INSMED Inc
Form 10-Q
May 05, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

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.)
10 Finderne Avenue, Building 10 **Bridgewater, New Jersey**	**08807**
(Address of principal executive offices)	(Zip Code)

(908) 977-9900

(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 x	Accelerated filer o
Non-accelerated filer o	Small Reporting Company o

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

As of May 1, 2016, there were 61,877,905 shares of the registrant s common stock, $0.01 par value, outstanding.

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INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

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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. IPLEX is a reg trademark and ARIKAYCE, INSMED and CONVERT are trademarks 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. CONSOLIDATED FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except par value and share data)

	As of March 31, 2016 (unaudited)	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 252,872	$ 282,876
Prepaid expenses and other current assets	5,618	5,242
Total current assets	258,490	288,118
In-process research and development	58,200	58,200
Fixed assets, net	8,899	8,092
Other assets	2,117	2,146
Total assets	$ 327,706	$ 356,556
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 8,688	$ 7,468
Accrued expenses	10,495	10,995
Other current liabilities	686	683
Current portion of long-term debt	5,674	3,113
Total current liabilities	25,543	22,259
Debt, long-term	19,114	22,027
Other long-term liabilities	586	572
Total liabilities	45,243	44,858
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 61,872,863 and 61,813,995 issued and outstanding shares at March 31, 2016 and December 31, 2015, respectively	619	618
Additional paid-in capital	904,342	900,043
Accumulated deficit	(622,495)	(588,963)
Accumulated other comprehensive loss	(3)	
Total shareholders equity	282,463	311,698
Total liabilities and shareholders equity	$ 327,706	$ 356,556

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands, except per share data)

	Three Months ended March 31,	
	2016	**2015**
Revenues	$	$
Operating expenses:		
Research and development	20,547	17,164
General and administrative	12,520	9,542
Total operating expenses	33,067	26,706
Operating loss	(33,067)	(26,706)
Investment income	170	23
Interest expense	(622)	(722)
Other income, net	15	36
Loss before income taxes	(33,504)	(27,369)
Provision for income taxes	28	
Net loss	$ (33,532)	$ (27,369)
Basic and diluted net loss per share	$ (0.54)	$ (0.55)
Weighted average basic and diluted common shares outstanding	61,858	49,957
Net loss	$ (33,532)	$ (27,369)
Other comprehensive loss:		
Cumulative translation adjustment	(3)	
Total comprehensive loss	$ (33,535)	$ (27,369)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (unaudited)

(in thousands)

	Three months ended March 31,	
	2016	**2015**
Operating activities		
Net loss	$ (33,532)	$ (27,369)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	514	432
Stock based compensation expense	4,219	4,522
Amortization of debt discount and debt issuance costs	38	106
Accrual of the end of term charge on the debt		27
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(316)	(202)
Accounts payable	527	(1,389)
Accrued expenses and other	(978)	(1,010)
Net cash used in operating activities	(29,528)	(24,883)
Investing activities		
Purchase of fixed assets	(588)	(1,264)
Net cash used in investing activities	(588)	(1,264)
Financing activities		
Proceeds from exercise of stock options	81	1,475
Net cash provided by financing activities	81	1,475
Effect of exchange rates on cash and cash equivalents	31	
Net decrease in cash and cash equivalents	(30,004)	(24,672)
Cash and cash equivalents at beginning of period	282,876	159,226
Cash and cash equivalents at end of period	$ 252,872	$ 134,554
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 975	$ 663
Cash received for taxes	$	$ 994

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Insmed is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The Company s lead product candidate is ARIKAYCE, or liposomal amikacin for inhalation (LAI), which is in late-stage development for patients with nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and which can be fatal. The Company s earlier stage pipeline includes INS1009, a nebulized prodrug formulation of treprostinil.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999 and its principal executive offices are located in Bridgewater, New Jersey. During 2015, the Company formed several subsidiaries in Europe in preparation for the commercialization of ARIKAYCE, upon approval in the European Union (EU), and to support its global tax structure. The Company has operations in the United States (US), Ireland, Germany, France, the United Kingdom (UK) and the Netherlands. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Transave, LLC, Insmed Pharmaceuticals, Inc., Insmed Limited, Celtrix Pharmaceuticals, Inc., Insmed Holdings Limited, Insmed Ireland Limited, Insmed France SAS, Insmed Germany GmbH and Insmed Netherlands B.V. All intercompany transactions and balances have been eliminated in consolidation.

