INSMED INC
Form 10-Q
November 05, 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 September 30, 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 October 31, 2013, there were 39,109,854 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 SEPTEMBER 30, 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)

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 128,025	$ 90,782
Certificate of deposit		2,153
Prepaid expenses and other current assets	1,720	643
Total current assets	129,745	93,578
In-process research and development	58,200	58,200
Other assets	101	117
Fixed assets, net	1,904	1,666
Total assets	$ 189,950	$ 153,561
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 4,661	$ 7,060
Accrued expenses	5,652	2,933
Accrued compensation	1,953	2,207
Accrued lease expense, current	303	295
Deferred rent	134	149
Capital lease obligations, current	64	96
Current portion of long term debt	7,055	3,007
Total current liabilities	19,822	15,747
Accrued lease expense, long-term	449	647
Capital lease obligations, long-term	16	64
Debt, long-term	12,538	16,221
Total liabilities	32,825	32,679
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 39,100,899 and 31,488,204 issued and outstanding shares at September 30, 2013 and December 31, 2012, respectively	391	315
Additional paid-in capital	532,141	455,325
Warrant to purchase common stock		790
Accumulated deficit	(375,407)	(335,548)
Total shareholders equity	157,125	120,882
Total liabilities and shareholders equity	$ 189,950	$ 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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Other revenue	$	$	$ 11,500	$
Operating expenses:				
Research and development	12,095	5,706	34,654	18,190
General and administrative	4,747	3,647	16,267	8,410
Total operating expenses	16,842	9,353	50,921	26,600
Operating loss	(16,842)	(9,353)	(39,421)	(26,600)
Investment income	40	193	141	901
Interest expense	(525)	(222)	(1,802)	(225)
Gain on sale of assets, net			2	5
Loss before income taxes	(17,327)	(9,382)	(41,080)	(25,919)
Provision (benefit) for income taxes			(1,221)	4
Net loss	$ (17,327)	$ (9,382)	$ (39,859)	$ (25,923)
Basic and diluted net loss per share	$ (0.46)	$ (0.38)	$ (1.19)	$ (1.04)
Weighted average basic and diluted common shares outstanding	37,389	25,013	33,577	24,916
Net loss	$ (17,327)	$ (9,382)	$ (39,859)	$ (25,923)
Comprehensive loss:				
Unrealized (loss) gain on short-term investments, net of taxes		199		385
Comprehensive loss	$ (17,327)	$ (9,183)	$ (39,859)	$ (25,538)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2013	**2012**
Operating activities		
Net loss	$ (39,859)	$ (25,923)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	475	412
Stock based compensation expense	6,410	1,518
Gain on sale of assets, net	(2)	(5)
Amortization of debt discount and debt issuance costs	256	55
Accrual of the end of term charge on the debt	126	
Changes in operating assets and liabilities:		
Accounts receivable		757
Prepaid expenses and other assets	(1,078)	(175)
Accounts payable	(2,399)	651
Accrued expenses and deferred rent	3,908	31
Accrued lease expense	(190)	(193)
Accrued compensation	(254)	786
Net cash used in operating activities	(32,607)	(22,086)
Investing activities		
Purchase of fixed assets	(713)	(122)
Proceeds from sale of asset	2	5
Maturity of a certifcate of deposit	2,153	
Sales of short-term investments		17,050
Net cash provided by investing activities	1,442	16,933
Financing activities		
Payments on capital lease obligations	(80)	(91)
Borrowings of long-term debt, net of issuance costs		9,726
Net proceeds from issuance of common stock	67,017	25,659
Proceeds from exercise of stock options	1,471	
Net cash provided by financing activities	68,408	35,294
Increase in cash and cash equivalents	37,243	30,141
Cash and cash equivalents at beginning of period	90,782	14,848
Cash and cash equivalents at end of period	$ 128,025	$ 44,989
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,416	$ 164
Cash paid for taxes	$	$ 4
Supplemental disclosures of non-cash investing and financing activities:		
Unrealized gain on investments	$	$ 385
Value of warrant exercised by converting the warrant into shares of common stock (net issuance method)	$ 790	$
Value of warrant granted in connection with debt financing	$	$ 790

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 an inhaled anti-infective to treat 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.

During July 2013, the Company reported top-line results from its Phase 3 registrational clinical trial of ARIKACE in cystic fibrosis (CF) patients who have lung infections caused by *Pseudomonas aeruginosa* (Pa) that was conducted in Europe and Canada. In summary, once-daily ARIKACE achieved its primary endpoint of non-inferiority when compared to twice-daily TOBI (tobramycin inhalation solution) for relative change in FEV_1 from baseline to the end of the study. The Company is conducting a Phase 2 clinical trial of ARIKACE in patients who have lung infections caused by non-tuberculous mycobacteria (NTM) in the U.S. and Canada. During October 2013, we concluded the patient enrollment phase of the study with 90 patients enrolled in the study. The Company is also conducting a two-year, open-label safety study that enrolled eligible patients who have also completed our Phase 3 registrational clinical trial in CF patients in Europe and Canada. 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 then 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 CF patients with Pa infections and patients with NTM infections.

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 and nine months ended September 30, 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.

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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 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 September 30, 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

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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 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 September 30, 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 September 30, 2013 and December 31, 2012.

	Level 1	
	As of September 30, 2013	As of December 31, 2012
	(in thousands)	
Cash, cash equivalents and money market funds	$ 128,025	$ 90,782
Certificate of deposit		2,153
	$ 128,025	$ 92,935

The Company s cash, cash equivalents, and money market funds consist of liquid investments with a maturity of three months or less from the date of purchase. The certificate of deposit matured on July 26, 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 and nine months ended September 30, 2013 and 2012. As of September 30, 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.

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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 As disclosed in more detail in Note 7, *License and Collaborative Agreements* , Other revenue during the nine months ended September 30, 2013 solely consists of an $11.5 million payment the Company received from Premacure Holdings AB and Premacure AB of Sweden (collectively Premacure) (which was since acquired by Shire plc) in May 2013 in exchange for the Company s right to receive future royalties under its license agreement with Premacure. The Company recorded this as Other revenue in the three months ended June 30, 2013, since all four revenue recognition criteria (see below) were met and the Company had no continuing performance obligations related to the payment received.

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.

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.

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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.

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. We also grant performance-based stock options to employees. The grant-date fair value of the performance-based stock options is recognized as compensation expense over the implicit service period using the accelerated attribution method once it is probable that the performance condition will be achieved. Stock-based compensation expense is included in both research and development expenses and general and administrative expenses in the Consolidated Statements of Comprehensive Loss.

Certain awards deemed to be granted outside of the Company s equity incentive plans, require the Company to use liability accounting. These type of awards are classified as a liability and are remeasured at fair value at the end of each reporting period until such time they are deemed to be granted under the Company s equity incentive plans. 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 Note 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 September 30, 2013 or December 31, 2012 that qualify for either

recognition or disclosure in the consolidated financial statements.

