Petitioners seek appraisal under Delaware law of their total combined common stock holdings of approximately 7.77 million shares of Transave, Inc. common stock (the "Transave Stock"). The Petitioners are challenging the value of the consideration that they would be entitled to receive for their Transave Stock under the terms of the merger.

Under the terms of the merger agreement, certain of the former stockholders of Transave are obligated to indemnify us for certain liabilities in connection with the appraisal action. We believe that the allegations contained in the amended petition 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.

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.

9. Subsequent Events

In May 2012, the FDA lifted the clinical hold on ARIKACE in the U.S. for the treatment of CF patients with Pseudomonas lung infections.

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

Cautionary Note Regarding 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," and 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 ability to develop ARIKACE; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the timing of responses to information and data requests from the U.S. Food and Drug Administration (the "FDA"); our clinical development of product candidates; our ability to obtain and maintain regulatory approval for our product candidates; our expectation as to the timing of regulatory review and approval; 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.

Index

Forward-looking statements are based upon our current expectations and beliefs. 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", Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011, as well as those discussed elsewhere in this report and in any other documents incorporated by reference. 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, 2011.

OVERVIEW

Insmed® Incorporated is a development-stage biopharmaceutical company with expertise in proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We develop innovative inhaled treatments for serious lung infections. Our proprietary liposomal technology is designed specifically for delivery of pharmaceuticals to the lung, and we believe it 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 on orphan markets with high unmet medical needs, which we believe presents 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 aeruginosa (which we refer to as Pseudomonas) lung infections in cystic fibrosis (CF) patients and patients with non-tuberculous mycrobacteria (NTM) lung infections.

On December 1, 2010, we completed a business combination, which we refer to as the merger, with Transave, Inc., or Transave, a privately-held, NJ-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our integration with Transave was completed in 2011, including the relocation of our corporate headquarters to Monmouth Junction, New Jersey, and cessation of operations at Richmond, Virginia, location as of December 31, 2011. On March 2, 2011, we completed a one-for-ten reverse stock split of our common stock. Unless otherwise noted, the per share amounts in this 10-Q give retroactive effect to the reverse stock split for all periods presented.

Immediately after giving effect to the merger, former Transave stockholders had approximately a 46.7% equity interest in the combined Company (on an as-converted, fully diluted basis), and legacy Insmed shareholders had a 53.3% equity interest. The shares retained by us pursuant to the merger agreement with Transave (approximately 1.76 million shares of common stock after giving effect to the conversion of the Series B Conditional Convertible Preferred Stock, or Series B Preferred Stock and the one-for-ten reverse stock split of our common stock) will be delivered on June 1, 2012 to certain former Transave stockholders, subject to reduction for any claims and indemnification payments that are pending.

Recent Developments

In August 2011 we announced that the FDA placed a clinical hold on our phase 3 U.S. clinical trials for ARIKACE in CF patients and NTM patients due to the results of a long-term rat carcinogenicity study. As part of the study, rats were given ARIKACE daily by inhalation for almost two years. Two of the 120 rats receiving the highest dose had a single lung tumor. The relevance of the observed rat tumors to the use of ARIKACE in humans is unknown.

Index

In January 2012, following the filing of a response to requests for information from the FDA, the agency lifted the clinical hold of ARIKACE in the NTM indication noting that the company could initiate a phase 2 clinical trial for patients with NTM under an agreed protocol.

In February 2012, we announced that we would be initiating the ARIKACE NTM trial as a phase 2 trial in the U.S., We are also proceeding with the previously planned phase 3 trial for ARIKACE in the CF indication in Europe and in Canada (CLEAR - 108). In April of 2012, we began enrolling patients in CLEAR- 108 and initiated the nine-month dog inhalation toxicity study. The CLEAR -108 study in CF patients with Pseudomonas lung infections is a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System (PARI Pharma GmbH), to TOBI®(1) (inhaled tobramycin solution), which is a commercially available inhaled antibiotic that is delivered twice daily via a PARI LC® Plus nebulizer. We anticipate that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by Insmed and the European Medicines Agency and Health Canada. Eligible patients will have the option to participate in a longer term open-label safety study.