The accompanying unaudited interim consolidated financial statements have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the US for complete consolidated financial statements are not included herein. The interim statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015.

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. The unaudited interim consolidated financial information presented herein reflects all normal adjustments that are, in the opinion of management, necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The Company is responsible for the unaudited interim consolidated financial statements included in this report.

2. Summary of Significant Accounting Policies

The following are interim updates to certain of the policies described in Note 2 to the Company s audited consolidated financial statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2015:

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 categorized based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Financial instruments in Level 1 generally include US treasuries and mutual funds listed in active markets.

The Company s only assets and liabilities which were measured at fair value as of March 31, 2016 and December 31, 2015 were Level 1 and such assets were comprised of cash and cash equivalents of $252.9 million and $282.9 million, respectively.

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The Company s cash and cash equivalents permit daily redemption and the fair values of these investments are based upon the quoted prices in active markets provided by the holding financial institutions. Cash equivalents consist of liquid investments with a maturity of three months or less from the date of purchase.

The Company recognizes transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no transfers in or out of Level 1, Level 2 or Level 3 during the three months ended March 31, 2016 and 2015.

As of March 31, 2016 and December 31, 2015, the Company held no securities that were in an unrealized gain or loss position. The Company reviews the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making its determination, the Company considers 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) the Company s ability and intent to retain the investment for a sufficient period of time for it to recover.

Net Loss Per Common Share - Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares and other dilutive securities outstanding during the period. Potentially dilutive securities from stock options, restricted stock units and warrants to purchase common stock 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 used to compute basic and diluted net loss per share for the three months ended March 31, 2016 and 2015 (in thousands, except per share data):

	Three Months Ended March 31,	
	2016	2015
Numerator:		
Net loss	$ (33,532)	$ (27,369)
Denominator:		
Weighted average common shares used in calculation of basic net loss per share	61,858	49,957
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 loss per share	61,858	49,957
Net loss per share:		
Basic and diluted net loss per share	$ (0.54)	$ (0.55)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of March 31, 2016 and 2015 as their effect would have been anti-dilutive (in thousands):

	2016	2015
Stock options to purchase common stock	6,221	4,821
Restricted stock units		53

New Accounting Pronouncements In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, Leases (Topic 842). This update requires an entity to recognize assets and liabilities for leases with lease terms of more than 12 months on the balance sheet. The Company plans to adopt this standard on January 1, 2019, and is still evaluating the impact that this standard will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The Company plans to adopt this standard on January 1, 2017, and is evaluating the impact that this standard will have on its consolidated financial statements.

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3. Identifiable Intangible Asset

The Company believes there are no indicators of impairment relating to its in-process research and development intangible asset as of March 31, 2016.

4. Accrued Expenses

Accrued expenses consist of the following:

	As of March 31, 2016	As of December 31, 2015
	(in thousands)	
Accrued clinical trial expenses	$ 5,355	$ 4,331
Accrued compensation	2,080	4,302
Accrued professional fees	1,870	1,202
Accrued technical operation expenses	552	702
Accrued interest payable	199	199
Accrued construction costs	100	57
Other accrued expenses	339	202
	$ 10,495	$ 10,995

5. Debt

In June 2012, the Company and its domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. (Hercules) that allowed the Company to borrow up to $20.0 million (Loan Agreement) at an interest rate of 9.25%. The interest rate for the term is floating and is defined as the greater of (i) 9.25% or (ii) 9.25% plus the sum of the US prime rate minus 4.50%. In December 2014, the Company and Hercules entered into a third amendment (the Third Amendment) to the Loan Agreement. In connection with the Third Amendment, the Company paid a commitment fee of $25,000, and at the closing, paid a facility fee of $125,000. Under the Third Amendment, the amount of borrowings was increased by $5.0 million to an aggregate total of $25.0 million and the interest-only period was extended through December 31, 2015. In December 2015, the Company entered into a fifth amendment (the Fifth Amendment) to the Loan Agreement, to exercise an option to extend the maturity date to January 1, 2018 with a payment to Hercules of $250,000. The Fifth Amendment extends the interest-only period, with principal repayments beginning in October 2016.