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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 and nine months ended September 30, 2013 and 2012.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(In thousands, except per share amounts)		(In thousands, except per share amounts)	
Numerator:				
Net income (loss):	$ (17,327)	$ (9,382)	$ (39,859)	$ (25,923)
Denominator:				
Weighted average common shares used in calculation of basic net income (loss) per share:	37,389	25,013	33,587	24,916
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	37,389	25,013	33,587	24,916
Net income (loss) per share:				
Basic and Diluted	$ (0.46)	$ (0.38)	$ (1.19)	$ (1.04)

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average common shares outstanding as of September 30, 2013 and 2012 as their effect would have been anti-dilutive.

	As of September 30,	
	2013	2012
	(In thousands)	
Stock options to purchase common stock	3,439	1,690
Warrant to purchase common stock		330
Restricted stock units	106	496

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.

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3. Accrued Expenses

Accrued expenses consist of the following:

	As of September 30, 2013	As of December 31, 2012
	(in thousands)	
Accrued clinical trial and manufacturing expenses	$ 5,033	$ 1,460
Liability for stock-based compensation awards		1,204
Accrued professional fees	465	185
Accrued interest payable	154	80
Other accrued expenses		4
	$ 5,652	$ 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 and collectively, the Notes) on June 29, 2012 and December 27, 2012, respectively. Notes A and B bear interest at 9.25%. Note A was originally scheduled 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 was originally scheduled 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 Loan Agreement provided that in certain circumstances the Company could delay the first principal payment by five months. In July 2013, subsequent to the completion of certain ARIKACE-related development milestones, the Company elected to extend the interest only period under the Notes from July 31, 2013 to December 31, 2013 and delay the first monthly principal repayments for Notes A and B from August 1, 2013 to January 1, 2014. The election did not change the maturity date for Notes A and B, which is January 1, 2016. The Current portion of long-term debt and Debt, long-term balances included in the consolidated Balance Sheet as of September 30, 2013 and the future principal repayments summarized in the table below reflect this extension of the interest-only period.

In connection with entering into 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. The Company will be required to pay an end of term charge of approximately $0.4 million upon termination of the Loan Agreement, 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%

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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 September 30, 2013.

		September 30, 2013 (in thousands)
Debt:		
Notes payable	$	20,000
Add:		
Accreted end of term charge		170
Less:		
Unamortized debt issuance fees paid to lender		(140)
Unamortized discount from warrant		(437)
Current portion of long-term debt		(7,055)
Long-term debt	$	12,538

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

Year Ending December 31:		
2014		9,519
2015		10,451
2016		30
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 September 30, 2013 approximates the gross carrying amount.

5. ***Shareholders Equity***

Common Stock As of September 30, 2013, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 39,100,899 shares of common stock issued and outstanding. Of the shares outstanding as of September 30, 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 September 30, 2013, the Company has reserved 3,438,621 shares of common stock for issuance upon the exercise of outstanding common stock options and 105,544 shares for issuance upon the vesting of restricted stock units.

On July 22, 2013, the Company completed an underwritten public offering of 6,900,000 shares of the Company s common stock, which included the underwriter s exercise in full of its over-allotment option of 900,000

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shares, at a price to the public of $10.40 per share. The Company s net proceeds from the sale of the shares, after deducting the underwriter s discount and offering expenses of $4.7 million, were $67.0 million.

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 is 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. On April 30, 2013, the lender exercised the warrant in full via the net issuance method specified in the warrant agreement. In accordance with such provisions, the Company issued and delivered 223,431 shares of common 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.

6. ***Stock Based Compensation***

The Company has three equity compensation plans: the 2013 Incentive Plan, which was approved by shareholders at the Company s Annual Meeting of Shareholders on May 23, 2013, 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 (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. Upon the approval of the 2013 Incentive Plan, no additional awards will be issued under the 2000 Stock Incentive Plan and the shares remaining for future grant under the 2000 Stock Incentive Plan were transferred to the 2013 Incentive Plan.

Under the terms of the 2013 Incentive Plan, the Company is authorized to grant a variety of incentive awards based on our common stock, including stock options (both incentive stock options and non-qualified stock options), performance shares and other stock awards, as well as the payment of incentive bonuses to all employees and non-employee directors. The 2013 Incentive Plan provides for a single aggregate per person annual sub-limit of 1,500,000 stock options, performance shares (including RSUs) and shares of restricted stock. The 2013 Incentive Plan provides for the issuance of a maximum of 3,053,833 shares of common stock. Shares subject to outstanding awards under the 2000 Stock Incentive Plan that are cancelled, expired, forfeited or otherwise not issued will also be added to the number of shares available under the 2013 Incentive Plan. As of September 30, 2013, 2,333,966 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 2013 Incentive Plan. The 2013 Incentive Plan will terminate on April 16, 2023 unless it is extended or terminated earlier pursuant to its terms.

Under the terms of the 2000 Stock Incentive Plan, the Company was authorized to grant a variety of incentive awards based on our common stock, including stock options, (both incentive stock options and non-qualified stock options), performance shares, and other stock awards to all employees and non-employee directors. 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. The 2000 Stock Incentive Plan ceased to be available for additional grants once the Company s shareholders approved the 2013 Incentive Plan on May 23, 2013.

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. Since the Company s merger with Transave, Inc. in 2010, the Company has not offered employees the right to purchase common stock under the Stock Purchase Plan. As of September 30, 2013, 150,000 shares of the Company s common stock were reserved for future issuances of common stock under the Stock

Purchase Plan (See Part II. Other Information, Item 5. Other Information, Termination of a Material Definitive Agreement for information regarding the termination of our Stock Purchase Plan on October 31, 2013).

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During the first quarter of 2013, the Company completed a review of equity compensation awards granted under its 2000 Stock Incentive Plan and determined that it had inadvertently exceeded the annual per-person sub-limits involving certain awards previously made to certain of its current and past officers and directors (the excess awards). The aggregate amount of common stock represented by these excess awards, which consisted of RSUs and stock options, was approximately 1.4 million shares. 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. On May 23, 2013 (the date of the Company s 2013 Annual Meeting of Stockholders), shareholders approved the grants associated with the excess awards, which as of this date, allowed the excess awards to be deemed granted under the 2000 Stock Incentive Plan. As a result, the excess awards were remeasured at fair value on May 23, 2013 and the liability was reclassified to Additional paid-in capital. The unrecognized fair value calculated for the excess awards as of May 23, 2013 will be recognized as compensation expense ratably over the remaining requisite service period for each award.

In connection with the appointment of the Company s Chief Commercial Officer on April 1, 2013, the Company made inducement grants of stock options totaling 300,000 shares of the Company s common stock.

