INSMED INC
Form 10-Q
May 07, 2013
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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, 2013

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 April 30, 2013, there were 31,795,357 shares of the registrant s common stock, $0.01 par value, outstanding.

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INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2013

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In this Form 10-Q, we use the words Insmed Incorporated to refer to Insmed Incorporated, a Virginia corporation, and we use the words Company, Insmed, Insmed Incorporated, we, us and our to refer to Insmed Incorporated and its consolidated subsidiaries. ARIKACE is a registered trademark and Insmed is a trademark of Insmed Incorporated. This Form 10-Q also contains trademarks of third parties. Each trademark of another company appearing in this Form 10-Q is the property of its owner.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except par value, share and per share data)

	March 31, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 79,434	$ 90,782
Certificate of deposit	2,173	2,153
Prepaid expenses and other current assets	1,418	643
Total current assets	83,025	93,578
In-process research and development	58,200	58,200
Other assets	110	117
Fixed assets, net	1,681	1,666
Total assets	$ 143,016	$ 153,561
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 8,184	$ 7,060
Accrued expenses	5,329	2,933
Accrued compensation	1,359	2,207
Accrued lease expense, current	298	295
Deferred rent	144	149
Capital lease obligations, current	83	96
Current portion of long term debt	4,875	3,007
Total current liabilities	20,272	15,747
Accrued lease expense, long-term	580	647
Capital lease obligations, long-term	48	64
Debt, long-term	14,511	16,221
Total liabilities	35,411	32,679
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 31,571,926 and 31,488,204 issued and outstanding shares at March 31, 2013 and December 31, 2012, respectively	316	315
Additional paid-in capital	455,725	455,325
Warrant to purchase 329,932 shares of common stock for $2.94 per share at March 31, 2013 and December 31, 2012	790	790
Accumulated deficit	(349,226)	(335,548)
Total shareholders equity	107,605	120,882

Total liabilities and shareholders equity	$ 143,016	$ 153,561

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,	
	2013	**2012**
Revenues	$	$
Operating expenses:		
Research and development	10,334	4,739
General and administrative	3,975	2,525
Total operating expenses	14,309	7,264
Operating loss	(14,309)	(7,264)
Investment income	51	418
Interest expense	(643)	(2)
Gain on sale of assets, net	2	5
Loss before income taxes	(14,899)	(6,843)
Provision (benefit) for income taxes	(1,221)	2
Net loss	$ (13,678)	$ (6,845)
Basic and diluted net loss per share	$ (0.43)	$ (0.28)
Weighted average basic and diluted common shares outstanding	31,554	24,860
Net loss	$ (13,678)	$ (6,845)
Comprehensive loss:		
Unrealized gains on investments, net of taxes		216
Comprehensive loss	$ (13,678)	$ (6,629)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2013	**2012**
Operating activities		
Net loss	$ (13,678)	$ (6,845)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	148	136
Stock based compensation expense	954	495
Gain on sale of assets, net	(2)	(5)
Amortization of debt discount and debt issuance costs	118	
Accrual of the end of term charge on the debt	49	
Changes in operating assets and liabilities:		
Accounts receivable		757
Prepaid expenses and other assets	(797)	263
Accounts payable	1,124	545
Accrued expenses and deferred rent	1,787	(609)
Accrued lease expense	(64)	(64)
Accrued compensation	(848)	(285)
Net cash used in operating activities	(11,209)	(5,612)
Investing activities		
Purchase of fixed assets	(163)	(66)
Proceeds from sale of asset	2	
Sales of short-term investments		12,907
Net cash provided by (used in) investing activities	(161)	12,841
Financing activities		
Payments on capital lease obligations	(29)	(34)
Proceeds from exercise of stock options	51	
Net cash provided by (used in) financing activities	22	(34)
Increase (decrease) in cash and cash equivalents	(11,348)	7,195
Cash and cash equivalents at beginning of period	90,782	14,848
Cash and cash equivalents at end of period	$ 79,434	$ 22,043
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 476	$ 2
Cash paid for taxes	$	$ 2
Supplemental disclosures of non-cash investing and financing activities:		
Unrealized gain on investments	$	$ 216

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Description of the Business and Basis of Presentation

Description of Business - Insmed is a biopharmaceutical company focused on developing and commercializing inhaled therapies for patients battling serious lung diseases that are often life threatening. The Company s lead product candidate, ARIKACE®, or liposomal amikacin for inhalation, is an inhaled antibiotic treatment that delivers a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of this therapeutic approach for patients.

Currently, the Company is conducting clinical trials of ARIKACE for two initial indications in orphan patient populations: a Phase 3 clinical trial in cystic fibrosis (CF) patients who have lung infections caused by *Pseudomonas aeruginosa* (*Pseudomonas*) and a Phase 2 clinical trial in patients who have lung infections caused by non-tuberculous mycobacteria (NTM). The Company s primary development focus is to obtain regulatory approval for ARIKACE for these two initial indications and to prepare for commercialization initially in Europe and Canada and eventually in the United States (US). If approved, ARIKACE will be the first once-a-day inhaled antibiotic treatment option available for these CF and NTM indications. The Company s strategy is to continue to develop ARIKACE for additional indications beyond *Pseudomonas* in CF patients and in NTM patients.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999 and its principal executive offices are located in Monmouth Junction, New Jersey.

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

Prior Period Reclassifications - Certain amounts in the prior years consolidated financial statements have been reclassified to conform to the current-year presentation. Specifically, the Company allocated a portion of certain operating expenses from general and administrative expense to research and development expense in 2013 and recast prior year amounts to conform to the current year presentation for comparability purposes.

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 GAAP 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, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013. The consolidated balance sheet as of December 31, 2012 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, 2012 filed with the SEC on March 18, 2013.

2. Summary of Significant Accounting Policies

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

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for each period 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, the warrant fair value calculation, impairment of intangibles and long lived assets and accounting for research and development costs. Actual results could differ from those estimates.

Investment Income and Interest Expense - Investment income consists of interest and dividend income earned on our cash, cash equivalents and short-term investments, along with realized gains (losses) on the sale of investments. Interest expense consists primarily of interest costs related to our debt and capital lease obligations.

Cash and Cash Equivalents and Short-Term Investments - The Company considers cash equivalents to be highly liquid investments with maturities of three months or less from the date of purchase. The Company invests its available cash primarily in mutual and money market funds US treasury obligations, and bank certificates of deposit. For purposes of determining realized gains and losses, the cost of securities sold is based on specific identification.

Fixed Assets, Net - Fixed assets are recorded at cost and are depreciated on a straight-line basis over the estimated useful lives of the assets. Estimated useful lives of three to seven years are used for computer equipment, laboratory equipment, office equipment and furniture and fixtures. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Long-lived assets, such as lab equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the fair value of the asset.

Identifiable Intangible Assets and Goodwill - Identifiable intangible assets are measured at their respective fair values and are not amortized until commercialization of the related product commences. Once commercialization occurs, these intangible assets will be amortized over their estimated useful lives. The fair values assigned to our intangible assets are based on reasonable estimates and assumptions given available facts and circumstances. Unanticipated events or circumstances may occur that may require us to review the assets for impairment. Events or circumstances that may require an impairment assessment include negative pre-clinical or clinical trial results, the non-approval of a new drug application by a regulatory agency, 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 performs its annual impairment test as of October 1 of each year. We are not aware of any indicators of impairment that would necessitate an impairment test as of March 31, 2013.

The Company uses the income approach to derive the fair value of in-process research and development assets. 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. The Company did not use a market based valuation approach because the Company lacks revenues and profits. The income approach requires significant management judgment with respect to unobservable inputs such as 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 are consistent with the Company s business plans.

Debt Issuance Costs - Debt issuance costs are amortized using the effective interest rate method, and are amortized to interest expense over the term of the debt. Debt issuance costs paid to the lender are reflected as a discount to the debt, and debt issuance costs paid to other third parties are reflected as other assets in the consolidated balance sheets.

Fair Value Measurements - The Company categorizes its 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

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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 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.

As of March 31, 2013 and December 31, 2012, the Company did not have any Level 2 or 3 financial assets or liabilities. The following table presents the Company s Level 1 assets measured at fair value as of March 31, 2013 and December 31, 2012.

	Level 1	
	As of March 31, 2013	As of December 31, 2012
	(in thousands)	
Cash, cash equivalents and money funds	$ 79,434	$ 90,782
Certificate of deposit	2,173	2,153
	$ 81,607	$ 92,935

The Company s cash, cash equivalents, and money funds consist of liquid investments with a maturity of three months or less from the date of purchase. The 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 transfers in or out of Level 1, Level 2 or Level 3 during the three months ended March 31, 2013 and 2012. As of March 31, 2013 and December 31, 2012, the Company held no securities that were in an unrealized loss or gain position.

The Company reviews 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.

Concentration of Credit Risk - Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company places its cash equivalents with financial institutions that it believes have high credit quality. The Company has established investment guidelines relative to credit ratings and maturities that seek to maintain safety and liquidity.

The Company sources each of its raw materials from a single supplier. In addition, the production of the Company s lead product candidate is performed by a sole manufacturer. The inability of the suppliers or manufacturer to fulfill supply requirements of the Company could materially adversely affect future operating results or the Company s business generally. A change in the relationship with the suppliers or manufacturer, or an adverse change in their business, could materially adversely affect the Company s future operating results.

Revenue Recognition - The Company recognizes revenues when all of the following four criteria are present: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

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Where the Company has continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenue as the related activities are performed. The period over which these activities are to be performed is based upon management s estimate of the development period. Changes in management s estimate could change the period over which revenue is recognized. Research and/or development payments are recognized as revenues as the related research and/or development activities are performed and when the Company has no continuing performance obligations related to the research and development payment received.

Where the Company has no continuing involvement under a collaborative arrangement, the Company records nonrefundable license fee revenues when the Company has the contractual right to receive the payment, in accordance with the terms of the collaboration agreement, and records milestones upon appropriate notification to the Company of achievement of the milestones by the collaborative partner.

The Company recognizes revenue from milestone payments when earned, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) the Company does not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the vendor s performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor s performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. Any amounts received by the Company under the agreement in advance of the Company s performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as the Company completes its performance obligations.

With regard to recognizing revenue for multiple deliverable revenue arrangements, each deliverable within a multiple-deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

In addition, multiple deliverable revenue arrangement consideration is allocated at the inception of an arrangement to all deliverables using the relative selling price method. The Company also applies a selling price hierarchy for determining the selling price of a deliverable, which includes (1) vendor-specific objective evidence, if available, (2) third-party evidence, if vendor-specific objective evidence is not available, and (3) estimated selling price if neither vendor-specific nor third-party evidence is available.