In connection with the Loan Agreement, the Company granted the lender a first position lien on all of the Company s assets, excluding intellectual property. Prepayment of the loans made pursuant to the Loan Agreement is subject to penalty and the Company was required to pay an end of term charge of $390,000, which was charged to interest expense (and accreted to the debt) using the effective interest method over the original life of the Loan Agreement. The end of term fee was paid in full as required in January 2016. Debt issuance fees 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.

The following table presents the components of the Company s debt balance as of March 31, 2016 (in thousands):

Debt:		
Notes payable	$	25,000
Fees paid to lender		(212)
Current portion of long-term debt		(5,674)
Debt, long-term	$	19,114

As of March 31, 2016, future principal repayments of the debt for each of the years ending December 31, were as follows (in thousands):

Year Ending in December 31:		
2016	$	2,873
2017		12,180
2018 (due in full on January 1, 2018)		9,947
	$	25,000

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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. The Company believes the estimated fair value at March 31, 2016 approximates the carrying amount.

6. *Shareholders Equity*

Common Stock As of March 31, 2016, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 61,872,863 shares of common stock issued and outstanding. In addition, as of March 31, 2016, the Company had reserved 6,220,983 shares of common stock for issuance upon the exercise of outstanding common stock options.

On April 6, 2015, the Company completed an underwritten public offering of 11,500,000 shares of the Company s common stock, which included the underwriter s exercise in full of its over-allotment option of 1,500,000 shares, at a price to the public of $20.65 per share. The Company s net proceeds from the sale of the shares, after deducting the underwriter s discount and offering expenses of $14.5 million, were $222.9 million.

Preferred Stock As of March 31, 2016 and December 31, 2015, the Company had 200,000,000 shares of preferred stock authorized with a par value of $0.01 and no shares of preferred stock were issued and outstanding.

7. Stock-Based Compensation

The Company s current equity compensation plan, the 2015 Incentive Plan, was approved by shareholders at the Company s Annual Meeting of Shareholders on May 21, 2015. The 2015 Incentive Plan is administered by the Compensation Committee and the Board of Directors of the Company. Under the terms of the 2015 Incentive Plan, the Company is authorized to grant a variety of incentive awards based on its common stock, including stock options (both incentive stock options and non-qualified stock options), performance options/shares and other stock awards, as well as the payment of incentive bonuses to all employees and non-employee directors. On May 21, 2015, 5,000,000 shares of the Company s common stock were authorized and as of March 31, 2016, there were 3,332,646 shares available for future grants (or issuances) of stock options, stock appreciation rights, restricted stock, restricted stock units and incentive bonuses under the 2015 Incentive Plan. The 2015 Incentive Plan will terminate on April 9, 2025 unless it is extended or terminated earlier pursuant to its terms. In addition, from time to time, the Company makes inducement grants of stock options. These awards are made pursuant to the NASDAQ inducement grant exception as a component of new hires employment compensation in connection with the Company s equity grant program.

Stock Options - The Company calculates the fair value of stock options granted using the Black-Scholes valuation model. The following table summarizes the Company s grant date fair value and assumptions used in determining the fair value of all stock options granted:

	Three Months Ended March 31,	
	2016	2015
Volatility	77%	79%-82%
Risk-free interest rate	1.16%-1.73%	1.31%-1.57%
Dividend yield	0.0%	0.0%
Expected option term (in years)	6.25	6.25
Weighted average fair value of stock options granted	$10.68	$11.66

For all periods presented, the volatility factor was based on the Company s historical volatility since the closing of the Company s merger with Transave in December 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 the actual percentage of option forfeitures since the closing of the Company s merger with Transave in December 2010, and this is the basis for future forfeiture expectations.

From time to time, the Company grants performance-condition options to certain of the Company s employees. Vesting of these options is subject to the Company achieving certain performance criteria established at the date of grant and the individuals fulfilling a service condition (continued employment). As of March 31, 2016, the Company had performance options totaling 158,334 shares outstanding which have not met the recognition criteria to date. For the three months ended March 31, 2015, approximately $1.5 million of non-cash compensation expense was recorded related to certain performance based options as the recognition criteria was met upon the marketing authorization application for ARIKAYCE being accepted for filing by the European Medicines Agency in February 2015.