Stock Options - The Company calculates the fair value of stock options granted using the Black-Scholes valuation model. The following table summarizes the grant date fair value and assumptions used in determining the fair value of stock options granted under the 2013 Incentive Plan and the 2000 Stock Incentive Plan, as well grants of inducement shares during the three and nine months ended September 30, 2013.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Volatility	87.7% - 90.3%	100.2% - 104.5%	87.7% - 96.0%	100.2% - 107.1%
Risk-free interest rate	1.39% - 1.65%	0.57% - 0.80%	0.65%-1.65%	0.57% - 0.99%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term (in years)	6.25	6.25	6.25	6.25
Weighted-average fair value of stock options granted	$8.91	$2.89	$7.53	$2.89

For the three and nine months ended September 30, 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 option term (in years) 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.

The following table summarizes stock option activity for stock options granted under the 2013 Incentive Plan and the 2000 Stock Incentive Plan, as well as grants of inducement shares during the nine months ended September 30, 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	1,983,800	9.84			
Exercised	(343,918)	4.28			
Forfeited and expired	(19,100)	10.03			
Options outstanding at September 30, 2013	3,438,621	7.36	9.16	$	28,364,114
Vested and expected to vest at September 30, 2013	3,197,438	7.33	9.15		26,490,791
Exercisable at September 30, 2013	387,187	3.81	7.85		4,570,290

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The following table summarizes the stock-based compensation recorded in the Consolidated Statements of Comprehensive Loss related to stock options during the three and nine months ended September 30, 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in millions)			
Research and development expenses	$ 0.3	$ 0.1	$ 0.7	$ 0.2
General and administrative expenses	0.9	0.3	4.1	0.5
Total	$ 1.2	$ 0.4	$ 4.8(1)	$ 0.7

(1) - Included in the $4.8 million is $2.9 million of expense that resulted from the remeasurement of certain stock options that occurred during May 2013.

As of September 30, 2013, there was $22.9 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted average period of 2.73 years. The following table summarizes by range of exercise prices the number of stock options outstanding and exercisable as of September 30, 2013:

Outstanding as of September 30, 2013					Exercisable as of September 30, 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	$ 3.29	305,712	8.18	$ 3.04	110,139	$	3.04
$ 3.40	$ 3.40	708,314	8.95	$ 3.40	177,079	$	3.40
$ 3.48	$ 6.65	474,645	8.42	$ 5.59	94,719	$	5.21
$ 6.70	$ 6.70	20,000	9.29	$ 6.70		$	6.50
$ 6.90	$ 6.90	384,700	9.47	$ 6.90		$	
$ 6.96	$ 7.44	109,500	9.27	$ 6.99		$	
$ 7.45	$ 7.45	375,000	9.50	$ 7.45		$	
$ 8.30	$ 11.46	312,950	9.68	$ 10.96	5,250	$	8.30
$ 12.44	$ 12.44	591,300	9.64	$ 12.44		$	
$ 12.78	$ 15.88	156,500	9.81	$ 13.98		$	

Restricted Stock and Restricted Stock Units The Company grants Restricted Stock Units (RSUs) to its directors and to employees, including 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. RSUs 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. 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. In prior years certain RSUs were granted in excess of certain plan sub-limits. Such awards were deemed to be granted outside the 2000 Stock Incentive Plan. The Company used liability accounting and remeasured these excess awards at fair value at the end of each reporting period, and changes in fair value were included in compensation expense in the Consolidated Statements of Comprehensive Loss. As of September 30, 2013, no outstanding RSUs are deemed to be granted outside of the Company s incentive plans.

The following table summarizes the RSU activity for awards granted under the 2000 Stock Incentive Plan during the nine months ended September 30, 2013:

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	Number of RSUs	Weighted Average Grant Price
Outstanding as of December 31, 2012	215,525	$ 6.26
Granted	53,730	$ 6.67
Released	(147,878)	$ 6.48
Forfeited	(15,833)	$ 5.90
Outstanding as of September 30, 2013	105,544	$ 6.24
Expected to Vest as of September 30, 2013	103,845	$ 6.24

The following table summarizes the stock-based compensation recorded in the Consolidated Statements of Comprehensive Loss related to RSUs during the three and nine months ended September 30, 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in millions)			
Research and development expenses	$ 0.1	$ 0.1	$ 0.9	$ 0.3
General and administrative expenses	0.1		0.7	0.5
Total	$ 0.2	$ 0.1	$ 1.6(1)	$ 0.8

(1) - Included in the $1.6 million is $1.0 million of expense that resulted from the remeasurement of certain RSUs that occurred during May 2013.

As of September 30, 2013, there was $0.3 million of unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted average period of 0.3 years.

7. License and Collaborative Agreements

Premacure (now Shire plc) - In May 2012, the Company entered into an agreement with Premacure (now Shire plc) 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. On April 29, 2013, Premacure exercised this option and paid the Company $11.5 million in exchange for a fully paid license. The Company recorded this payment as Other revenue in the three months ended June 30, 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 under the Premacure License Agreement.

8. Income Taxes

The provision (benefit) for income taxes was $0 during the three months ended September 30, 2013 and 2012, and ($1.2 million) and $0 during the nine months ended September 30, 2013 and 2012, respectively. The Company s effective tax rate was 0% during the three months ended September 30, 2013 and 2012, and (3.0%) and 0% for the nine months ended September 30, 2013 and 2012, respectively. The benefit for income taxes recorded and the effective tax rate for the nine months ended September 30, 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 September 30, 2013 remains fully offset by a valuation allowance due to the Company s history of losses.

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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 September 30, 2013, 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.

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. Utilization of the Company s NOL and general business tax credit carryforwards generated in prior years through September 2012 (the September 2012 and prior NOLs) are likely subject to substantial limitations under Section 382 of the Internal Revenue Code (Section 382) due to ownership changes that occurred at various points during years prior to 2012 and during September 2012. 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, likely resulted in multiple changes in ownership, as defined by Section 382 since the Company s formation in 1999. The substantial limitations on the use of the September 2012 and prior NOLs are likely to result in expiration of a substantial portion of these NOL or general business tax credit carryforwards before utilization which would substantially reduce the Company s gross deferred tax assets. The Company plans to complete a Section 382 analysis regarding the limitation of its NOL and general business tax credit carryforwards and intends to disclose the results of this analysis when it is completed.

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 $0.9 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 $1.5 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 $0.8 million as of September 30, 2013.

Rent expense charged to operations was $0.2 million for each of the three month periods ended September 30, 2013 and 2012. Future minimum rental payments required under the Company s operating leases are as follows (in thousands).

Year Ending December 31:	
2013	$ 297
2014	1,201
2015	498

2016		425
Total	$	2,421

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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 sought compensatory and punitive monetary damages and 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, and 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. On January 19, 2013, the Court granted the Company s Motion for Summary Judgment and dismissed all of the outstanding claims. Plaintiff appealed the Court s decision to the U.S. Court of Appeals for the Second Circuit. The Company anticipates a decision 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*, the Petitioners filed an Amended Petition for Appraisal of Stock.

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 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 nearly completed and the trial is expected to begin during the first quarter of 2014. Following trial, the court will determine the fair value of the Transave Stock. 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

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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.

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: failure or delay of European, Canadian, U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting the Company s product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to the Company s product candidates, unexpected regulatory actions, delays or requests, the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations, the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in Company s prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies, the inability to successfully develop the Company s product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, changes in the Company s financing requirements or ability raise additional capital; 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; 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.