In May 2012, the FDA lifted the clinical hold on ARIKACE in the U.S. for the treatment of CF patients with Pseudomonas lung infections. We reached agreement with the FDA on a revised CF clinical trial population consisting of adult patients who have chronic Pseudomonas lung infections and FEV-1 % predicted between 25% and 75%. We are continuing discussions with the FDA to finalize additional details of the phase 3 study protocol for a potential clinical trial for CF patients. At the same time, we are evaluating possible next steps for the ARIKACE U.S. CF clinical program in light of ongoing CLEAR - 108 and U.S. NTM clinical programs described above and anticipated resource requirements.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenues

Our revenue in 2011 consisted of secondary revenue streams for IPLEX® 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 manufacture IPLEX and the cost recovery revenues from our IPLEX EAP in Europe ceased in December 2011, when our IPLEX inventory was fully 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 primarily depend mainly on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. 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 to Merck & Co., Inc., or Merck, 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 merger, our focus is now principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. Our initial priority was to conduct phase 3 studies for ARIKACE® in treating CF patients with Pseudomonas lung infections and patients with NTM lung infections.

Index

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 ARIKACE in the CF and NTM indications to represent our main development effort for the remainder of 2012 and the foreseeable future.

Our clinical trials with our product candidates are subject to numerous risks and uncertainties that are outside of our control, including that necessary regulatory approvals may not be obtained. In addition, 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 proposed 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, reimbursement 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, if at all.

General and Administrative Expenses

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 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 general and administrative expenses will increase with the continued development and commercialization of our product candidates.

Index

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 capital leases.

RESULTS OF OPERATIONS

Three months ended March 31, 2012 compared to three months ended March 31, 2011

Net loss attributable to common stockholders for the three months ended March 31, 2012 was $6.8 million, (or $0.28 per common share – basic and diluted), compared to net loss of $16.1 million, (or $0.85 per common share – basic and diluted), for the three months ended March 31, 2011. The $9.3 million reduction in the net loss quarter on quarter was primarily due to the $9.2 million non-cash charge for the beneficial conversion feature of the Series B Preferred Stock incurred in the first quarter of 2011, which increased net loss attributable to holders of our common shares and, in turn, reduced our loss 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 Series B Preferred Stock of $7.10 per share and its carrying value of $6.10 per share. The carrying value of the Series B 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, 2012 were zero, as compared to $1.6 million for the three months ended March 31, 2011. The $1.6 million decrease was due to a combination of the elimination of IPLEX EAP revenues following the depletion of IPLEX inventory in December 2011 and the receipt of $0.25 million in license fees for our CISPLATIN lipid complex in Q1 2011, as compared to zero in the current quarter.

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2012 and 2011 were comprised of the following:

	Three Months Ended March 31,		Increase (Decrease)	
	2012	2011	$	%
	(in thousands)			
Clinical development	$2,525	$2,937	$(412)	-14%
Clinical manufacturing	313	1,076	(763)	-71%
Regulatory and quality assurance	93	178	(85)	-48%
Compensation and related	1,556	1,569	(13)	-1%
	$4,487	$5,760	$(1,273)	-22%

Research and development expenses decreased to $4.5 million in the three months ended March 31, 2012 from $5.8 million for the three months ended March 31, 2011. The decrease of $1.3 million in 2012 is attributable primarily to the lower development and manufacturing costs associated with initiating two clinical trials at present as compared to the same period in 2011, when three trials were being planned. The Company is currently in the process of initiating two clinical trials consisting of a European phase 3 CF trial and a U.S. phase 2 NTM trial. In May 2012, the FDA lifted the clinical hold on the U.S. phase 3 CF trial. We are continuing discussions with the FDA to finalize additional

details of the phase 3 study protocol for a potential clinical trial for CF patients and we are evaluating possible next steps for the ARIKACE U.S. CF clinical program.

Index

General and Administrative Expenses

General and administrative expenses decreased to $2.8 million in the three months ended March 31, 2012 from $3.3 million for the three months ended March 31, 2011. The $0.5 million decrease was due largely to lower finance, legal and consulting fees related to post Transave merger matters and the reverse stock split transaction on March 2, 2011.