Deferred revenue associated with a non-refundable payment received under a collaborative agreement that is terminated prior to its completion results in an immediate recognition of the deferred revenue.

Research and Development - Research and development expenses consist primarily of salaries, benefits and other related costs, including stock based compensation, for personnel serving in our research and development functions, and other internal operating expenses, the cost of manufacturing our drug candidate, including the medical devices for drug delivery, for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. The Company s expenses related to manufacturing its drug candidate and medical devices for clinical study are primarily related to activities at contract manufacturing organizations that manufacture ARIKACE and the medical devices for the Company s use. The Company s expenses related to clinical trials are primarily related to activities at contract research organizations that conduct and manage clinical trials on the Company s 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. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

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Stock-Based Compensation The Company recognizes stock-based compensation expense for awards of equity instruments to employees and directors based on the grant-date fair value of those awards. The grant-date fair value of the award is recognized as compensation expense ratably over the requisite service period, which generally equals the vesting period of the award, and if applicable, is adjusted for expected forfeitures. Stock-based compensation expense is included in both research and development expenses and general and administrative expenses in the Consolidated Statements of Comprehensive Loss. For awards deemed to be granted outside of the Company s 2000 Stock Incentive Plan, the Company uses liability accounting. These awards are classified as a liability and are remeasured at fair value at the end of each reporting period. Changes in fair value are included in compensation expense in the Consolidated Statements of Comprehensive Loss (see additional disclosures related to awards granted outside of the 2000 Stock Incentive Plan in Footnote 6, Stock-Based Compensation).

Income Taxes - The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to operating loss carryforwards and differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is recorded to reduce the deferred tax assets to the amount that is expected to be realized. In evaluating the need for a valuation allowance, we take into account various factors, including the expected level of future taxable income and available tax planning strategies. If actual results differ from the assumptions made in the evaluation of our valuation allowance, we record a change in valuation allowance through income tax expense in the period such determination is made.

The Company uses a model for how it measures, presents and discloses an uncertain tax position taken or expected to be taken in a tax return. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based solely on the technical merits of the position. The tax benefits recognized in the financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood to be sustained upon ultimate settlement. The Company has no uncertain tax positions as of March 31, 2013 or December 31, 2012 that qualify for either recognition or disclosure in the consolidated financial statements.

The Company s policy for interest and penalties related to income tax exposures is to recognize interest and penalties as a component of the income taxes on continuing operations in the Consolidated Statements of Comprehensive Loss.

Net Income (Loss) Per Common Share - Basic net income (loss) per common share is computed by dividing net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) attributable to common shareholders by the weighted average number of common shares and other dilutive securities outstanding during the period. Potentially dilutive securities from stock options, the restricted stock units and the warrant would be antidilutive as the Company incurred a net loss. Potentially dilutive common shares resulting from the assumed exercise of outstanding stock options and warrants are determined based on the treasury stock method.

The following table sets forth the reconciliation of the weighted average number of shares attributable to common stockholders used to compute basic net income (loss) per share for the three months ended March 31, 2013 and 2012.

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	Three Months Ended March 31,	
	2013	2012
	(In thousands, except per share amounts)	
Numerator:		
Net income (loss):	$ (13,678)	$ (6,845)
Denominator:		
Weighted average common shares used in calculation of basic net income (loss) per share:	31,554	24,860
Effect of dilutive securities:		
Common stock options		
Restricted stock and restricted stock units		
Common stock warrant		
Weighted average common shares outstanding used in calculation of diluted net income (loss) per share	31,554	24,860
Net income (loss) per share:		
Basic and Diluted	$ (0.43)	$ (0.28)

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average common shares outstanding as of March 31, 2013 and 2012 as their effect would have been anti-dilutive.

	Three Months Ended March 31,	
	2013	2012
	(In thousands)	
Stock options to purchase common stock	2,348	845
Warrant to purchase common stock	330	158
Restricted stock units	200	494

Segment Information - The Company currently operates in one business segment, which is the development and commercialization of inhaled therapies for patients with serious lung infections. A single management team that reports to the Chief Executive Officer comprehensively manages the entire business. The Company does not operate separate lines of business with respect to its products or product candidates. Accordingly, the Company does not have separate reportable segments.

Recently Adopted Accounting Pronouncements - In February 2013, an Accounting Standards Update was issued that requires companies to present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income (loss) based on its source and the income statement line items affected by the reclassification. This update became effective for the Company on January 1, 2013 and its adoption did not affect the Company s consolidated financial statements.

In July 2012, an Accounting Standards Update was issued that allows companies to assess qualitative factors to determine the likelihood of indefinite-lived intangible asset impairment and whether it is necessary to perform the quantitative impairment test currently required. This update became effective for the Company on January 1, 2013 and its adoption did not impact the disclosures in the Company s consolidated financial statements.

3. Accrued Expenses

Accrued expenses consist of the following:

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	As of March 31, 2013	As of December 31, 2012
	(in thousands)	
Accrued clinical trial expenses	$ 2,941	$ 1,460
Liability for stock-based compensation awards	1,808	1,204
Accrued professional fees	417	185
Accrued interest payable	159	80
Other accrued expenses	4	4
	$ 5,329	$ 2,933

4. Debt

On June 29, 2012, the Company and its domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement that allowed the Company to borrow up $20.0 million in $10.0 million increments (Loan Agreement). The Company borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Note A and Note B) on June 29, 2012 and December 27, 2012, respectively. Notes A and B bear interest at 9.25%. Note A is to be repaid over a 42-month period with the first twelve monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. Note B is to be repaid over a 36-month period with the first six monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. The interest only period is currently scheduled to end on July 31, 2013, but is extendable to December 31, 2013, contingent upon completion of certain ARIKACE-related development milestones. The principal monthly repayments for Notes A and B are scheduled to begin on August 1, 2013, or if extended, January 1, 2014, and in either case will end on January 1, 2016. In connection with the Loan Agreement, the Company granted the lender a first position lien on all of the Company s assets, excluding intellectual property. Prepayment of the loans made pursuant to the Loan Agreement is subject to a prepayment penalty and the Company is required to pay an end of term charge of approximately $0.4 million, which is being charged to interest expense (and accreted to the debt) using the effective interest method over the term of the Notes. Debt issuance costs paid to the lender were recorded as a discount on the debt and are being amortized to interest expense using the effective interest method over the life of the Loan Agreement. Debt issuance costs paid to third parties were capitalized and are being amortized to interest expense using the effective interest method over the term of the Notes.

The Loan Agreement also contains representations and warranties by the Company and the lender, indemnification provisions in favor of the lender, customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but no financial covenants), and events of default (including with respect to payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the lender s security interest or in the collateral, and events relating to bankruptcy or insolvency). Upon the occurrence of an event of default, a default interest rate of the base rate plus an additional 5% may accrue on the outstanding loan balances, and the lender may terminate its lending commitment, declare all outstanding obligations immediately due and payable, and take such other actions as set forth in the Loan Agreement. In addition, pursuant to the Loan Agreement, the lender has the right to participate, in an amount of up to $1.0 million, in certain future private equity financing(s) by the Company.

In conjunction with entering into the Loan Agreement, the Company granted a warrant to the lender to purchase shares of the Company s common stock. Since the warrant was granted in conjunction with entering into the Loan Agreement, the relative fair value of the warrant was recorded as equity and debt discount. The portion of the fair value allocated to debt discount is being amortized to interest expense over the term of the related debt using the effective interest method.

The following table presents the components of the Company s debt balance as of March 31, 2013.

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	March 31, 2013 (in thousands)
Debt:	
Notes payable	$ 20,000
Add:	
Accreted end of term charge	92
Less:	
Unamortized debt issuance fees paid to lender	(169)
Unamortized discount from warrant	(537)
Current portion of long-term debt	(4,875)
Long-term debt	$ 14,511

Future principal repayments of the two Notes are as follows (in thousands):

Year Ending December 31:	
2013	$ 3,007
2014	7,724
2015	8,481
2016	788
Total	$ 20,000

The estimated fair value of the debt (categorized as a Level 2 liability for fair value measurement purposes) is determined using current market factors and the ability of the Company to obtain debt at comparable terms to those that are currently in place. We believe the estimated fair value at March 31, 2013 approximates the gross carrying amount.

5. ***Shareholders Equity***

Common Stock As of March 31, 2013, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 31,571,926 shares of common stock issued and outstanding. Of the shares outstanding as of March 31, 2013, 1,765,271 shares represent holdback shares held by the Company as security for potential indemnification payments, as described in the Agreement and Plan of Merger with Transave, Inc. (the Merger Agreement), filed as Exhibit 2.1 to the Company s Annual Report on Form 10-K for the year ended December 31, 2012 (see Footnote 9, Commitments and Contingencies, Legal Proceedings, Pilkiewicz v. Transave LLC for additional information regarding these holdback shares). In addition, as of March 31, 2013, the Company has reserved 2,347,919 shares of common stock for issuance upon the exercise of outstanding common stock options, 200,452 for issuance upon the vesting of restricted stock units, and 329,932 shares of common stock for issuance upon the exercise of the outstanding warrant (see Note 10. Subsequent Events, Warrant Exercise).

Warrant - In conjunction with entering into the Loan Agreement (See Note 4 Debt), the Company granted a warrant to the lender to purchase 329,932 shares of the Company s common stock at an exercise price of $2.94 per share. The fair value of the warrant of $0.8 million was calculated using the Black-Scholes warrant-pricing methodology at the date of issuance and was recorded as equity and as a discount to the debt and is being amortized to interest expense over the term of the promissory notes using the effective interest method. This warrant expires on June 29, 2017, which is five years from the date of grant (see Note 10. Subsequent Events, Warrant Exercise).

6. ***Stock Based Compensation***

The Company has two equity compensation plans; the Amended and Restated 2000 Stock Incentive Plan, as amended (the 2000 Stock Incentive Plan) and the Amended and Restated 2000 Employee Stock Purchase Plan

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(the Stock Purchase Plan). Both the 2000 Stock Incentive Plan and the Stock Purchase Plan were adopted by the Company s Board of Directors in 2000.