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OVERVIEW

Insmed is a biopharmaceutical company focused on developing and commercializing an inhaled anti-infective to treat 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.

Recent Developments and ARIKACE Clinical Summary

We are conducting a Phase 2 clinical trial in patients who have lung infections caused by non-tuberculous mycobacteria (NTM) in the U.S and Canada. During October 2013, we concluded the patient enrollment phase of the study with 90 patients enrolled in the study. In addition, Insmed commenced the Scientific Advice Working Party (SAWP) process with the European Medicines Agency (EMA) and expects to have discussions with the EMA regarding ARIKACE for NTM lung disease during the fourth quarter of 2013.

In July 2013, we reported top-line results from our Phase 3 registrational clinical trial of ARIKACE in cystic fibrosis (CF) patients who have lung infections caused by *Pseudomonas aeruginosa* (*Pa*) that was conducted in Europe and Canada. In summary, once-daily ARIKACE achieved its primary endpoint of non-inferiority when compared to twice-daily TOBI (tobramycin inhalation solution) for relative change in FEV1 from baseline to the end of the study. On October 17, 2013, we reported additional results from this study at the North American Cystic Fibrosis Conference that were consistent with our previously reported top-line results. We are also conducting a two-year, open-label safety study that enrolled patients who also completed our Phase 3 registrational clinical trial in CF patients in Europe and Canada.

Our 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 then 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 CF patients with Pa infections and patients with NTM lung infections. The following table summarizes the current status of ARIKACE development.

Product Candidate/Target Indications	**Status**	**Next Expected Milestone(s)**
ARIKACE Pa lung infections in CF patients	• Completed a Phase 3 registrational clinical trial that was conducted in Europe and Canada. • Reported top-line results from our Phase 3 registrational clinical trial in July 2013 and reported additional results during October 2013. • Conducting a two-year, open-label safety study in patients that completed our Phase 3 registrational clinical trial in Europe and Canada. We expect to complete this study in mid-2015.	• We expect to submit regulatory filings with the European Medicines Agency (EMA) and Health Canada during the first half of 2014. • We plan to evaluate our plans for CF in the US after reviewing the results from our Phase 2 clinical trial in NTM. • If approved, we plan to commercialize ARIKACE ourselves in Europe and in Canada and it would be the only once-a-day treatment for Pa lung infections in CF patients.

- Granted orphan drug designation in Europe and the US.

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ARIKACE Non-tuberculous mycobacteria (NTM) lung infections	• Completed enrollment of 90 patients in a Phase 2 clinical trial in the US and Canada. • Commenced the SAWP process with the EMA. • Granted Qualified Infectious Disease Product (QIDP) designation by the U.S. Food and Drug Administration (FDA) in June 2013. • Granted Fast Track designation by the FDA in June 2013. • Granted orphan drug designation in the US.	• We expect to launch a single arm, open-label, supportive study in the U.S. and Europe during the fourth quarter of 2013. • We expect to have discussions with the EMA under the SAWP process during the fourth quarter of 2013. • We expect to report top-line clinical results from our Phase 2 clinical trial and related regulatory pathway dialogue with the FDA by the end of the first quarter of 2014. • If approved, ARIKACE would be the first approved inhaled antibiotic treatment for NTM lung infections. • If approved, we plan to commercialize ARIKACE ourselves initially in the U.S. and eventually in Europe and in Canada.
ARIKACE Pa 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 2 clinical trial in patients with NTM infections.

ARIKACE is considered a new molecular entity (NME) by the 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 Pa and NTM. ARIKACE is in the aminoglycoside class of antibiotics.

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 our Phase 3 study in CF patients with Pa lung infections, ARIKACE, administered once-daily demonstrated improvements in patient lung function that were comparable to TOBI (tobramycin inhalation solution), administered twice-daily and that remained above baseline at the end of the study.

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If approved for CF patients with Pa 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 Pa 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 during the fourth quarter of 2013. On June 28, 2013, ARIKACE was granted QIDP designation and Fast Track designation by the FDA for the treatment of Non-Tuberculous Mycobacterial lung infections.

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 Pa 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 for the treatment of certain lung infections 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. 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 Pa infections, this means penetration of biofilm and facilitated drug release by factors that are secreted by the bacteria, and for NTM, this 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.

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ARIKACE for CF Patients with *Pseudomonas aeruginosa* (Pa) Lung Infections

Disease

CF is an inherited chronic disease that affects the lungs and digestive system and 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, the 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, in CF patients a defective gene and its protein product cause the body to produce unusually thick, sticky mucus that clogs the lungs. This creates an ideal environment for various pathogens, such as Pa, to colonize and lead to chronic infection of the lung, inflammation and progressive loss of lung function. In fact, chronic bronchial infections with Pa are a major cause of morbidity and mortality among patients with CF. Once a CF patient acquires a Pa 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 Pa in CF patients increases with age. It is estimated that 70% of adult CF patients have chronic infection due to Pa (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

We completed a registrational Phase 3 clinical trial of ARIKACE for CF patients with Pa lung infections in Europe and Canada during the second quarter of 2013. The Phase 3 trial was a randomized, open label, multi-center study designed to access the comparative safety and efficacy of once-daily ARIKACE administered for approximately 13 minutes via the eFlow Nebulizer System and twice-daily TOBI (tobramycin inhalation solution) administered for approximately 15 minutes per treatment via the PARI LC Plus Nebulizer System for a daily total of approximately 30 minutes per day in CF patients with Pa. A total of 302 adult and pediatric CF patients with chronic Pa were randomized to receive 28-days of ARIKACE treatment or TOBI delivered twice-daily via the PARI LC Plus® Nebulizer System over a 24-week treatment period. The primary endpoint of the study was relative change in forced expiratory volume in one second (FEV1) measured after three treatment cycles, with each cycle consisting of 28 days on treatment and 28 days off treatment. The study was designed to demonstrate non-inferiority to TOBI at a 5% non-inferiority margin with 80% power agreed upon by us and the European Medicines Agency (EMA). Secondary endpoints measured were relative changes in FEV1 at other time points, time to and number of pulmonary exacerbations, time to antibiotic rescue treatment, change in density of Pa in sputum, respiratory hospitalizations and changes in Patient Reported Outcomes assessing Quality of Life. Top-line results from this study indicated:

- ARIKACE achieved its primary endpoint of non-inferiority to TOBI for relative change in FEV1 from baseline to the end of the study;

- Overall, secondary endpoints, as summarized above, showed comparability of once-daily ARIKACE compared with twice-daily TOBI; and

- The safety profile of ARIKACE was comparable to TOBI during all three treatment cycles, with adverse events consistent with those seen in similar studies and expected in a population of CF patients receiving inhaled antibiotics. There was no difference between arms in the reporting of serious adverse events and there were no unexpected adverse events.

On October 17, 2013, we presented additional results from this study at the North American Cystic Fibrosis Conference that were consistent with our previously reported top-line results.