Investment Income and Interest Expense

Investment income decreased by $0.1 million to $0.4 million in the three months ended March 31, 2012 from $0.5 million in the three months ended March 31, 2011. The decrease is a result of the reduction on our cash and short-term investments totaling $32.0 million from March 31, 2011 to March 31, 2012.

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. 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. We will continue to incur losses to the extent we expand our research and development and we do not expect material revenues for at least the next several years. Furthermore, revenues from our EAP in Italy associated with cost recovery were eliminated by the end of the fourth quarter of 2011, when our current IPLEX inventory, which had been fully expensed, was depleted. As of March 31, 2012, we had total cash, cash equivalents, short-term investments, and certificate of deposits on hand of $72.9 million, consisting of $70.8 million in cash and short-term investments and $2.1 million in a certificate of deposit, as compared to $78.4 million of cash on hand as of December 31, 2011. The $5.5 million decrease in total cash was due primarily to the funding of operations which consists mainly of research and development activities.

Even though we believe we currently have sufficient funds to meet our financial needs for fiscal year 2012, 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.

Cash Flows

Net cash used in operations for the three months ended March 31, 2012 was $5.6 million. This was comprised of the net loss for the three months ended March 31, 2012 of $6.8 million, reduced by depreciation and non-cash stock expense totaling $0.6 million and the change in other operating assets and liabilities of $0.6 million, which primarily consisted of the change in accounts payable and accrued expenses. Net cash used in operations for the three months ended March 31, 2011 was $5.1 million due to the net loss for the three months ended March 31, 2011 of $6.9 million, reduced by depreciation and stock compensation expense of $0.2 million and a $1.5 million change in operating assets

and liabilities.

Index

Net cash provided by investing activities was $12.8 million for the three months ended March 31, 2012 compared with $16.5 million provided by investing activities for the three months ended March 31, 2011. Net cash provided by investing activities in 2012 and 2011 is primarily a result of the sale of short-term marketable security investments.

Zero cash was used in or provided by financing activities for the three months ended March 31, 2012 and 2011.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

During the three months ended March 31, 2012, 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, 2011, “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, 2012, had approximately $72.9 million invested in money market instruments, 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, 2012, 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, 2012, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level. There were no significant changes during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect our disclosure controls or procedures.

Index

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Cacchillo v. Insmed

On October 6, 2010, a complaint was filed against us by Angeline Cacchillo ("Plaintiff") in the U.S. District Court for the Northern District of New York (the "Court"), captioned Cacchillo v. Insmed, Inc., No. 1:10-cv-0199, seeking monetary damages and a court order requiring Insmed 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"). In the complaint, Plaintiff alleged (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) breach of contract, seeking monetary and non-monetary damages, (v) intentional infliction of emotional distress by refusing to support Plaintiff's compassionate use application after providing IPLEX, (vi) violation of an assumed duty of care to Plaintiff, (vii) breach of fiduciary duty to Plaintiff, (viii) negligence and (ix) 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 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 U.S. Court of Appeals for the Second Circuit, which affirmed the trial court's order denying the Plaintiff's motion for a preliminary injunction.

We filed a motion with the Court to dismiss all of the outstanding claims, and on June 29, 2011, the Court dismissed six of Plaintiff's claims, leaving outstanding the claims for (i) fraudulent inducement, (ii) negligent misrepresentation, and (iii) breach of contract. We filed an answer and affirmative defenses with the Court on July 12, 2011. Plaintiff's claim for monetary damages with respect to these claims remains outstanding. The parties are engaged in discovery. Trial is currently scheduled to begin in January 2013.

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.

Pilkiewicz v. Transave LLC

On March 28, 2011, Frank G. Pilkiewicz and other former stockholders of Transave (collectively, the "Petitioners") filed an appraisal action against our subsidiary Transave, LLC in the Delaware Court of Chancery captioned Frank G. Pilkiewicz, et al. v. Transave, LLC, C.A. No. 6319-CS. On December 13, 2011, following the mailing of the revised notice of appraisal rights in accordance with the settlement terms of Mackinson et al. v. Insmed, an Amended Petition for Appraisal of Stock was filed by the Petitioners.