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The following table summarizes the Company s aggregate stock option activity for the three months ended March 31, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2015	5,273,722	$ 13.64		
Granted	988,500	$ 15.68		
Exercised	(15,314)	$ 5.30		
Forfeited or expired	(25,925)	$ 16.57		
Options outstanding at March 31, 2016	6,220,983	$ 13.97	8.11	$ 12,819
Vested and expected to vest at March 31, 2016	5,944,982	$ 13.82	8.06	$ 12,753
Exercisable at March 31, 2016	2,333,130	$ 9.24	7.05	$ 10,619

The total intrinsic value of stock options exercised during the three months ended March 31, 2016 and 2015 was $0.1 million and $1.3 million, respectively.

As of March 31, 2016, there was $30.9 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.7 years. Included in unrecognized compensation expense was $1.2 million related to outstanding performance-based options. The following table summarizes the range of exercise prices and the number of stock options outstanding and exercisable:

		Outstanding as of March 31, 2016			Exercisable as of March 31, 2016	
Range of Exercise Prices ($)		Number of Options	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price (S)	Number of Options	Weighted Average Exercise Price ($)
3.03	3.03	131,923	5.73	3.03	131,923	3.03
3.14	3.40	719,490	6.43	3.40	629,714	3.40
3.60	6.96	674,486	6.70	6.14	492,337	6.00
8.77	12.44	676,516	7.52	12.03	341,649	12.05
12.58	14.24	833,643	8.11	13.26	318,677	13.35
14.32	16.09	525,250	8.60	15.91	145,747	15.83
16.16	16.16	812,900	9.77	16.16		
16.19	20.49	794,375	8.36	19.25	265,083	19.64
20.92	22.14	106,300	8.89	21.54	8,000	21.52
22.76	27.38	946,100	9.14	22.92		

Restricted Stock and Restricted Stock Units The Company may grant Restricted Stock (RS) and Restricted Stock Units (RSUs) to eligible employees, including its executives, and non-employee directors. Each RS and 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. RS and RSU awards granted are generally valued at the market price of the Company s common stock on the date of grant. The Company recognizes noncash compensation expense for the fair values of these RS and RSUs on a straight-line basis over the requisite service period of these awards. The

following table summarizes the Company s RSU award activity during the three months ended March 31, 2016:

	Number of RSUs		Weighted Average Grant Price
Outstanding at December 31, 2015	43,554	$	16.07
Granted			
Released	(43,554)		16.07
Outstanding at March 31, 2016		$	

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The following table summarizes the aggregate stock-based compensation recorded in the Consolidated Statements of Comprehensive Loss related to stock options and RSUs during the three months ended March 31, 2016 and 2015:

	Three months ended March 31,	
	2016	2015
	(in millions)	
Research and development expenses	$ 1.4	$ 1.3
General and administrative expenses	2.8	3.2
Total	$ 4.2	$ 4.5

8. Income Taxes

The Company s provision for income taxes was $28,000 for the three months ended March 31, 2016. The current year provision was a result of certain of the Company s subsidiaries in Europe, which had taxable income during the three months ended March 31, 2016. In jurisdictions where the Company has net losses, there was a full valuation allowance recorded against the Company s deferred tax assets and therefore no tax benefit was recorded. The Company is subject to US federal, US state and foreign income taxes. The statute of limitations for tax audit is open for the federal tax returns for the years ended 2011 and later and is generally open for certain states for the years 2010 and later. The Company s US federal tax return for the year ended December 31, 2013 is currently under audit by the Internal Revenue Service. The Company has incurred net operating losses since inception, with the exception of 2009. Such loss carryforwards are subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. As of March 31, 2016 and December 31, 2015, the Company has recorded no reserves for unrecognized income tax benefits, nor has it recorded 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.

9. Commitments and Contingencies

Commitments

The Company has an operating lease for office and laboratory space located in Bridgewater, NJ, its corporate headquarters, for which the initial lease term expires in November 2019. Future minimum rental payments under this lease are $3.7 million. The Company also holds a lease that expires in October 2016 for office space in Richmond, VA, the Company s former corporate headquarters.