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We are conducting a two-year, open label safety study in patients that also completed our registrational Phase 3 clinical study of ARIKACE for CF patients with Pa lung infections in Europe and Canada. Approximately 75% of the eligible patients that completed our registrational Phase 3 clinical study consented to participate in the safety study. The patients in this study will receive ARIKACE for up to a two year period, using the same cycles of a 28 day on-treatment period and a 28 day off-treatment period. We expect to use interim data from this study as part of our regulatory filings with the EMA and Health Canada, which we expect to submit during the first half of 2014, and we expect to complete this study in mid-2015.

ARIKACE has been granted orphan drug status in the US and Europe for the treatment of Pa lung infections.

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 in certain countries in Europe, as well as outside of Europe, and Canada and the US.

In 2013, we commenced preparations for the potential commercialization of ARIKACE, including hiring Matt Pauls, our chief commercial officer. We plan to fill several other new positions to support our sales and marketing efforts.

ARIKACE for Patients with NTM Lung Infections

Disease

Non-tuberculous *mycobacteria,* or NTM, are bacteria commonly found 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 with NTM often are immuno-compromised or have structural damage in their lungs at the time of the infection.

NTM are bacteria 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 pulmonary 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).

In the US, the prevalence of human disease attributable to NTM has increased over the past two decades. In 2012, in collaboration with the NIH, we funded a study performed by Clarity Pharma Research that showed there were an estimated 50,000 cases in the US in 2011 and that such cases were estimated to be growing at a rate of 10% per year. NTM is four to five times more prevalent than TB in the US (Incidence of TB from Center for Disease Control and Prevention Morbidity and Mortality Weekly Report, March 2012). In a decade-long study, researchers found that the diagnosis of NTM is increasing at approximately 8% per year and that those NTM patients over the age of 65 are 40% more likely to die than those who do not have the disease (Adjemian et al. Prevalence of Pulmonary Nontuberculous Mycobacterial Disease among Medicare Beneficiaries, USA, 1997-2007, American Journal of Respiratory and Critical Care Medicine, April 2012).

Although there are many species of NTM that have been reported to cause lung infections, ARIKACE is intended to treat two of the most common, *Mycobacterium Avium* Complex (MAC) and *Mycobacterium abscessus*

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(*M. abscessus*). MAC accounts for the vast majority of NTM lung infections with prevalence rates from 72% to more than 85% in the US. The reported prevalence rates for *M. abscessus* range from 3% to 11% in the US and the rate may even be higher in recalcitrant patients. The diagnosed prevalence of NTM species causing lung infections varies geographically with MAC rates of 25% to 55% reported in Europe.

We conducted a chart audit to more specifically quantify the incidence of NTM lung infections in both Europe and Japan. We believe the diagnosed prevalence of NTM lung disease in Europe is approximately 30,000 patients, and we believe the diagnosed prevalence of NTM lung disease in Japan is also approximately 30,000 patients.

Current Clinical Program

We are currently conducting a Phase 2 clinical trial in the US and Canada for ARIKACE in adult patients with recalcitrant NTM lung infections. We began enrolling patients in June 2012 and during October 2013, we concluded patient enrollment with 90 patients enrolled in this Phase 2 clinical study. In addition, during October 2013 Insmed commenced the Scientific Advice Working Party (SAWP) process with the European Medicines Agency (EMA) and expects to have discussions with the EMA regarding ARIKACE for NTM lung disease during the fourth quarter of 2013.

The Phase 2 clinical trial is a randomized, placebo-controlled study of 90 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 American Thoracic Society and Infectious Disease Society of America (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 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 semi-quantitative measurement of the change in mycobacterial density on a seven-point scale from baseline (day one) to the end of the randomized portion of the trial on the 84th day 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, tertiary and exploratory endpoints, including but not limited to 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 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.

On June 28, 2013, the FDA designated ARIKACE as a Qualified Infectious Disease Product (QIDP) for the treatment of NTM. The QIDP designation for ARIKACE enables us to benefit from certain incentives for the development of new antibiotics, including potentially more frequent and ongoing dialogue with FDA, priority review, and if ARIKACE is ultimately approved by the FDA, a five-year exclusivity extension under the The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. These incentives are

provided under the Generating Antibiotic Incentives Now Act (the GAIN Act), which was signed into law in July 2012.

Additionally, on June 28, 2013, the FDA granted Fast Track designation to ARIKACE for the treatment of NTM. The Fast Track designation is intended to expedite the review of new drugs that have the potential to serve unmet medical needs in serious or life-threatening conditions.

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

Pursuant to ARIKACE s recently designated QIDP status, we expect to continue our dialogue with the FDA regarding the regulatory pathway for registration and approval of ARIKACE for the treatment of NTM, and

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we expect to complete our review of the results from this clinical trial and related dialogue with the FDA by the end of the first quarter of 2014.

In addition to the Phase 2 clinical trial outlined above, we intend to launch a single arm, open label supportive study in the U.S. and Europe during the fourth quarter of 2013. We currently anticipate enrolling approximately 50 patients in this study who have NTM lung infections that were not eligible for enrollment into our Phase 2 clinical trial. We believe that clinical data collected from our experience with these patients will further help regulatory authorities evaluate ARIKACE s safety and suitability for treating patients with NTM lung infections.

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 believe there will be substantial overlap among lung specialist physicians who treat CF patients and Pa lung infections and those who have NTM lung infections thereby allowing us to leverage our commercial infrastructure across both indications. We may seek to out-license ARIKACE in certain countries in Europe, as well as outside of Europe, Canada and the US.

In 2013, we commenced preparations for the potential commercialization of ARIKACE, including hiring Matt Pauls, our chief commercial officer. We plan to fill several other new positions to support our sales and marketing efforts.

ARIKACE for Non-CF Bronchiectasis Patients with *Pseudomonas aeruginosa* (Pa) Lung Infections

Disease

We believe ARIKACE has the potential to be used to treat non-CF bronchiectasis characterized by Pa lung infections. However, we are currently concentrating our development efforts on the treatment of Pa 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 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

In May 2009, we completed our randomized, placebo controlled US Phase 2 study (TR02-107) of ARIKACE for the treatment of chronic Pa 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 Pa 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 duration and self-limiting. One patient discontinued treatment due to dysphonia (hoarseness or difficulty speaking) and cough.

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There was a statistically significant reduction in Pa 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-Pa 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 Pa lung infections and for patients with NTM lung infections. Following those studies, we will evaluate whether to develop ARIKACE further for non-CF bronchiectasis.

ARIKACE has been granted orphan drug status in the US for the treatment of bronchiectasis in patients with Pa or other susceptible pathogens.