Under the terms of the 2000 Stock Incentive Plan, the Company is 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 to all employees and non-employee directors. At the Company s Annual Meeting of Shareholders held on May 18, 2011, the Company s shareholders approved an amendment to increase the number of authorized shares under this plan by 3,000,000 shares. As of March 31, 2013, the 2000 Stock Incentive Plan provides for the issuance of a maximum of 3,925,000 shares of common stock. On March 15, 2013 the Company s Board of Directors amended the 2000 Stock Incentive Plan to provide for a single aggregate per person annual sub-limit for the issuance of a maximum of 1,500,000 stock options, performance shares (including RSUs) and shares of restricted stock.

On April 17, 2013, the Company s Board of Directors approved a new plan, the 2013 Incentive Plan, which provides for an additional 3,000,000 shares of the Company s common stock to be reserved for future grants under the 2013 Incentive Plan. This increase will be presented to the Company s shareholders for their approval at the Company s annual meeting of shareholders to be held on May 23, 2013. If approved by the Company s shareholders, any remaining shares reserved for future grants under the 2000 Incentive Plan will be transferred to the 2013 Incentive Plan. As of March 31, 2013, 135,583 shares of the Company s common stock were reserved for future grants (or issuances) of restricted stock, restricted stock units, stock options, and stock warrants under the 2000 Stock Incentive Plan.

Under the terms of the Stock Purchase Plan, eligible employees may, from time-to-time, 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 Stock Purchase Plan provides for the issuance of a maximum of 150,000 shares of our common stock to participating employees. The Company has not offered employees the right to purchase common stock under the Stock Purchase Plan since prior to our merger with Transave in December 2010. As of March 31, 2013, 150,000 shares of the Company s common stock were reserved for future issuances of common stock under the Stock Purchase Plan.

Stock Options - The Company calculates the fair value of stock options granted using the Black-Scholes valuation model. The Company calculates the fair value of stock options granted outside of the 2000 Stock Incentive Plan using liability accounting. These awards are classified as a liability and remeasured at fair value at the end of each reporting period using the Black-Scholes valuation model and changes in fair value are included in compensation expense in the Consolidated Statements of Comprehensive Loss (see additional disclosures related to stock options granted outside the 2000 Stock Incentive Plan at the end of this footnote).

The following table summarizes the grant date fair value and assumptions used in determining the fair value of stock options granted under and outside the 2000 Stock Incentive Plan during the three months ended March 31, 2013.

	Three Months Ended March 31,	
	2013	**2012**
Volatility	95.5%	104.6%
Risk-free interest rate	0.8%	1.0%
Dividend yield	0.0%	0.0%
Expected option term (in years)	6.25	6.25
Weighted-average fair value of stock options granted	$ 6.85	$ 3.29

For the three months ended March 31, 2013, the volatility factor was based on the Company s historical volatility since the closing of the merger with Transave on December 1, 2010. 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 US Treasury yield in effect at the date of grant. Forfeitures are based on actual percentage of option forfeitures since the closing of the merger on December 1, 2010, and are the basis for future forfeiture expectations.

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The following table summarizes stock option activity for stock options granted under and outside the 2000 Stock Incentive Plan for the three months ended March 31, 2013 as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value
Options outstanding at December 31, 2012	1,817,839	$ 4.10		
Granted	552,250	6.85		
Exercised	(17,170)	3.03		
Forfeited and expired	(5,000)	10.10		
Options outstanding at March 31, 2013	2,347,919	4.74	8.19	$ 6,507,867
Vested and expected to vest at March 31, 2013	2,180,927	4.72	8.08	6,092,692
Exercisable at March 31, 2013	426,919	4.57	2.27	1,304,426

The Company recognized stock-based compensation expense related to stock options of approximately $0.7 million and $0.2 million for the three months ended March 31, 2013 and 2012, respectively. General and administrative expenses include $0.6 million and $0.1 million and research and development expenses include $0.1 million and $0.1 million of stock-based compensation expense in the Consolidated Statement of Comprehensive Loss for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, there was $8.6 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 3.31 years.

Outstanding as of March 31, 2013					Exercisable as of March 31, 2013	
Range of Exercise Prices		Number of Options	Weighted Average Remaining Contractual Term (in Years)	Weighted Average Excersise Price	Number of Options	Weighted Average Excersise Price
$ 3.03	$ 3.13	465,135	6.16	$ 3.03	224,419	$ 3.03
$ 3.14	$ 3.39	21,400	9.19	$ 3.24		$
$ 3.40	$ 3.47	708,314	9.45	$ 3.40		$
$ 3.48	$ 5.89	405,070	5.53	$ 5.18	186,750	$ 5.89
$ 5.90	$ 6.33	240,250	9.5	$ 6.55	5,250	$ 6.50
$ 6.34	$ 6.89	385,750	9.97	$ 6.90		$
$ 6.90	$ 7.43	105,500	9.76	$ 6.96		$
$ 7.44	$ 8.29	6,000	9.98	$ 7.44		$
$ 8.30	$ 17.59	5,250	1.11	$ 8.30	5,250	$ 8.30
$ 17.60	$ 17.60	5,250	0.11	$ 17.60	5,250	$ 17.60

Restricted Stock and Restricted Stock Units The Company grants Restricted Stock Units (RSUs) to eligible employees, including our executives. Each RSU represents a right to receive one share of the Company s common stock upon the completion of a specific period of continued service or achievement of a certain milestone. RSU awards granted under the Company s 2000 Stock Incentive Plan are generally valued at the market price of the Company s common stock on the date of grant. In prior years certain RSUs were granted in excess of certain plan sub-limits. As of March 31, 2013, such awards that are still considered to be granted outside the 2000 Stock Incentive Plan are classified as a liability and remeasured at fair value at the end of each reporting period and

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changes in fair value are included in compensation expense in the Consolidated Statements of Comprehensive Loss (see additional disclosures related to RSUs granted outside the 2000 Stock Incentive Plan at the end of this footnote). The Company recognizes compensation expense for the fair values of these RSUs on a straight-line basis over the requisite service period of these awards, which is generally one to three years.

The following table summarizes the RSU activity for awards granted both under and outside of the 2000 Stock Incentive Plan during the three months ended March 31, 2013:

	Number of RSUs		Weighted Average Grant Price
Outstanding as of December 31, 2012	215,525	$	6.26
Granted	53,730	$	6.67
Released	(68,803)	$	3.69
Forfeited			
Outstanding as of March 31, 2013	200,452	$	7.26
Expected to Vest as of March 31, 2013	192,388	$	7.25

The Company recognized stock-based compensation expense related to RSUs of approximately $0.3 million for each of the three month periods ended March 31, 2013 and 2012. General and administrative expenses include $0.2 million and $0.3 million and research and development expenses include $0.1 million and less than $0.1 million of stock-based compensation expense in the Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, there was $0.6 million of unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 0.9 years.

Awards Granted Outside of the 2000 Stock Incentive Plan - In connection with a recent review of equity compensation awards made under the 2000 Stock Incentive Plan, the Company determined that it had inadvertently exceeded the annual per-person sub-limits in connection with awards previously made to certain of its current and past officers and directors. The aggregate amount of common stock represented by these awards in excess of the per person annual sub-limits during the three months ended March 31, 2013 and the two years ended December 31, 2012, which consisted of RSUs and stock options, is approximately 1.4 million shares. Such awards are included in the stock option and RSU tables and related disclosures above. The awards that exceeded the per person sub-limits included certain awards issued immediately following the Company s business combination with Transave, awards negotiated with new hires pursuant to employment agreements or offers of employment, and certain other awards made subsequent to the Company s 2011 one-for-ten reverse stock split. As of March 31, 2013, these awards were deemed to be granted outside of the 2000 Stock Incentive Plan and as such the Company applied liability accounting to these awards and recorded a liability of $1.8 million which is included in accrued expenses as of March 31, 2013.

7. License and Collaborative Agreements

Premacure (now Shire plc) - In May, 2012, the Company entered into an agreement with Premacure Holdings AB and Premacure AB of Sweden (collectively, Premacure) pursuant to which the Company granted to Premacure an exclusive, worldwide license to develop, manufacture and commercialize IGF-1, with its natural binding protein, IGFBP-3, for the prevention and treatment of complications of preterm birth in exchange for royalty payments on commercial sales of IGF-1 (the Premacure License Agreement). In March 2013, we amended the Premacure License Agreement to provide Premacure with the option, exercisable by Premacure any time prior to April 30, 2013, to pay us $11.5 million (the Buyout Amount) and assume any of our royalty obligations to other parties in exchange for a fully paid license (see Note 10. Subsequent Events, Exercise of Buyout Option).

8. Income Taxes

The provision (benefit) for income taxes was ($1.2 million) and $0 during the three months ended March

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31, 2013 and 2012. The Company s effective tax rate was (8.2%) and 0% for the three months ended March 31, 2013 and 2012, respectively. The benefit for income taxes recorded and the effective tax rate for the three months ended March 31, 2013 solely reflect the reversal of a valuation allowance previously recorded against the Company s New Jersey State net operating losses (NOL) that resulted from the Company s sale of $27.0 million of its New Jersey State NOLs under the State of New Jersey s Technology Business Tax Certificate Transfer Program (the Program) for cash of $1.2 million, net of commissions. The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits for cash. The remaining net deferred tax asset as of March 31, 2013 remains fully offset by a valuation allowance due to the Company s history of losses.

As of December 31, 2012, the Company had NOL carryforwards for income tax purposes of $350.0 million available to offset future taxable income, if any. The NOL carryforwards expire in various years beginning in 2013. The Company is not currently subject to any open tax audits and the statute of limitations for tax audits is generally open for the years 2009 and later. However, except in 2009, the Company has incurred net operating losses since inception. Such loss carryforwards would be subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin.

The Company s policy is to recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has not recorded such expenses. As of December 31, 2012, the Company did not record any reserves for unrecognized income tax benefits, nor did it record any accrued interest or penalties related to uncertain tax positions. The Company does not anticipate any material changes in the amount of unrecognized tax positions over the next twelve months.

Utilization of the NOLs and general business tax credits carryforwards may be subject to a substantial limitation under Section 382 of the Internal Revenue Code of 1986 due to changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company s formation, it has raised capital through the issuance of common stock on several occasions which, combined with the purchasing shareholders subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, and it issued a substantial amount of shares of common stock as part of its merger with Transave, Inc. in December 2010. Due to the significant complexity and cost associated with a change in control study, and because there could be additional changes in control in the future, the Company has not yet formally assessed whether there has been one or more changes in control since the Company s formation. If the Company experienced a change of control at any time since Company formation, utilization of its NOL or general business tax credit carryforwards would be subject to the limitation rules under Section 382. Any limitation may result in expiration of a portion of the NOL or general business tax credit carryforwards before utilization which would reduce the Company s gross deferred tax assets.