Rent expense charged to operations was $0.2 million for each of the three months ended March 31, 2016 and 2015. Future minimum rental payments required under the Company s operating leases for the period from April 1, 2016 to December 31, 2016 and for each of the next five years are as follows (in thousands):

Year Ending December 31:

2016 (remaining)	$	1,029
2017		1,004
2018		1,025
2019		964
2020		
2021		
	$	4,022

Legal Proceedings

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 business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company s consolidated financial position, results of operations or cash flows.

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

Cautionary Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward looking statements. Forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as may, will, should, could, would, expects, plans, anticipates, believes, estimates, projects, predicts, intends, potential, continues, and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements.

Forward-looking statements are based upon our current expectations and beliefs, and involve known and unknown risks, 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, 2015 filed with the Securities and Exchange Commission (SEC) on February 25, 2016, and the following: our ability to complete development of, receive regulatory approval for, and successfully commercialize ARIKAYCE, or liposomal amikacin for inhalation (LAI), and INS1009, inhaled treprostinil prodrug; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; status, timing, and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the timing of responses to information and data requests from the US Food and Drug Administration (the FDA), the European Medicines Agency (the EMA), and other regulatory authorities; our clinical development of product candidates; our ability to obtain and maintain regulatory approval for our product candidates; our expectation as to the timing of regulatory review and approval; our estimates regarding our capital requirements and our needs for additional financing; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract third parties with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate license agreements and other third party efforts, including those relating to the development and commercialization of our product candidates; the degree of protection afforded to us by our intellectual property 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, scope and rate 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.

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, 2015.

OVERVIEW

We are a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. Our lead product candidate is ARIKAYCE, or liposomal amikacin for inhalation (LAI), which is in late-stage development for patients with nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. Our earlier stage pipeline includes INS1009, a nebulized prodrug formulation of the prostanoid, treprostinil. We believe INS1009 may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF), sarcoidosis, and severe refractory asthma.

We are conducting a global phase 3 clinical study of ARIKAYCE (the 212 or CONVERT study) in adult patients with NTM lung disease caused by *Mycobacterium avium* complex (MAC), which is the predominant infective species in NTM lung disease in the United States (US), Europe, and Japan. The European Medicines Agency s (EMA) Committee for Medicinal Products for Human Use (CHMP) is reviewing our Marketing Authorization Application (MAA) seeking approval of ARIKAYCE for the treatment of MAC lung disease in adult patients who have persistent positive sputum cultures despite the use of medically appropriate first-line therapy. We have recently completed a phase 1 study of INS1009 in healthy subjects and have submitted the results for presentation at a medical meeting in the second half of 2016. This first-in-human study of INS1009 was designed to determine the maximum-tolerated

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dose of a single dose of INS1009 and to characterize the pharmacokinetic profile of free treprostinil and INS1009 in healthy volunteers. In addition to INS1009, our earlier-stage pipeline includes preclinical compounds that we are exploring in multiple rare diseases of unmet medical need, including methicillin-resistant staph aureus (MRSA), NTM, PAH, and sarcoidosis. We are also evaluating additional formulations and delivery options for treprostinil, including delivery via a metered dose inhaler. To complement our internal research and development, we actively seek in-licensing and acquisition opportunities for a broad range of rare diseases.

The following table summarizes the current status of and anticipated milestones for ARIKAYCE and INS1009 development:

Product Candidate/Target Indications	**Status**	**Next Expected Milestones**
ARIKAYCE for adult patients with refractory NTM lung infections caused by MAC	• We are advancing the CONVERT study, a randomized, open-label global phase 3 clinical study of ARIKAYCE in adult patients with treatment refractory NTM lung disease caused by MAC. • We recently submitted our written responses to the CHMP s 180-day list of outstanding issues (LOIs) and we have requested an oral explanation meeting to add clarification to our responses. The 120-day and 180-day communications are part of CHMPs official review timetable. • The US Food and Drug Administration (FDA) has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP). Breakthrough therapy features intensive guidance on efficient drug development and offers the potential for a rolling review. A QIDP-designated product qualifies for fast track designation and is eligible for priority review. • The European Commission granted an orphan designation for ARIKAYCE for the treatment of NTM lung disease.	• We expect to achieve our enrollment objective in the CONVERT study in the second half of 2016. • We expect to participate in an oral explanation meeting with the CHMP in the second quarter of 2016 and the CHMP to render an opinion on our MAA around the middle of 2016. • If approved, we expect ARIKAYCE would be the first inhaled antibiotic specifically indicated for the treatment of NTM lung infections in North America, Europe, and Japan. • If approved, we plan to commercialize ARIKAYCE in certain countries in Europe, the US, and eventually Canada and Japan and certain other countries.
INS1009 (nebulized treprostinil prodrug) *for rare pulmonary disorders*	• We recently completed a phase 1 study of INS1009. The phase 1 study was a randomized, double-blind,	• We expect to present the results of our phase 1 study of INS1009 in healthy volunteers at a

	placebo-controlled single ascending dose study of INS1009 for inhalation to determine its safety, tolerability, and pharmacokinetics in healthy volunteers.	medical meeting in the second half of 2016.

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Product Pipeline

ARIKAYCE ***for patients with NTM lung disease***

Our lead product candidate is ARIKAYCE, or LAI, a novel, once-daily formulation of amikacin that is in late-stage clinical development for patients with NTM lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and which can be fatal. Amikacin solution for parenteral administration is an established drug that has activity against a variety of NTM; however, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function (Peloquin et al., 2004). Our advanced liposome technology uses charge-neutral liposomes to deliver amikacin directly to the lung where it is taken up by the lung macrophages where the NTM infection resides. This prolongs the release of amikacin in the lungs while minimizing systemic exposure thereby offering the potential for decreased systemic toxicities. ARIKAYCE s ability to deliver high levels of amikacin directly to the lung distinguishes it from intravenous amikacin. ARIKAYCE is administered once-daily using an optimized, investigational eFlow® Nebulizer System manufactured by PARI Pharma GmbH, a novel, highly efficient and portable aerosol delivery system.

The CONVERT study

ARIKAYCE is currently being evaluated in a global phase 3 randomized, open-label clinical study designed to confirm the culture conversion results seen in our phase 2 clinical trial. This phase 3 study, which is known as the CONVERT (or 212) study, is enrolling non-cystic fibrosis (non-CF) patients 18 years and older with an NTM lung infection caused by MAC that is refractory to a stable multi-drug regimen for at least six months with the regimen either ongoing or completed within 12 months of screening. In our completed phase 2 study, the subgroup of non-CF patients with NTM lung infection caused by MAC demonstrated the greatest response to treatment with ARIKAYCE. The CONVERT study also excludes subjects whose susceptibility scores indicate that their MAC NTM infection is resistant to amikacin. We believe the CONVERT study will confirm the culture conversion results seen in the phase 2 study and provide the basis for submitting a New Drug Application (NDA) to the FDA, as well as regulatory submissions in Japan and other countries.

After a screening period of approximately 10 weeks, eligible subjects are randomized 2:1 to once-daily ARIKAYCE plus a multi-drug regimen or a multi-drug regimen without ARIKAYCE. The primary efficacy endpoint is the proportion of subjects who achieve culture conversion at Month 6 in the ARIKAYCE plus multi-drug regimen arm compared to the arm in which subjects receive a multi-drug regimen without ARIKAYCE. A converter is defined as a subject with three consecutive negative sputum cultures collected monthly without relapse or recurrence; all others will be considered non-converters. The study s key secondary endpoints include the change from baseline in the six-minute walk test and off-treatment assessments to evaluate durability of effect. The study also includes a comprehensive pharmacokinetic sub-study in Japanese subjects in lieu of a separate local pharmacokinetic study in Japan.

At Month 8, after all sputum culture results are known up to and including Month 6, subjects will be assessed as converters or non-converters for the primary efficacy endpoint. All converters will continue on their randomized treatment regimen for 12 months beginning from the first negative culture that defined culture conversion. All converters will return for off-treatment follow-up visits. A 12-month off-treatment study visit will be the last visit for the CONVERT study. All non-converters in the study at Month 8 may be eligible to enter a separate open-label study (the 312 study). The primary objective of the 312 study is to evaluate the long-term safety and tolerability of ARIKAYCE for up to 12 months. The secondary endpoints of the 312 study include evaluating the proportion of subjects achieving culture conversion (three consecutive negative sputum cultures without relapse or recurrence) by Month 6 and the proportion of subjects achieving culture conversion by Month 12 (end of treatment).