INTELLECTUAL PROPERTY

Patents

In addition to the intellectual property already granted to us, during September and October 2013, we were informed of two U.S. patent allowances as follows:

- The U.S. Patent and Trademark Office (USPTO) intends to grant U.S. Patent Application No. 13/666,420 for ARIKACE in a patent titled, Lipid-based compositions of anti-infectives for treating pulmonary infections and methods of use thereof. Once granted, it will provide exclusivity at least through December 5, 2026. This new patent will cover an aerosolized composition of Insmed s novel, once-daily inhalation formulation comprising amikacin and liposomal delivery technology for the treatment of pulmonary infections, including *Pseudomonas aeruginosa* and mycobacterial infections, among others.

- The USPTO intends to grant U.S. Patent Application No. 13/527,213 for ARIKACE in a patent entitled, Lipid-based compositions of anti-infectives for treating pulmonary infections and methods of use thereof. Once granted, it will provide exclusivity at least through December 5, 2026. This new patent will cover a method for treating a pulmonary infection, including a *Pseudomonas aeruginosa* and a mycobacterial infection, among others, in a cystic fibrosis patient, with an aerosolized pharmaceutical formulation comprising an aminoglycoside together with Insmed s liposomal delivery technology. Specifically, the patent will cover a method for treating a pulmonary infection in a cystic fibrosis patient comprising administering to the patient an aerosolized composition comprising ARIKACE.

On September 4, 2013, the European Patent Office granted Patent No. 1909759 entitled Sustained Release of Anti-infective Aminoglycosides for ARIKACE. The granted patent provides protection for novel anti-infective formulations comprising an aminoglycoside and our liposomal

delivery technology, including ARIKACE. The composition of matter patent provides exclusivity in any of the European Patent Office s member states where we choose to validate the patent, at least through July 19, 2026. The granted patent also includes claims relating to the use of the aforementioned aminoglycoside/lipid formulations for treating pulmonary infections, including those caused by Pa lung infections and certain mycobacterial infections, among others.

On October 16, 2013, the European Patent Office granted EU Patent No. 1581236, for ARIKACE in a patent titled, Sustained release of anti-infectives. This patent provides exclusivity at least through October 29, 2023 in any European Patent Office member state where Insmed chooses to validate the patent. The patent provides protection for the use of ARIKACE s formulation comprising amikacin and liposomal delivery technology for the treatment of pulmonary infections in CF patients. Specifically, the patent includes claims relating to the use of the

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aforementioned formulation for treating *Pseudomonas aeruginosa* pulmonary infections, as well as certain mycobacterial infections, among others.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Other Revenue

Other revenue during the nine months ended September 30, 2013 solely consists of an $11.5 million payment the Company received from Premacure (now Shire plc) in exchange for the Company s right to receive royalties under its license agreement with Premacure (see Note 7. *License and Collaborative Agreements* to the consolidated financial statements included in Part 1. Financial Information, Item 1. Financial Statements for additional information regarding our agreement with Premacure). The Company recorded this as Other revenue after all four revenue recognition criteria were present and the Company had no continuing performance obligations related to the payment received.

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 a contract manufacturing organization that manufactures 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 recently completed a registrational Phase 3 clinical trial of ARIKACE for CF patients with Pa lung infections in Europe and Canada. We are currently conducting two clinical trials: (1) a two-year, open label safety study in consenting patients who completed the Phase 3 trial of ARIKACE for CF patients with Pa lung infections in Europe and Canada, and (2) a Phase 2 trial in the US in which we are evaluating ARIKACE for NTM infections. Since our business combination with Transave through September 30, 2013, our external research and development expenses for our ARIKACE program have been approximately $68.8 million. We expect that our development efforts during the remainder of 2013 and 2014 will principally relate to the study 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, and audit, 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 lead product candidate, ARIKACE.

Investment Income and Interest Expense

Investment income consists of interest and dividend income earned on our cash and cash equivalents, and in the prior year periods also includes realized gains (losses) on the sale of our short-term investments. Interest expense consists primarily of interest costs related to our debt.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2013 and 2012

Net Loss

Net loss for the three months ended September 30, 2013 was $17.3 million (or $0.46 per common share basic and diluted) compared with a net loss of $9.4 million (or $0.38 per common share basic and diluted) for the three months ended September 30, 2012. The increase in our net loss in 2013 of $7.9 million was primarily due to:

- A $6.4 million increase in our research and development expenses that primarily resulted from (1) a $2.6 million increase in expense for our two-year extension study in CF patients in Europe and Canada and our Phase 2 NTM clinical study in the US, (2) a $2.1 million increase in costs related to process improvements (and related validation work) to our ARIKACE manufacturing process, and (3) a $1.0 million increase in compensation expenses resulting from an increase in headcount; and

- A $1.1 million increase in our general and administrative expenses primarily resulted from a $1.3 million increase in professional fees related to market research and other related costs, and legal fees.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2013 and 2012 comprised the following:

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	Three Months Ended September 30,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands)			
External expenses				
Clinical development	$ 4,731	$ 2,116	$ 2,615	124%
Manufacturing	3,291	1,179	2,112	179%
Regulatory and quality assurance	550	632	(82)	-13%
Subtotal - external	8,572	3,927	4,645	118%
Internal expenses				
Compensation and related expenses	2,482	1,491	991	66%
Other internal operating expenses	1,041	288	753	261%
Subtotal - internal	3,523	1,779	1,744	98%
Total	$ 12,095	$ 5,706	$ 6,389	112%

Research and development expenses increased to $12.1 million during the three months ended September 30, 2013 from $5.7 million in the same period in 2012. The $6.4 million increase is primarily due to a $4.6 million increase in external costs primarily consisting of (1) a $2.6 million increase in expenses for our two-year, open-label safety study in CF patients in Europe and Canada and our Phase 2 NTM clinical study in the US and Canada, and (2) a $2.1 million increase in costs related to process improvements (and related validation work) we made to our ARIKACE manufacturing process during the three months ended September 30, 2013. We initiated the Phase 2 NTM study in the second quarter of 2012 and the two-year extension study in October 2012. Also contributing to the $6.4 million increase was a $1.7 million increase in internal expenses, including a $1.0 million increase in compensation and related expenses and a $0.7 million increase in recruiting expenses, travel expenses to clinical trial sites and manufacturing locations, consulting fees and other internal research and development expenses.

General and Administrative Expenses

General and administrative expenses increased to $4.7 million during the three months ended September 30, 2013 from $3.6 million in the same period in 2012. The $1.1 million increase was primarily due to a $1.3 million increase in professional fees that was primarily related to market research and other related costs, and legal fees. Partially offsetting this increase was a $0.2 million net decrease in other general and administrative expenses.

Investment Income

Investment income decreased to $0.0 million during the three months ended September 30, 2013 from $0.2 million in the same period in 2012. The $0.2 million decrease is a result of our decision to amend our investment policy and only invest in certain types of mutual and money market funds, US Treasury obligations, and bank certificates of deposit. During the three months ended September 30, 2013, the majority of our cash was invested in money market 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 $0.5 million during the three months ended September 30, 2013 from $0.2 in 2012. The $0.3 million increase was due to the second increment of $10.0 million we borrowed in December 2012 under our Loan Agreement we entered into in June 2012.