9. Commitments and Contingencies

Commitments

The Company has two operating leases for office and laboratory space located in Monmouth Junction, NJ through December 31, 2014. Future minimum rental payments under these two leases total approximately $1.3 million. We continue to lease office space in Richmond, VA, where the Company s corporate headquarters were previously located through October 2016. Future minimum rental payments under this lease total approximately $1.7 million. During 2011, we recorded a net present value charge of $1.2 million in general and administrative expenses associated with vacating the Richmond facility. The remaining accrual for this charge was $0.9 million as of March 31, 2013.

Rent expense charged to operations was $0.2 million for each of the three month periods ended March 31, 2013 and 2012. Future minimum rental payments required under the Company s operating leases are as follows (in thousands).

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Year Ending December 31:		
2013	$	890
2014		1,201
2015		498
2016		425
Total	$	3,014

Legal Proceedings

Cacchillo v. Insmed

On October 6, 2010, a complaint was filed against the Company 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 Plaintiff s compassionate use application to the FDA and if approved, to provide Plaintiff with IPLEX. Plaintiff was a participant in the Phase 2 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 2 clinical trial with the false promise to support Plaintiff s compassionate use application to the FDA, (iii) negligent representation that the Company 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. The Company 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 completed discovery on or about June 1, 2012. The Company filed a Motion for Summary Judgment on August 1, 2012 seeking judgment in our favor on the three claims remaining in the case and the motion was fully submitted on October 9, 2012. On January 19, 2013, the Court granted the Company s Motion for Summary Judgment and dismissed all of the outstanding claims. Plaintiff filed a Notice of Appeal on March 15, 2013. The Company expects that the parties will submit briefs before the end of 2013, with a decision expected in the first half of 2014.

Pilkiewicz v. Transave LLC

On March 28, 2011, Frank G. Pilkiewicz and other former stockholders of Transave, Inc. (collectively, the Petitioners) filed an appraisal action against the Company s 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 representing total dissenting shares of approximately 7.77 million shares of Transave, Inc. common stock (the

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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, Inc. (the Transave Stockholders) are obligated to indemnify the Company for certain liabilities in connection with the appraisal action. The Company notified the Transave Stockholders in May 2012 that the Company is seeking indemnification in accordance with the Merger Agreement and that it will continue to retain the aggregate amount of the holdback shares totaling 1,765,271 shares, as security for any indemnification payments due under the Merger Agreement. Discovery is ongoing and the trial is scheduled to begin September 30, 2013. The Company believes 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, the Company is a party to various other 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 materially adversely affect the Company s business, consolidated financial position, results of operations or cash flows.

10. Subsequent Events

Exercise of Buyout Option As disclosed in more detail in Note 7. License and Collaborative Agreements , in May 2012, the Company entered into a license agreement with Premacure pursuant to which the Company granted to Premacure an exclusive, worldwide license to develop, manufacture and commercialize IGF-1, with its natural binding protein, IGFBP-3, in exchange for royalty payments on commercial sales of IGF-1 (the Premacure License Agreement). In March 2013, the Premacure License Agreement was amended to provide Premacure with the option, exercisable by Premacure any time prior to April 30, 2013, to pay us $11.5 million and assume any of our royalty obligations to other parties in exchange for a fully paid license. On April 29, 2013, Premacure exercised this option and is now obligated to pay the Company $11.5 million on or before May 9, 2013. The Company is not entitled to any additional future royalties from Premacure, and Premacure has assumed the Company s royalty obligations to other parties.

Warrant Exercise As disclosed in more detail in Note 4. Debt and Note 5. Shareholders Equity , in June 2012, in conjunction with entering into a Loan Agreement with the Company, the Company granted a warrant to the lender to purchase 329,932 shares of the Company s common stock at an exercise price of $2.94 per share. On April 30, 2013, the lender exercised the warrant in full via the net issuance method. In accordance with the provisions of the net issuance method as contained in the warrant agreement, the Company issued and delivered 223,431 Common Shares (the Warrant Shares) to the lender on May 1, 2013. As a result of the exercise, the warrant is no longer outstanding and there are no additional shares issuable under this instrument.

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

Cautionary Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward looking statements. Forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that 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, continues, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements.

Forward-looking statements include, but are not limited to: our ability to complete development of, receive regulatory approval for, and successfully commercialize 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, timing, 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 US Food and Drug Administration (the FDA) and other regulatory authorities; 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 third parties with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate license agreements and other third party efforts, including those relating to the development and commercialization of our product candidates; the degree of protection afforded to us by our intellectual portfolio; the safety and efficacy of our product candidates; sources of revenues and anticipated revenues, including contributions from license agreements and other third party 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 availability of adequate supply and manufacturing capacity and quality for our product candidates.

Forward-looking statements are based upon our current expectations and beliefs, and involve known and unknown risk, uncertainties and other factors, which may cause our actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such factors include, among others, the factors discussed in Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 18, 2013. 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, 2012.

OVERVIEW

Insmed is a biopharmaceutical company focused on developing and commercializing inhaled therapies for patients battling serious lung diseases that are often life threatening. Our lead product candidate, ARIKACE® or liposomal amikacin for inhalation, is an inhaled antibiotic treatment that delivers a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of this therapeutic approach for patients.

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Currently, we are conducting clinical trials of ARIKACE for two initial indications in orphan patient populations: a Phase 3 clinical trial in cystic fibrosis (CF) patients who have lung infections caused by *Pseudomonas aeruginosa* (*Pseudomonas*) and a Phase 2 clinical trial in patients who have lung infections caused by non-tuberculous mycobacteria (NTM). Our primary development focus is to obtain regulatory approval for ARIKACE in these two initial indications and to prepare for commercialization initially in Europe and Canada and eventually in the United States (US). If approved, ARIKACE will be the first once-a-day inhaled antibiotic treatment option available for these CF and NTM indications. Our strategy is to continue to develop ARIKACE for additional indications beyond *Pseudomonas* in CF and NTM. The following table summarizes the current status of ARIKACE development.

Product Candidate/Target Indications	**Status**	**Next Expected Milestone(s)**
ARIKACE *Pseudomonas aeruginosa* lung infections in CF patients	• In a Phase 3 registrational clinical trial in Europe and Canada that completed the patient treatment phase of the trial in early May 2013. • In a two-year open-label extension study that is enrolling patients from the Phase 3 registrational clinical trial and is expected to be completed during the first half of 2015. • Granted orphan drug designation in Europe and the US.	• We expect to report top-line clinical results from our Phase 3 registrational clinical trial in mid-2013. • If approved, ARIKACE would be the only once-a-day treatment for *Pseudomonas* lung infections in CF patients. • If approved, we plan to commercialize ARIKACE ourselves in Europe and in Canada. • We plan to evaluate our plans for CF in the US after reviewing the results from our Phase 3 clinical trial in Europe and Canada.
ARIKACE Non-tuberculous mycobacteria (NTM) lung infections	• In a Phase 2 clinical trial in the US and Canada that began enrolling patients in June 2012. • Granted orphan drug designation in the US.	• We expect to report top-line clinical results from our Phase 2 clinical trial during the fourth quarter of 2013. • We expect to commence a limited compassionate use program in the second half of 2013. • If approved, ARIKACE would be the first approved inhaled antibiotic treatment for NTM lung infections. • If approved, we plan to commercialize ourselves initially in the US and eventually in Europe and in Canada.
ARIKACE *Pseudomonas aeruginosa* and other susceptible organisms causing lung infections in non-CF bronchiectasis patients	• Phase 2 clinical trial in the US completed. • Granted orphan drug designation in the US.	• We expect to evaluate development and commercialization strategies when we complete our Phase 3 clinical trial in CF patients with *Pseudomonas* lung infections and Phase 2 clinical trial in patients with NTM infections.

ARIKACE is considered a new molecular entity (NME) by the US Food and Drug Administration (FDA) primarily due to its proprietary liposomal technology. The key active ingredient, amikacin, is an FDA-approved antibiotic with proven efficacy in the treatment of a broad range of gram-negative infections, including *Pseudomonas* and NTM. ARIKACE is in the aminoglycoside class of antibiotics.

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ARIKACE is differentiated from other inhaled antibiotics used to treat serious lung infections by our proprietary advanced liposomal technology, which is designed specifically to enhance the delivery profile, safety and efficacy of pharmaceuticals delivered to the lung via inhalation. We believe ARIKACE provides potential improvements over existing treatments for these indications. In Phase 2 studies in CF patients with *Pseudomonas* lung infections, ARIKACE demonstrated improved patient lung function during treatment as well as in the period following treatment (the off-treatment period). In a Phase 2 open label extension study, ARIKACE also demonstrated statistically significant effectiveness for up to 56 days off-treatment over multiple treatment cycles.

If approved for CF patients with *Pseudomonas* lung infections, we expect ARIKACE would be the first inhaled antibiotic to be approved for once-daily administration in this indication. If approved for NTM patients, we expect ARIKACE would be the first and only approved treatment for NTM lung infections. ARIKACE has been granted orphan drug designation for CF patients who have *Pseudomonas* lung infections in both the European Union (EU) and the US, and for NTM patients in the US. We plan to file for orphan drug designation for NTM lung infections in Europe in 2013.

Corporate History

We were incorporated in the Commonwealth of Virginia on November 29, 1999. 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 and innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections. Our current operations are based on the technology and product candidates historically developed by Transave.

Lead Product Candidate - ARIKACE

Our lead product candidate, ARIKACE or liposomal amikacin for inhalation, is a once-a-day inhaled antibiotic treatment engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections. There are two key components of ARIKACE: the liposomal formulation of the drug and the nebulizer device through which ARIKACE is inhaled through the mouth and into the lung. The nebulizer technology is owned by PARI Pharma GmbH (PARI), but through our licensing agreement with PARI, we have exclusive access to this technology, which is specifically developed for the delivery of our liposomal encapsulation of amikacin. Our proprietary liposomal technology and nebulizer are designed specifically for delivery of pharmaceuticals to the lung and provides for potential improvements to existing treatments. We believe that ARIKACE has potential usage for at least two orphan patient populations with high unmet need: CF patients who have *Pseudomonas* lung infections and patients who have NTM lung infections. We estimate the combined global market potential for these two orphan indications to be approximately $1 billion.