The Petitioners seek appraisal under Delaware law of their total combined common stock holdings of approximately 7.77 million shares of Transave, Inc. common stock (the "Transave Stock"). The Petitioners are challenging the value of

the consideration that they would be entitled to receive for their Transave Stock under the terms of the merger.

Index

Under the terms of the merger agreement, certain of the former stockholders of Transave are obligated to indemnify us for certain liabilities in connection with the appraisal action. We believe that the allegations contained in the amended petition 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.

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.

ITEMRISK FACTORS
1A.

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, 2011. 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. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

As previously disclosed in our Current Report on Form 8-K filed with the Securities Exchange Commission on March 9, 2012, our board of directors (the “Board”) adopted the Amended and Restated Bylaws (the “Amended and Restated Bylaws”) on March 6, 2009. The Amended and Restated Bylaws amended and restated our prior bylaws in their entirety, and became effective upon the approval by the Board. The primary changes relate to the procedures required to be followed by a shareholder who wishes to propose business or make nominations for the election of directors at a meeting of our shareholders. The Amended and Restated Bylaws were also revised to provide clarifying language as it relates to shareholder proposals and nominations and contain enhanced shareholder disclosure requirements.

For more detailed description of the material changes in our Amended and Restated Bylaws, please refer to our Current Report on Form 8-K filed on March 9, 2012. The foregoing description of the Amended and Restated Bylaws

is qualified in its entirety by reference to the full text of the Amended and Restated Bylaws filed as Exhibit 3.1 to the Current Report on Form 8-K.

Index

ITEM	EXHIBITS
6.	
3.1	Articles of Incorporation of Insmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
3.2	Amended and Restated Bylaws of Insmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmed 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 Insmed 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 Insmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001 and incorporated herein by reference).
3.4	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmed 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 Insmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously field as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
3.6	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for one for ten reverse stock split (previously filed as Exhibit 3.1 to Insmed 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 Insmed Incorporated (previously filed as Exhibit 3.2 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
3.8	Amended and Restated Bylaws of Insmed Incorporated (previously filed as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 9, 2012, and incorporated herein by reference).
31.1	Certification of Timothy Whitten, Chief Executive Officer of Insmed 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 Insmed 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 Insmed 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 Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.

Index

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 8, 2012	By:	/s/ Kevin P. Tully Name: Kevin P. Tully, C.G.A., Title: Executive Vice President and Chief Financial Office (Principal Financial Officer and Principal Accounting Officer)

Index

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
3.1	Articles of Incorporation of Insmed Incorporated, as amended (previously filed as Annex H to the Joint Proxy Statement/Prospectus contained in Part I of Insmed Incorporated's Registration Statement on Form S-4 (Registration No. 333-30098) and incorporated herein by reference).
3.2	Amended and Restated Bylaws of Insmed Incorporated (previously filed as Annex I to the Joint Proxy Statement/Prospectus contained in Part I of Insmed 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 Insmed 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 Insmed Incorporated and First Union National Bank, as Rights Agent, filed as Exhibit 4.4 to Insmed Incorporated's Registration Statement on Form 8-A filed on May, 17, 2001 and incorporated herein by reference).
3.4	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for Reverse Split (previously filed as Exhibit 3.4 to Insmed 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 Insmed Incorporated's Articles of Incorporation, as amended, to create a new series of Preferred Stock designated as Series B Conditional Convertible Preferred Stock (previously field as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
3.6	Articles of Amendment to Insmed Incorporated's Articles of Incorporation, as amended, for one-for-ten reverse stock split (previously filed as Exhibit 3.1 to Insmed 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 Insmed Incorporated (previously filed as Exhibit 3.2 to Insmed Incorporated's Current Report on Form 8-K filed on December 2, 2010, and incorporated herein by reference).
3.8	Amended and Restated Bylaws of Insmed Incorporated (previously filed as Exhibit 3.1 to Insmed Incorporated's Current Report on Form 8-K filed on March 9, 2012, and incorporated herein by reference).
31.1	Certification of Timothy Whitten, Chief Executive Officer of Insmed 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 Insmed 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 Insmed 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 Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2003.*
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.