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Comparison of the Nine Months Ended September 30, 2013 and 2012

Net Loss

Net loss for the nine months ended September 30, 2013 was $39.9 million (or $1.19 per common share basic and diluted) compared with a net loss of $25.9 million (or $1.04 per common share basic and diluted) for the nine months ended September 30, 2012. The increase in our net loss in 2013 of $14.0 million was primarily due to a $16.5 million increase in our research and development expenses that primarily resulted from the activities under our Phase 3 clinical study in CF patients and related two-year, open-label safety study in Europe and Canada, and our Phase 2 NTM clinical study in the US. We initiated the Phase 2 CF study and Phase 2 NTM study in the second quarter of 2012 and initiated the two-year extension study in October 2012. Also contributing to the increase in the net loss was a $7.9 million increase in our general and administrative expenses that was primarily due to a $3.9 million increase in compensation expense (including $3.7 million in non-cash stock-based compensation expense) and a $3.9 million increase in professional fees, including a $2.2 million increase in legal fees related to the investigation, accounting and reporting of excess equity awards and $1.8 million for consulting expenses, mainly for market research and other related costs. Partially offsetting these increases in operating expenses was Other revenue of $11.5 million related to a one-time payment for the sale of the Company s right to receive future royalties under its license agreement with Premacure (now Shire plc).

Other Revenue

Other revenue during the nine months ended September 30, 2013 solely consists of a one-time $11.5 million payment the Company received from Premacure (now Shire plc) in exchange for the Company s right to receive royalties under its license agreement with Premacure. The Company recorded this as Other revenue during the three months ended June 30, 2013, since all revenue recognition criteria were present and the Company has no continuing performance obligations related to the payment received.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2013 and 2012 comprised the following:

	Nine Months Ended September 30,		Increase (Decrease)	
	2013	2012	$	%
	(in thousands)			
External expenses				
Clinical development	$ 16,685	$ 6,075	$ 10,610	175%
Manufacturing	6,447	5,242	1,205	23%
Regulatory and quality assurance	1,357	1,550	(193)	-12%
Subtotal - external	24,489	12,867	11,622	90%
Internal expenses				
	7,124	4,451	2,673	60%

Compensation and related expenses						
Other internal operating expenses		3,041		872	2,169	249%
Subtotal - internal		10,165		5,323	4,842	91%
Total	$	34,654	$	18,190	$ 16,464	91%

Research and development expenses increased to $34.7 million during the nine months ended September 30, 2013 from $18.2 million in the same period in 2012. The $16.5 million increase is primarily due to:

- An $11.6 million increase in external costs primarily consisting of a $10.6 million increase in expenses for our Phase 3 CF clinical study and our two-year, open-label safety study in Europe and Canada, and our Phase 2 NTM clinical study in the US during the nine months ended September 30, 2013. We initiated the Phase 2 CF study and Phase 2 NTM study in the second quarter of 2012 and initiated the two-year extension study in October 2012. Also contributing to the $11.6 million increase was a $1.2 million

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increase in costs related to process improvements we made to our ARIKACE manufacturing process; and

- A $4.8 million increase in internal expenses, including a $2.7 million increase in compensation and related expenses (including a $1.2 million in non-cash stock-based compensation expense), a $0.7 million increase in recruiting expenses, a $0.5 million increase in travel expenses to clinical trial sites and manufacturing locations, and a $0.9 million increase in other research and development expenses.

General and Administrative Expenses

General and administrative expenses increased to $16.3 million during the nine months ended September 30, 2013 from $8.4 million in the same period in 2012. The $7.9 million increase was primarily due to:

- A $3.9 million increase in compensation expense (including $3.7 million in non-cash stock-based compensation expense); and

- A $3.9 million increase in professional fees that was primarily related to a $2.2 million increase in legal fees primarily resulting from the investigation, accounting and reporting of excess equity awards (see Note 6, Stock Based Compensation to the consolidated financial statements for additional information) and $1.8 million for consulting expenses, mainly for market research and other related costs.

Investment Income

Investment income decreased to $0.1 million during the nine months ended September 30, 2013 from $0.9 million in the same period in 2012. The $0.8 million decrease is a result of our decision to amend our investment policy and only invest in certain types of mutual and money market funds, U.S. Treasury obligations, and bank certificates of deposit. During the nine months ended September 30, 2013, the majority of our cash was invested in money market 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 $1.8 million during the nine months ended September 30, 2013 from $0.2 million in the same period in 2012. The $1.6 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 $0.0 during the nine months ended September 30, 2013 and 2012, respectively. The Company s effective tax rate was (3.0%) and 0% for the nine months ended September 30, 2013 and 2012, respectively. The benefit for income taxes recorded and the effective tax rate for the nine months ended September 30, 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 September 30, 2013 remains fully offset by a valuation allowance due to the Company s history of losses.

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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 September 30, 2013, we had total cash and cash equivalents on hand of $128.0 million, as compared with $92.9 million of cash, cash equivalents, and a certificate of deposit on hand as of December 31, 2012. The $35.1 million net increase was due principally to $67.0 million of net proceeds we received from an underwritten public offering of our common stock we completed during July 2013 and an $11.5 million payment we received from Premacure (now Shire plc) during May 2013. These inflows were partially offset by our use of $44.1 million to fund our operations. Our working capital was $109.9 million as of September 30, 2013.

On July 22, 2013, the Company completed an underwritten public offering of 6,900,000 shares of the Company s common stock, which includes the underwriter s exercise in full of its over-allotment option of 900,000 shares, at a price to the public of $10.40 per share. The Company s net proceeds from the sale of the shares, after deducting the underwriter s discount and estimated offering expenses of $4.7 million, were $67.0 million.

We believe that our cash and cash equivalents of $128.0 million as of September 30, 2013 will be sufficient to fund our operations through 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 $32.6 million and $22.1 million for the nine months ended September 30, 2013 and 2012, respectively. Absent the one-time $11.5 million cash payment we received from Premacure in May 2013, net cash used in operating activities for the nine months ended September 30, 2013 would have been $44.1 million. 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 two of these clinical trials through September 2013 and completion of one of these clinical trials during the quarter ended September 30, 2013.

Net cash provided by investing activities was $1.4 million and $16.9 million during the nine months ended September 30, 2013 and 2012, respectively. The net cash provided by investing activities in 2013 of $1.4 million related to the maturity of a certificate of deposit of $2.2 million that was partially offset by fixed asset purchases of $0.7 million for lab and computer equipment. The net cash provided by investing activities in the nine months ended September 30, 2012 was primarily a result of $17.1 million of sales of short-term investments.

Net cash provided by financing activities was $68.4 million and $35.3 million for the nine months ended September 30, 2013 and 2012, respectively. The net cash provided by financing activities of $68.4 million during 2013 primarily consists of $67.0 million of net proceeds we received from an underwritten public offering of our common stock we completed during July 2013 and $1.5 million of proceeds received from stock option exercises. The net cash provided by financing activities of $35.3 million during 2012 primarily consisted of $25.7 million of proceeds received from the issuance of common stock and $9.7 million of borrowings of long-term debt.