ARIKACE has the potential to be differentiated from other marketed drugs for the treatment of chronic lung infections by improving efficacy, safety and patient convenience. We believe efficacy may be improved due to the ability of ARIKACE to deliver high, sustained levels of amikacin directly to the lung and to the specific site of the underlying infection. We also believe that ARIKACE may have increased durability of effect, benefiting patients when off treatment. In addition, the inhalation delivery of ARIKACE may reduce the potential for adverse events such as ototoxicity (hearing loss, ringing in the ears and/or loss of balance) and nephrotoxicity (toxicity to the kidneys), as compared with intravenous (IV) administration of amikacin. If approved, we expect that ARIKACE will be administered once daily for approximately 13 minutes via inhalation using the eFlow® Nebulizer System, which has been optimized specifically for ARIKACE by PARI. We believe that this nebulizer system will reduce treatment time or dosing frequency, as compared with the currently marketed inhaled antibiotics, which require dosing two to three times daily with treatment times ranging from approximately 10 to 40 minutes per day. By easing the patient s treatment burden we believe that ARIKACE can potentially improve patient compliance, which we believe may in turn lead to a reduction in the

development of antibiotic resistance and, ultimately, lead to clinical benefit.

We believe that ARIKACE may provide: (1) improved efficacy resulting from sustained deposition of drug in the lung and improved ability to reach the site of infection (for CF *Pseudomonas* infections, this means penetration of biofilm and facilitated drug release by factors that are secreted by the bacteria, and for NTM, this

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means enhanced uptake into macrophages, where NTM often grows); (2) decreased adverse events and improved tolerability as compared with amikacin delivered intravenously; and (3) reduced dosing frequency or treatment time as compared to existing products.

ARIKACE for CF Patients with *Pseudomonas* Lung Infections

Disease

CF is an inherited chronic disease that is often diagnosed before the age of two. CF occurs primarily in individuals of central and western European origin. CF affects roughly 70,000 children and adults worldwide, including 30,000 children and adults in the US (Cystic Fibrosis Foundation Patient Registry, 2011) and 35,000 patients in Europe (Hoiby, BMC Medicine, 2011, 9:32). There is no cure for CF.

Despite extensive treatment with multiple antibiotics, improved nutrition, and other treatments, life expectancy of a CF patient is only about 37 years (Cystic Fibrosis Foundation Patient Registry, 2011). Median predicted age of survival is calculated using life table analysis (as calculated by actuaries) given the ages of the patients in the registry and the distribution of deaths. Using this calculation, half of the people in the patient registry are expected to live beyond the median predicted survival age, and half are expected to live less than the median predicted survival age.

Among other issues, CF causes thick, sticky mucus to develop in and clog the lungs. This creates an ideal environment for various pathogens, such as *Pseudomonas*, to colonize and lead to chronic infection of the lung, inflammation and progressive loss of lung function. In fact, chronic bronchial infections with *Pseudomonas* are a major cause of morbidity and mortality among patients with CF. Once a CF patient acquires a *Pseudomonas* infection, it is difficult to eradicate. The current, best available treatment is chronic administration of antibiotics to suppress the bacteria, reduce inflammation and preserve lung function for as long as possible. The rate of infection with *Pseudomonas* in CF patients increases with age. It is estimated that 70% of adult CF patients have chronic infection due to *Pseudomonas* (CFF Patient Registry, 2011). A study reported in the *Journal of Cystic Fibrosis* (Liou, 2010) found that deterioration in lung function of CF patients is the main cause of death and that, despite best efforts, lung function declines by 1% to 3% annually.

Current Clinical Program

ARIKACE was granted orphan drug status in the US and Europe for the treatment of Pseudomonas lung infections.

We are conducting a registrational Phase 3 clinical study of ARIKACE for CF patients with *Pseudomonas* lung infections in Europe and Canada. The Phase 3 trial includes 302 patients and is a 1:1 randomized trial comparing ARIKACE 560 mg, delivered once daily for approximately 13 minutes via the eFlow Nebulizer System, to Tobi (inhaled tobramycin solution), which is delivered twice daily approximately 15 minutes per treatment for a daily total of approximately 30 minutes per day. The first patient in this trial was dosed in April 2012, and the trial met target enrollment in November 2012. The study s primary endpoint is relative change in forced expiratory volume in one second (FEV1) from baseline measured after the completion of three cycles, each comprising a 28-day on-treatment period and a 28-day off-treatment period. Approximately 260 patients are required to demonstrate non-inferiority at an agreed-upon margin with 80% power. Secondary endpoints for the study include change in pulmonary function, time to and the proportion of patients experiencing pulmonary exacerbation, the time

elapsed to first antipseudomonal antibiotic treatment for pulmonary exacerbation, time to and number of hospitalizations, reduction in bacteria as measured by reduction in colony forming units, change in patient-reported symptoms and evaluation of safety and tolerability. We previously agreed with the European Medicines Agency (EMA) on the study design. The last patient, last visit for this study occurred on May 6, 2013. We currently expect to announce clinical results from the Phase 3 trial in mid-2013.

In addition, patients completing the initial 24 week Phase 3 study will have the option to enroll in a two-year open-label extension study. The patients in this study will receive ARIKACE for a two year period, using the same cycles of a 28 day on-treatment period and a 28 day off-treatment period.

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Strategy for Commercialization

We currently plan to retain marketing rights for ARIKACE in certain countries in Europe, and in Canada and the US. We believe ARIKACE will require a limited commercial infrastructure in these regions because of the small focused nature of the potential physician prescribing population for CF patients. We may license ARIKACE for certain indications in certain countries in Europe, as well as outside of Europe, and in Canada and the US. In 2013, we commenced preparations for the potential commercialization of ARIKACE in Europe and Canada, including hiring Matt Pauls, our chief commercial officer. We plan to hire several other positions to support our sales and marketing efforts.

ARIKACE for Patients with NTM Lung Infections

Disease

Non-tuberculous *mycobacteria,* or NTM, are organisms common in soil and water that have been associated with lung disease in select patient groups. NTM have characteristics that are similar to tuberculosis, or TB, but NTM are not contagious. Many people have NTM in their bodies, but NTM do not normally lead to an infection, perhaps because the body s immune system successfully overcomes the threat of infection. It is not completely understood why certain individuals are susceptible to NTM infections. However, the patients who become infected by NTM often are immune-compromised or have structural damage in their lungs at the time of the infection.

NTM are organisms that invade and multiply chiefly within macrophages. They are characteristically resistant to most antibiotics. NTM lung infections are chronic, debilitating and progressive and often require lengthy, repeat hospitalizations. Signs and symptoms of NTM pulmonary disease are variable and nonspecific. They include chronic cough, sputum production and fatigue. Less commonly, malaise, dyspnea, fever, hemoptysis, and weight loss also can occur, usually with advanced NTM disease. Evaluation is often complicated by the symptoms caused by co-existing lung diseases. According to a study published in the *American Journal of Respiratory and Critical Care Medicine*, these conditions include chronic obstructive airway disease associated with smoking, bronchiectasis, previous mycobacterial diseases, CF and pneumoconiosis (Olivier et al. 2003).

Current Clinical Program

ARIKACE was granted orphan drug designation in the US for the treatment of patients with NTM.

We are currently conducting a Phase 2 clinical trial in the US and Canada for ARIKACE in adult patients with NTM lung infections. We began enrolling patients in June 2012. The Phase 2 clinical trial is a randomized, placebo-controlled study of approximately 100 adult patients with recalcitrant NTM lung infections. There are two parts to the study: a randomized portion and an open-label portion.

In the randomized portion of the study, patients are screened initially to include in the study those who have NTM lung infections with persistent sputum culture for MAC or *M. abscessus* while on ATS/IDSA-guidelines-based treatment regimen for at least six months prior to screening. Patients who are NTM culture positive and meet the eligibility criteria to enroll in the study will receive, in addition to their ongoing antibiotic treatment regimen, either ARIKACE 560 mg or a placebo both delivered once daily for approximately 13 minutes via an optimized, investigational eFlow Nebulizer System.

The primary efficacy endpoint for this study is the change in mycobacterial density from baseline to the end of 84 days of treatment. At a public workshop discussion in September 2012, the FDA agreed that the microbiological end-point is an appropriate primary end-point for NTM lung disease. The study will also measure secondary endpoints, including the proportion of patients with culture conversion to negative, the time to rescue anti-mycobacterial drugs, the change from baseline in six-minute walk distance and oxygen saturation, the change

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from baseline in patient reported outcomes, and evaluation of safety and tolerability. At the conclusion of the randomized portion of the study, eligible patients will receive ARIKACE once daily for an additional 84 days during the open-label portion of the study, primarily to measure longer-term safety and efficacy. We previously agreed with the FDA on this clinical trial design. We expect results from this clinical trial in the fourth quarter of 2013.

In addition to the Phase 2 clinical trial outlined above, we intend to pursue a limited compassionate use program starting in the second half of 2013. We currently anticipate this program s participants will consist of approximately 25 patients who have NTM lung infections but are not eligible for entry into our Phase 2 clinical trial. We believe that clinical data collected from the experience with these patients will help regulatory authorities to evaluate ARIKACE s safety and suitability for treating NTM lung infection patients.

Strategy for Commercialization

We currently plan to retain marketing rights for ARIKACE in certain countries in Europe, and in Canada and the US. Given the current lack of approved treatments for NTM lung infections, we believe we will immediately have a strong market position if ARIKACE is approved for commercialization in the NTM indication. We believe ARIKACE will require a limited commercial infrastructure in these regions because of the small focused nature of the potential physician prescribing population for NTM patients. We may seek to license ARIKACE for certain indications in certain countries in Europe, as well as outside of Europe, Canada and the US. We believe there will be substantial carryover between lung specialist physicians who treat CF patients with pseudomonas lung infections and those who have NTM lung infections thereby allowing us to leverage our commercial infrastructure across both indications.

ARIKACE for Non-CF Bronchiectasis Patients with *Pseudomonas* Lung Infections

Disease

We believe ARIKACE has the potential to be used to treat non-CF bronchiectasis characterized by *Pseudomonas* lung infections. However, we are currently concentrating our development efforts on the treatment of *Pseudomonas* lung infections in CF patients and patients with NTM lung infections. We will evaluate our development and commercialization strategies for this indication when we complete our Phase 3 study in CF patients with *Pseudomonas* lung infections and Phase 2 study in patients with NTM infections.

Non-CF bronchiectasis is a serious pulmonary condition characterized by localized, irreversible enlargement of the bronchial tubes. Accumulation of mucus in the bronchi leads to frequent infections, which causes inflammation and further reduces lung function. Patients evolve to a chronic inflammation-infection cycle. Disease burden has primarily been linked to productive cough and high levels of sputum production.

Development Program

ARIKACE was granted orphan drug status in the US for the treatment of bronchiectasis in patients with *Pseudomonas* or other susceptible pathogens.

In May 2009, we completed our randomized, placebo controlled US Phase 2 study (TR02-107) of ARIKACE for the treatment of chronic *Pseudomonas* infection in non-CF patients with bronchiectasis. In the study, 64 study subjects were randomized (1:1:1) to receive ARIKACE 280 mg, ARIKACE 560 mg or a placebo on a daily basis during a 28-day on-treatment period. The subjects completed follow-up assessments at the end of a 28-day off-treatment period. This study provided an initial evidence of safety, tolerability and clinically meaningful improvement in pulmonary function throughout the on-treatment period in the treatment of chronic *Pseudomonas* infection in non-CF patients with bronchiectasis.

In the study, both ARIKACE 280 mg and ARIKACE 560 mg were well tolerated. The adverse events experienced by patients during the study were consistent with underlying chronic lung disease in bronchiectasis patients. There was no evidence of renal toxicity or ototoxicity. Patients in the 560-mg cohort appear to have a slightly higher frequency of dry cough post administration than patients in the 280 mg cohort. Cough was of short

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duration and self-limiting. One patient discontinued treatment due to dysphonia (hoarseness or difficulty speaking) and cough.

There was a statistically significant reduction in *Pseudomonas* density observed in the 560 mg ARIKACE cohort relative to the placebo cohort. Patients receiving ARIKACE experienced fewer pulmonary exacerbations at a rate of 4.7%, as compared to 10.5% in those receiving placebo. No patients in the ARIKACE cohorts required anti-*Pseudomonas* rescue treatment, whereas 15% of patients in the placebo cohort required treatment. Hospitalization from any cause occurred at a 5.3% rate for patients in the placebo cohort, as compared to a 2.3% rate for patients in the ARIKACE cohort. Patients receiving ARIKACE achieved improvements in patient respiratory symptoms and quality of life assessments compared with patients receiving placebo.

Although we believe there is an opportunity to develop ARIKACE for non-CF bronchiectasis, we do not intend to initiate further clinical studies with respect to a non-CF bronchiectasis indication until we have completed additional clinical studies for CF patients with *Pseudomonas* lung infections and for patients with NTM lung infections. Following those studies, we will evaluate whether to develop ARIKACE further for non-CF bronchiectasis.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Research and Development Expenses

Research and development expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our research and development functions, and other internal operating expenses, the cost of manufacturing our drug candidate for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. Our expenses related to manufacturing our drug candidate for clinical study are primarily related to activities at contract manufacturing organizations that manufacture ARIKACE for our use. Our expenses related to clinical trials are primarily related to activities at contract research 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. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Since 2011, we have focused our development activities principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. We are conducting three clinical trials: (1) a Phase 3 trial in Europe and Canada in which we are evaluating ARIKACE in CF patients with *Pseudomonas* lung infections, (2) an open label extension study in which patients that complete the Phase 3 trial have the option to receive ARIKACE for a period of two years and (3) a Phase 2 trial in the US in which we are evaluating ARIKACE for NTM infections. Since our business combination with Transave, our research and development expenses for our ARIKACE program were approximately $54.3 million. We expect that our development efforts in 2013 and 2014 will principally relate to the use of ARIKACE in the CF and NTM indications.

Our clinical trials with ARIKACE are subject to numerous risks and uncertainties that are outside of our control, including the possibility that necessary regulatory approvals may not be obtained. In addition, the duration and the cost of clinical trials may vary significantly from trial to trial over the life of a project as a result of differences in the study protocol for each trial as well as 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

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- the efficacy and safety profile of the product candidate.

Our clinical trials may be subject to delays, particularly if we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our clinical trials. Moreover, all of our product candidates must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. 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 when, if at all, we will generate positive cash inflow from these projects.

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 and accounting, legal, market research, and human resource functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, insurance, board of director fees, tax and accounting services. We expect that our general and administrative expenses will increase in order to support increased levels of development activities and commencement of commercialization activities for 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, along with realized gains (losses) on the sale of investments. Interest expense consists primarily of interest costs related to our debt and capital lease obligations.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2013 and 2012

Net loss for the three months ended March 31, 2013 was $13.7 million (or $0.43 per common share basic and diluted) compared with a net loss of $6.8 million (or $0.28 per common share basic and diluted) for the three months ended March 31, 2012. The increase in our net loss in 2013 of $6.9 million was primarily due to a $5.6 million increase in our research and development expenses that primarily resulted from the activities under our Phase 3 CF clinical study and our two-year extension study in Europe and Canada, and our Phase 2 NTM clinical study in the US. We were in the process of initiating the Phase 2 CF study and Phase 2 NTM study in the first quarter of 2012 and did not initiate the two-year extension study until October 2012. Also contributing to the increase in the net loss was a $1.5 million increase in our general and administrative expenses that was primarily due to a $1.0 million increase in professional fees. The increase in professional fees primarily related to the investigation, accounting and reporting of equity awards we previously granted to our employees and directors that at the time of the grants were in excess of annual per-person sub-limits included in our 2000 Stock Incentive Plan (see Item 4. Controls and Procedures included herein in

Part I of this Quarterly Report on Form 10-Q for additional information regarding equity awards granted in excess of sub-limits included in our 2000 Stock Incentive Plan).

Research and Development Expenses

Research and development expenses for the three months ended March 31, 2013 and 2012 comprised the following:

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	Three Months Ended March 31,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands)			
External expenses				
Clinical development	$ 6,853	$ 2,525	$ 4,328	171%
Clinical manufacturing	563	313	250	80%
Regulatory and quality assurance	123	93	30	32%
Subtotal - external	7,539	2,931	4,608	157%
Internal expenses				
Compensation and related expenses	1,808	1,532	276	18%
Other internal operating expenses	987	276	711	258%
Subtotal - internal	2,795	1,808	987	55%
Total	$ 10,334	$ 4,739	$ 5,595	118%

Research and development expenses increased to $10.3 million during the three months ended March 31, 2013 from $4.7 million in the same period in 2012. The $5.6 million increase is primarily due to a $4.6 million increase in external costs associated with the activities under our Phase 3 CF clinical study and our two-year extension study in Europe and Canada, and our Phase 2 NTM clinical study in the US during the three months ended March 31, 2013. We were in the process of initiating the Phase 2 CF study and Phase 2 NTM study in the first quarter of 2012 and did not initiate the two-year extension study until October 2012. Also contributing to the $5.6 million increase was a $1.0 million increase in internal expenses, including a $0.4 million increase in lab expenses, a $0.3 million increase in recruiting fees and a $0.3 million increase in compensation and related expenses.

General and Administrative Expenses

General and administrative expenses increased to $4.0 million during the three months ended March 31, 2013 from $2.5 million in the same period in 2012. The $1.5 million increase was due to a $1.0 million increase in professional fees that was primarily related to the investigation, accounting and reporting of excess equity awards we previously granted to our employees and directors that at the time of the grants were in excess of annual per-person sub-limits included in our 2000 Stock Incentive Plan, and a $0.5 million increase in compensation expenses, of which $0.3 million was non-cash stock compensation expense resulting from remeasuring at fair value certain stock options deemed granted outside of our 2000 Stock Incentive Plan.

Investment Income

Investment income decreased to $0.1 million during the three months ended March 31, 2013 from $0.4 million in the same period in 2012. The $0.3 million decrease is a result of our decision to amend our investment policy and only invest in mutual and money market funds, US Treasury obligations, and bank certificates of deposit. During the three months ended March 31, 2013, the majority of our cash was invested in money funds that have lower rates of return than the returns we received from our short-term investments in the same period in 2012.

Interest Expense

Interest expense increased to $0.6 million during the three months ended March 31, 2013 from $0.0 in 2012. The $0.6 million increase was due to the $20.0 million of borrowings ($10.0 million in June 2012 and $10.0 million in December 2012) under our Loan Agreement we entered into in June 2012.

Provision (Benefit) for Income Taxes

The provision (benefit) for income taxes was ($1.2 million) and $0 during the three months ended March 31, 2013 and 2012. The Company s effective tax rate was (8.2%) and 0% for the three months ended March 31, 2013 and 2012, respectively. The benefit for income taxes recorded and the effective tax rate for the three months

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ended March 31, 2013 solely reflect the reversal of a valuation allowance previously recorded against the Company s New Jersey State net operating losses (NOL) that resulted from the Company s sale of $27.0 million of its New Jersey State NOLs under the State of New Jersey s Technology Business Tax Certificate Transfer Program (the Program) for cash of $1.2 million, net of commissions. The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits for cash. The remaining net deferred tax asset as of March 31, 2013 remains fully offset by a valuation allowance due to the Company s history of losses.

LIQUIDITY AND CAPITAL RESOURCES

Overview

There is considerable time and cost associated with developing a potential drug or pharmaceutical product to the point of regulatory approval and commercialization. Historically, we have funded our operations through public and private placements of equity securities, through debt financing, from the proceeds from the sale of our follow-on biologics (FOB) platform to Merck in 2009 and from revenues related to sales of product and our IPLEX expanded access program, which was discontinued in 2011. We expect to continue to incur losses because we plan to fund our research and development activities and commercial launch activities, and we do not expect material revenues for at least the next few years.

As of March 31, 2013, we had total cash, cash equivalents, and a certificate of deposit on hand of $81.6 million, consisting of $79.4 million in cash and cash equivalents and $2.2 million in a certificate of deposit, as compared with $92.9 million of cash, cash equivalents, and a certificate of deposit on hand as of December 31, 2012. The $11.3 million net decrease was due to our use of $11.2 million in operations. Our working capital was $60.6 million as of March 31, 2013, which excludes our certificate of deposit of $2.2 million that matures in July 2013.

We believe that our cash, cash equivalents and certificate of deposit totaling $81.6 million as of March 31, 2013 will fund our operations into 2014. However, our business strategy may require us to, or we may otherwise determine to, raise additional capital at any time through equity or debt financing(s), strategic transactions or otherwise. Such additional funding may be necessary to continue to develop our potential product candidates, to pursue the license or purchase of complementary technologies, to commercialize our product candidates or to purchase other products. In addition, we may determine to raise capital opportunistically. We cannot assure you that adequate capital will be available on favorable terms, or at all, when needed. If we are unable to obtain sufficient additional funds when required, we may be forced to delay, restrict or eliminate all or a portion of our research or development programs, dispose of assets or technology or cease operations.