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 increments by signing two Secured Promissory Notes (Note A and Note B and collectively, the Notes) on

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June 29, 2012 and December 27, 2012, respectively. Notes A and B bear interest at 9.25%. Note A was originally scheduled 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 was originally scheduled 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 Loan Agreement provided that in certain circumstances the Company could delay the first principal payment by five months. In July 2013, subsequent to the completion of certain ARIKACE-related development milestones, the Company elected to extend the interest only period under the Notes from July 31, 2013 to December 31, 2013 and delay the first monthly principal repayments for Notes A and B from August 1, 2013 to January 1, 2014. The election did not change the maturity date for Notes A and B, which is 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 will be required to pay an end of term charge of $0.4 million upon termination of the Loan Agreement.

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 $0.9 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 $1.5 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 $0.8 million as of September 30, 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 have a capital lease for leasehold improvements with monthly payments through December 2014. As of September 30, 2013, future payments under the two promissory notes (taking into consideration the extension of the interest-only period from August 1, 2013 to December 31, 2013 that we executed with our lender during July 2013), the capital lease and minimum future payments under non-cancellable operating leases are as follows:

	As of September 30, 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	$ 7,055	$ 12,945	$	$
Contractual interest	2,481	1,656	825		
Capital lease obligations					
Debt maturities	80	64	16		
Contractual interest	1	1			
Operating leases	2,421	1,196	1,182	42	
Purchase obligations					
Total contractual obligations	$ 24,983	$ 9,972	$ 14,968	$ 42	$

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

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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 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 U.S. 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 and patients with NTM;
- 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.

During July 2013, we issued approximately $71.8 million of our common stock utilizing the $100.0 million shelf registration statement we filed with the Securities and Exchange Commission in May 2013. We believe that our cash and cash equivalents totaling $128.0 million as of September 30, 2013 will be sufficient to fund our operations through 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 from product sales. We do not expect to generate significant revenue from product sales 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

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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 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. We also grant performance-based stock options to employees. The grant-date fair value of the performance-based stock options is recognized as compensation expense over the implicit service period using the accelerated attribution method once it is probable that the performance condition will be achieved. 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 incentive plans, 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 and nine months ended September 30, 2013 and 2012.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Volatility	87.7% - 90.3%	100.2% - 104.5%	87.7% - 96.0%	100.2% - 107.1%
Risk-free interest rate	1.39% - 1.65%	0.57% - 0.80%	0.65%-1.65%	0.57% - 0.99%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term (in years)	6.25	6.25	6.25	6.25

For the three and nine months ended September 30, 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 September 30, 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2013, our cash and cash equivalents were in cash accounts or were invested in money market funds. Such accounts or investments are not insured by the federal government.

As of September 30, 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

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June 2012. A hypothetical 10% change in interest rates occurring on September 30, 2013 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 U.S. 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 operation and during the three and nine month periods ended September 30, 2013 and 2012, our results of operation 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:

- 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

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- 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 review of our equity compensation grants, we determined that we had inadvertently exceeded the annual per-person sub-limits that, at the time, were 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 (the excess awards). Among other items, we agreed to condition the continued vesting and exercise of the excess awards on approval of the excess awards by our shareholders. Such approval was received at our Annual Meeting of Shareholders held on May 23, 2013 (2013 Annual Meeting). We have not exceeded the overall share reserve previously provided for by the 2000 Stock Incentive Plan or currently provided for by our 2013 Incentive Plan, which was approved by our shareholders at our 2013 Annual Meeting, 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 Vice-President, Finance. During the second quarter of 2013, we hired an Assistant Controller and during the third quarter of 2013, we hired a new General Counsel and Corporate Secretary. We believe these additions have helped strengthen our internal control environment and our internal controls. Remediation efforts we have implemented to date include modification of certain forms, adding and strengthening internal controls within certain processes, training of certain personnel and our Board members, rotation of Board members to different committees or committee positions, 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. Additional remediation efforts we expect to implement include, among other things, adding and continued strengthening of internal controls within certain processes, additional training of certain personnel, 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 September 30, 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, and 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. On January 19, 2013, the Court granted our Motion for Summary Judgment and dismissed all of the outstanding claims. Plaintiff appealed the Court s decision to the U.S. Court of Appeals for the Second Circuit. We anticipate a decision 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 payments due to us. Discovery is nearly complete and the trial is expected to begin during the first quarter of 2014. Following trial, the court will determine the fair value of the Transave Stock. 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.

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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 and our Quarterly Report on Form 10-Q for the three months ended June 30, 2013. 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 and our Quarterly Report on Form 10-Q for the three months ended June 30, 2013.

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 September 30, 2013.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Adoption of an Executive Bonus Plan

On October 31, 2013, the Company s Board of Directors adopted the Insmed Incorporated Senior Executive Bonus Plan (the Executive Bonus Plan). Under its terms, the Executive Bonus Plan is available to members of the Company s senior executive team that are Section 16 reporting persons. For each fiscal year, the Company s Compensation Committee will express a performance bonus amount payable in terms of a target bonus. Bonuses are to be paid after the completion of a fiscal year upon the achievement of targets and designated performance criteria, as specified in the Executive Bonus Plan. To receive a bonus payment under the Executive Bonus Plan, an individual must be employed by the Company on the date such bonus is paid. A copy of the Executive Bonus Plan is attached as an exhibit to this Form 10-Q.

Termination of a Material Definitive Agreement

On October, 31, 2013, the Company s Board of Directors terminated the Amended and Restated Insmed Incorporated 2000 Employee Stock Purchase Plan (the Stock Purchase Plan). Under the terms of the Stock

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Purchase Plan, employees were entitled to purchase common stock of the Company at a price equal to 85% of the fair market value of the shares on the purchase date. The Stock Purchase Plan was intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code.

The foregoing description does not purport to be a complete description of the rights and obligations of the Company or the participants under the Stock Purchase Plan. The above description is qualified in its entirety by reference to the Stock Purchase Plan, a copy of which is included as Exhibit 10.22 in the Company s Annual Report on Form 10-K for the year ended December 31, 2006, filed with the Securities and Exchange Commission on March 16, 2007.

Departure of Director and Appointment of New Director

On October 30, 2013, the Board of Directors of the Company appointed Mr. David W.J. McGirr as a director of the Board and as a member of the Company s Audit Committee. On October 31, 2013, the Board appointed Mr. McGirr to be Chairman of the Audit Committee and Mr. Richard Kollender tendered his resignation from the Board and as Chairman of the Audit Committee. As a result of Mr. Kollender s resignation and Mr. McGirr s appointment, the Insmed Board of Directors currently consists of seven directors, including six independent directors.

ITEM 6. EXHIBITS

A list of exhibits filed herewith is included on the Exhibit Index, which immediately 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: November 5, 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 July 29, 2013, between Insmed Incorporated and Christine Pellizzari
10.2	Insmed Incorporated Senior Executive Bonus 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 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
32.1	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
32.2	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