Cash Flows

Net cash used in operating activities was $11.2 million and $5.6 million for the three months ended March 31, 2013 and 2012, respectively. The net cash used in operating activities during 2013 and 2012 was primarily for the clinical development of our lead product candidate, ARIKACE, which included the initiation of three clinical trials for the study of ARIKACE during 2012 and the continued advancement of these three clinical trials during the first quarter of 2013.

Net cash (used in) provided by investing activities was $(0.2) million and $12.8 million during the three months ended March 31, 2013 and 2012, respectively. The net cash used in investing activities in 2013 related to fixed asset purchases of $0.2 million for lab and computer equipment. The net cash provided by investing activities in the three months ended March 31, 2012 was primarily a result of $12.9 million of net sales of short-term investments.

Net cash provided by (used in) financing activities was $22 thousand and $(34) thousand for the three months ended March 31, 2013 and 2012, respectively.

On June 29, 2012, we entered into a Loan and Security Agreement that allowed us to borrow up $20.0 million in $10.0 million increments (Loan Agreement). We borrowed the first and second $10.0 million

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increments by signing two Secured Promissory Notes (Note A and Note B) on June 29, 2012 and December 27, 2012, respectively. Notes A and B bear interest at 9.25%. Note A is to be repaid over a 42-month period with the first twelve monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. Note B is to be repaid over a 36-month period with the first six monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. The interest only period is currently scheduled to end on July 31, 2013, but is extendable to December 31, 2013, contingent upon completion of certain ARIKACE-related development milestones. The principal monthly repayments for Notes A and B are scheduled to begin on August 1, 2013, or if extended, January 1, 2014, and in either case will end on January 1, 2016. In connection with the Loan Agreement, we granted the lender a first position lien on all of our assets, excluding intellectual property. Prepayment of the loans made pursuant to the Loan Agreement is subject to a prepayment penalty and we are required to pay an end of term charge of $0.4 million.

Contractual Obligations

We have two operating leases for office and laboratory space located in Monmouth Junction, NJ that terminate on December 31, 2014. Future minimum rental payments under these two leases total approximately $1.3 million. We continue to lease office space in Richmond, VA where our corporate headquarters were previously located. Future minimum rental payments under this lease total approximately $1.7 million. During 2011, we recorded a net present value charge of $1.2 million in general and administrative expenses associated with vacating the Richmond, VA facility. The remaining accrual for this charge was $0.9 million as of March 31, 2013.

We executed two secured promissory notes totaling $20.0 million; $10.0 million in June 2012 and $10.0 million in December 2012. We also entered into three capital leases for lab equipment and leasehold improvements with monthly payments through December 2014. As of March 31, 2013, future payments under the two promissory notes, the capital leases and minimum future payments under non-cancellable operating leases are as follows:

	As of March 31, 2013 Payments Due By Period				
	Total	Less than 1 year	1-3 Years	4-5 Years	After 5 Years
			(In thousands)		
Debt obligations					
Debt maturities	$ 20,000	$ 4,875	$ 15,125	$	$
Contractual interest	3,156	1,746	1,404	6	
Capital lease obligations					
Debt maturities	131	83	48		
Contractual interest	1	1			
Operating leases	3,014	1,191	1,526	297	
Purchase obligations					
Total contractual obligations	$ 26,302	$ 7,896	$ 18,103	$ 303	$

This table does not include (a) any milestone payments which may become payable to third parties under our license and collaboration agreements as the timing and likelihood of such payments are not known, (b) any royalty payments to third parties as the amounts of such payments, timing and/or the likelihood of such payments are not known, and (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above.

We currently have a licensing agreement with PARI for use of the optimized eFlow Nebulizer System for delivery of ARIKACE in treating patients with CF, bronchiectasis and NTM infections. We have rights to several US and foreign issued patents, and patent applications involving improvements to the optimized eFlow Nebulizer System. Under the licensing agreement, PARI is entitled to receive payments either in cash, qualified stock or a combination of both, at PARI s discretion, based on achievement of certain milestone events including Phase 3 trial initiation (which occurred in 2012), first acceptance of MAA submission (or equivalent) in the US of ARIKACE and the device, first receipt of marketing approval in the US for ARIKACE and the device, and first receipt of

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marketing approval in a major EU country for ARIKACE and the device, and NDA acceptance and regulatory approval of ARIKACE. In addition, PARI is entitled to receive royalty payments on commercial sales of ARIKACE pursuant to the licensing agreement.

In 2005 and 2009, we entered into a research funding agreements with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) whereby we received $1.7 million and $2.2 million for each respective agreement in research funding for the development of its ARIKACE product. If ARIKACE becomes an approved product for CF patients in the US, we will owe a payment to CFFT of up to $13.4 million that is payable over a three-year period after approval as a commercialized drug in the US. Furthermore, if certain sales milestones are met within 5 years of the drug commercialization approval in the US, we would owe an additional $3.9 million in additional payments. Since there is significant development risk associated with ARIKACE, we have not accrued these obligations.

In 2009 and 2012, we entered into a cooperative research and development agreement (CRADA) with National Institutes of Allergy and Infectious Diseases (NIAID) to design and conduct our Phase 2 study of ARIKACE in patients with NTM. NIAID has also agreed to provide biostatistical advisory input in connection with the Phase 2 NTM study. If we decide not to continue with the commercialization of ARIKACE in NTM, NIAID will have the right to complete the clinical trial. Further NIAID may elect to pursue its rights to obtain license rights to certain inventions made under the CRADA.

Future Funding Requirements

We may need to raise additional capital to fund our operations and to develop and commercialize ARIKACE. Our future capital requirements may be substantial and will depend on many factors, including:

- the decisions of the FDA and EMA with respect to our applications for marketing approval of ARIKACE in the US and Europe; the costs of activities related to the regulatory approval process; and the timing of approvals, if received;
- the timing and cost of our anticipated clinical trials of ARIKACE for the treatment of adult patients with CF;
- the cost of putting in place the sales and marketing capabilities necessary to be prepared for a potential commercial launch of ARIKACE, if approved;
- the cost of filing, prosecuting and enforcing patent claims;
- the costs of our manufacturing-related activities;
- the costs associated with commercializing ARIKACE if we receive marketing approval; and
- subject to receipt of marketing approval, the levels, timing and collection of revenue received from sales of approved products, if any, in the future.

In June 2012, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission. This shelf registration statement permits us to offer, from time to time, any combination of common stock, preferred stock, debt securities, units and warrants up to an aggregate offering price of $75.0 million. In October 2012, we issued approximately $25.7 million of our common stock utilizing the shelf registration statement. We believe that our cash, cash equivalents and certificate of deposit totaling $81.6 million as of March 31, 2013 will fund our operations into 2014. However, our business strategy may require us to, or we may otherwise determine to, raise additional capital at any time through equity or debt financing(s), strategic transactions or otherwise. Such additional funding may be necessary to continue to develop our potential product candidates, to pursue the license or purchase of complementary technologies, to commercialize our product candidates or to purchase other products. In addition, we may determine to raise capital opportunistically. If we are unable to obtain additional financing, we may be required to reduce the scope of our planned product development and commercialization or our plans to establish a sales and marketing force, any of which could harm our business, financial condition and results of operations. The source, timing and availability of any future financing will depend principally upon equity and debt market conditions, interest rates and, more specifically, our continued progress in our regulatory, development and commercial activities. We cannot assure you that such capital funding will be available on favorable terms or at all. If we are unable to obtain sufficient additional funds when required, we may be forced to delay, restrict or eliminate all or a portion of our research or development programs, dispose of assets or technology or cease operations.

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To date, we have not generated any revenue from ARIKACE. We do not know when or if we will generate any revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize, ARIKACE.

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 material effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We do not have any interest in special purpose entities, structured finance entities or other variable interest entities.

CRITICAL ACCOUNTING POLICIES

Preparation of financial statements in accordance with generally accepted accounting principles in the US requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expenses and the disclosures of contingent assets and liabilities. We use our historical experience and other relevant factors when developing our estimates and assumptions. We continually evaluate these estimates and assumptions. The amounts of assets and liabilities reported in our consolidated balance sheets and the amounts of revenue reported in our consolidated statements of comprehensive loss are effected by estimates and assumptions, which are used for, but not limited to, the accounting for research and development, revenue recognition,, stock-based compensation, in process research and development intangible assets, and accrued expenses. The accounting policies discussed below are considered critical to an understanding of our consolidated financial statements because their application places the most significant demands on our judgment. Actual results could differ from our estimates. For additional information about our significant accounting policies, see Note 2 to our Consolidated Financial Statements Summary of Significant Accounting Policies.

Research and Development

Research and development expenses consist primarily of the cost of conducting our clinical trials, the cost of manufacturing our drug candidate for use in our clinical studies, salaries, benefits and other related costs, including stock-based compensation, for personnel serving our research and development functions, and other internal operating expenses, and the cost of conducting preclinical and research activities. Our expenses related to manufacturing our drug candidate for use in our clinical studies are primarily related to activities at contract manufacturing organizations that manufacture ARIKACE for our use. Our expenses related to clinical trials are primarily related to activities at contract research organizations that conduct and manage clinical trials on our behalf, as well as activities at the location(s) of the trials. 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.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Revenue Recognition

We recognize revenues when all of the following four criteria are present: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Where we have continuing performance obligations under the terms of a collaborative arrangement, non-refundable upfront license payments received upon contract signing are recorded as deferred revenue and recognized as revenue as the related activities are performed. The period over which these activities are to be performed is based upon management s estimate of the development period. Changes in management s estimate could change the period over which revenue is recognized. Research and/or development payments are recognized as revenues as the

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related research and/or development activities are performed and when we have no continuing performance obligations related to the research and development payment received.

Where we have no continuing involvement under a collaborative arrangement, we record nonrefundable license fee revenues when we have the contractual right to receive the payment, in accordance with the terms of the collaboration agreement, and record milestones upon appropriate notification to us of achievement of the milestones by the collaborative partner.

We recognize revenue from milestone payments when earned, provided that (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone earned. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either the vendor s performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor s performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. Any amounts received by us under the agreement in advance of our performance, if deemed substantive, are recorded as deferred revenue and recognized as revenue as we complete our performance obligations.

With regard to recognizing revenue for multiple deliverable revenue arrangements, each deliverable within a multiple-deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

In addition, multiple deliverable revenue arrangement consideration is allocated at the inception of an arrangement to all deliverables using the relative selling price method. We also apply a selling price hierarchy for determining the selling price of a deliverable, which includes (1) vendor-specific objective evidence, if available, (2) third-party evidence, if vendor-specific objective evidence is not available, and (3) estimated selling price if neither vendor-specific nor third-party evidence is available.

Deferred revenue associated with a non-refundable payment received under a collaborative agreement that is terminated prior to its completion results in an immediate recognition of the deferred revenue.

Stock-Based Compensation

We recognize stock-based compensation expense for awards of equity instruments to employees and directors based on the grant-date fair value of those awards. The grant-date fair value of the award is recognized as compensation expense ratably over the requisite service period, which generally equals the vesting period of the award, and if applicable, is adjusted for expected forfeitures. Stock-based compensation expense is included in both research and development expenses and general and administrative expenses in the Consolidated Statements of Comprehensive Loss. For awards deemed to be granted outside of the Company s 2000 Stock Incentive Plan, the Company uses liability accounting. These awards are classified as a liability and are remeasured at fair value at the end of each reporting period. Changes in fair value are included in compensation expense in the Consolidated Statements of Comprehensive Loss.

The following table summarizes the assumptions used in determining the fair value of stock options granted during the three months ended March 31, 2013 and 2012.

	Three Months Ended March 31,	
	2013	**2012**
Volatility	95.5%	104.6%
Risk-free interest rate	0.8%	1.0%
Dividend yield	0.0%	0.0%
Expected option term (in years)	6.25	6.25

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For the three months ended March 31, 2013, the volatility factor was based on our historical volatility since the closing of our merger with Transave on December 1, 2010. 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 US Treasury yield in effect at the date of grant. Forfeitures are based on actual percentage of option forfeitures since the closing of the merger with Transave on December 1, 2010 and are the basis for future forfeiture expectations.

Identifiable Intangible Assets

Identifiable intangible assets are measured at their respective fair values and are not amortized until commercialization of the related product commences. Once commercialization occurs, these intangible assets will be amortized over their estimated useful lives. The fair values assigned to our intangible assets are based on reasonable estimates and assumptions given available facts and circumstances. Unanticipated events or circumstances may occur that may require us to review the assets for impairment. Events or circumstances that may require an impairment assessment include negative pre-clinical or clinical trial results, the non-approval of a new drug application by a regulatory agency, material delays in our development program or a sustained decline in market capitalization. We are not aware of any indicators of impairment that would necessitate an impairment test as of March 31, 2013.

We use the income approach to derive the fair value of in-process research and development assets. 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. We did not use a market based valuation approach because we lack revenues and profits. The income approach requires significant management judgment with respect to unobservable inputs such as 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 are consistent with our business plans.

Accrued Expenses

We are required to estimate accrued expenses as part of our process of preparing financial statements. This process involves estimating the level of service performed on our behalf and the associated cost incurred in instances where we have not been invoiced or otherwise notified of actual costs. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for preclinical development, clinical trials and manufacturing of clinical materials. We accrue for expenses associated with these external services by determining the total cost of a given study based on the terms of the related contract. We accrue for costs incurred as the services are being provided by monitoring the status of the trials and the invoices received from our external service providers. In the case of clinical trials, the estimated cost normally relates to the projected costs of having subjects enrolled in our trials, which we recognize over the estimated term of the trial according to the number of subjects enrolled in the trial on an ongoing basis, beginning with subject enrollment. As actual costs become known to us, we adjust our accruals.

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In February 2013, an Accounting Standards Update was issued that requires companies to present either in a single note or parenthetically on the face of the financial statements, the effect of significant amounts reclassified from each component of accumulated other comprehensive income (loss) based on its source and the income statement line items affected by the reclassification. This update became effective for us on January 1, 2013 and its adoption did not impact our consolidated financial statements.

In July 2012, an Accounting Standards Update was issued that allows companies to assess qualitative factors to determine the likelihood of indefinite-lived intangible asset impairment and whether it is necessary to perform the quantitative impairment test currently required. This update became effective for the Company on January 1, 2013 and its adoption did not impact the disclosures in the Company s consolidated financial statements.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2013, our cash and cash equivalents were in cash accounts or were invested in money funds. Such accounts or investments are not insured by the federal government.

As of March 31, 2013, we had $20.0 million of fixed rate borrowings in the form of two secured promissory notes that bear interest at 9.25% outstanding under a Loan and Security Agreement we entered into in June 2012. If a 10% change in interest rates was to have occurred on March 31, 2013, this change would not have had a material effect on the fair value of our debt as of that date, nor would it have had a material effect on our future earnings or cash flows.

The majority of our business is conducted in US dollars. However, we do conduct certain transactions in other currencies, including Euros or British Pounds. Historically, fluctuations in foreign currency exchange rates have not materially affected our results of operations, and during the three months periods ended March 31, 2013 and 2012, our results of operations were not materially affected by fluctuations in foreign currency exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act of 1934 (the Exchange Act) as of the end of the period covered by this report. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms of the SEC. These disclosure controls and procedures include, among other things, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, management is required to apply its judgment in evaluating the benefits of possible disclosure controls and procedures relative to their costs to implement and maintain.

Based on management s evaluation as of the end of the period covered by this report, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are not designed at a reasonable assurance level and are not effective, as a result of the material weakness over the administration, accounting and oversight of our 2000 Stock Incentive Plan discussed below under Update on Management s Annual Report on Internal Control Over Financial Reporting , to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Update on Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our board of directors and management to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and board of directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis.

Based on management s assessment, including consideration of the control deficiencies discussed below, management concluded that the company s internal control over financial reporting was ineffective as of December 31, 2012, due to the fact that there was a material weakness in our internal control over the administration, accounting and oversight of its 2000 Stock Incentive Plan. Specifically, as initially disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 18, 2013, in connection with a recent review of our equity compensation grants, we determined that we had inadvertently exceeded the annual per-person sub-limits applicable to grants of equity awards provided for by our 2000 Stock Incentive Plan. During the three months ended March 31, 2013 and the two years ended December 31, 2012, we granted equity compensation to employees and directors relating to an aggregate of 1.4 million shares of common stock in excess of such sub-limits, which resulted in additional stock based compensation expense of $0.3 million and a liability of $1.8 million in the consolidated financial statements for the three month period ending and as of March 31, 2013. We have not exceeded the overall 3,925,000 share reserve currently provided for by the 2000 Stock Incentive Plan and approved by shareholders, whether as a result of previously-issued awards or currently outstanding awards.

Remediation Plan

Management and our Board of Directors are actively engaged in implementing a remediation plan to address the material weakness over the administration, accounting and oversight of our 2000 Stock Incentive Plan. In November 2012, we hired a new Chief Financial Officer and in the first quarter of 2013, we hired a new Senior Vice President of Human Resources and a senior director to our finance staff which we believe will help strengthen our internal controls. Remediation efforts we have implemented to date include modification of certain forms and processes, training of certain personnel, and pursuant to our Board s approval, amendment to our 2000 Stock Incentive Plan to replace the three individual annual per person sub-limits with a single aggregate stock option, performance share and restricted stock sub-limit of 1,500,000 shares. We did not change the overall share reserve for the 2000 Stock Incentive Plan of 3,925,000 shares, which was approved by our shareholders in 2011. Additional remediation efforts we expect to implement include, among other things, strengthening of internal controls within certain processes, additional training of certain personnel and possible rotation of Board members to different committees and a review of

each of the charters for our Board committees.

Except for the changes in internal control resulting from the implementation of our remediation plan as described above, there were no other changes in internal control over financial reporting during the three months ended March 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 Plaintiff s compassionate use application to the FDA and if approved, to provide Plaintiff with IPLEX. Plaintiff was a participant in the Phase 2 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 2 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 completed discovery on or about June 1, 2012. We filed a Motion for Summary Judgment on August 1, 2012 seeking judgment in our favor on the three claims remaining in the case and the motion was fully submitted on October 9, 2012. On January 19, 2013, the Court granted our Motion for Summary Judgment and dismissed all of the outstanding claims. Plaintiff filed a Notice of Appeal on March 15, 2013. We expect that the parties will submit briefs before the end of 2013, with a decision expected in the first half of 2014.

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*, Petitioners filed an Amended Petition for Appraisal of Stock.

The Petitioners seek appraisal under Delaware law of their common stock holdings, representing approximately 7.77 million dissenting shares of Transave common stock (the Transave Stock). The Petitioners have challenged 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 (the Transave Stockholders) are obligated to indemnify us for certain liabilities in connection with the appraisal action. Certain indemnification and other obligations of the Transave Stockholders were secured by a holdback of 1,765,271 shares of our common stock. In May 2012, we notified the Transave Stockholders that we are seeking indemnification from them and that we will continue to retain all 1,765,271 holdback shares as security for any indemnification

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payments due to us. Discovery is ongoing and the trial is scheduled to begin September 30, 2013. We believe 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 other lawsuits, claims and other legal proceedings that arise in the ordinary course of our business. While the outcome of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will materially adversely affect our business, financial position, results of operations, or cash flows.

ITEM 1A. RISK FACTORS

Except for the historical information in this report, the matters contained in this report include forward-looking statements that involve risks and uncertainties. Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. These 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 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, 2012. Each of these risk factors could adversely affect our business, results of operations and financial condition, as well as adversely affect the value of an investment in our common stock. There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

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

There were no unregistered sales of the Company s equity securities during the quarter ended March 31, 2013.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

A list of exhibits filed herewith is included on the Exhibit Index, which immediate precedes such exhibits and is incorporated herein by reference.

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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

Date: May 7, 2013

By /s/ Andrew T. Drechsler
Andrew T. Drechsler
Chief Financial Officer

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EXHIBIT INDEX

10.1	Employment Agreement, effective as of April 1, 2013, between Insmed Incorporated and Matthew Pauls
10.2	License agreement dated April 25, 2008 between Transave, Inc. and PARI Pharma GmbH (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 SEC.)
10.3	Amended and Restated 2000 Stock Incentive Plan
31.1	Certification of William H. Lewis, 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 2002
31.2	Certification of William H. Lewis, 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 2002
32.1	Certification of Andrew T. Drechsler, Chief Financial 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 2002
32.2	Certification of Andrew T. Drechsler, Chief Financial Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.CAL	XBRL Taxonomy Extension Definition Linkbase Document
101.CAL	XBRL Taxonomy Extension Label Linkbase Document
101.CAL	XBRL Taxonomy Extension Presentation Linkbase Document