The protocol for the CONVERT study incorporates feedback from the FDA and the EMA via its scientific advice working party process, as well as local health authorities in other countries, including Japan s Pharmaceuticals and Medical Devices Agency. If the CONVERT study meets the primary endpoint of culture conversion at Month 6, we believe we would be eligible to submit an NDA pursuant to 21 CFR 314 Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses), which permits FDA to approve a drug based on a surrogate endpoint provided the sponsor commits to study the drug further to verify and describe the drug s clinical benefit. We believe that efficacy data from the CONVERT study after Month 6 will suffice to meet this commitment. We are currently conducting CONVERT at more than 130 sites in North America, Europe, Australia, New Zealand and Asia. The CONVERT study is designed to enroll enough subjects to ensure at least 261 patients are evaluable for the primary endpoint.

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Phase 2 study (112 study)

Our completed phase 2 study, which is also known as the 112 study, was a randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of ARIKAYCE in adults with NTM lung disease due to MAC or *Mycobacterium abscessus* (*M. abscessus*) that was refractory to guideline-based therapy. Eligibility for the 112 study required patients to have been on the American Thoracic Society/Infectious Disease Society of America (ATS/IDSA) guideline therapy for at least six months prior to screening and to have had persistently positive mycobacterial cultures. The study included an 84-day double-blind phase in which patients were randomized 1:1 either to ARIKAYCE once-daily plus a multi-drug regimen or to placebo once-daily plus a multi-drug regimen. After completing the 84-day double-blind phase, patients had the option of continuing in an 84-day open-label phase during which all patients received ARIKAYCE plus a multi-drug regimen. The study also included 28-day and 12-month off-ARIKAYCE follow-up assessments to evaluate durability of effect.

Eighty-nine patients were randomized and dosed in the study. Of the 80 patients who completed dosing in the 84-day study, 78 patients elected to continue in the open-label phase and received ARIKAYCE plus a multi-drug regimen for an additional 84 days. Seventy-six percent (76% or 59/78) of patients who elected to continue in the open-label phase of the study completed the open-label phase.

The primary efficacy endpoint of the study was the change from baseline (day 1) to the end of the double-blind phase of the trial (day 84) in a semi-quantitative measurement of the change in mycobacterial density on a seven-point scale. ARIKAYCE did not meet the pre-specified level for statistical significance although there was a positive trend (p=0.072) in favor of ARIKAYCE. The p-value for the key secondary endpoint of culture conversion to negative at Day 84 (defined as a negative culture on Day 84) was 0.003, in favor of ARIKAYCE.

After establishing the primary endpoint for the CONVERT study, we explored the microbiologic outcomes from the 112 study using the more stringent definition of culture conversion, which is defined as at least three consecutive monthly sputum samples that test negative for NTM bacteria. This definition of culture conversion is in the ATS/IDSA Guidelines (Griffith et al., 2007) and used in clinical practice. The preliminary results of these analyses are summarized below:

- Twenty patients who received ARIKAYCE in the 112 study achieved culture conversion status over the 168-day treatment phase (13 received ARIKAYCE in the double-blind phase and seven received ARIKAYCE in the open-label phase).

- Three additional patients who started ARIKAYCE in the open-label phase achieved culture conversion by the 28-day off-ARIKAYCE follow-up assessment.

- Of these 23 patients who achieved culture conversion by the 28-day end-of-study follow-up visit, four converted at baseline (day 1) prior to the administration of study drug.

The 112 study included a 12-month off-ARIKAYCE follow-up visit in order to collect sputum culture results. These results were collected and analyzed to assess the durability of the ARIKAYCE treatment effect for both the group of subjects who achieved culture conversion and the group of subjects who did not achieve culture conversion during the 168-day treatment phase. The preliminary results of these analyses are summarized below:

- Seventeen of the total 23 subjects who achieved culture conversion during the study attended their 12-month off-ARIKAYCE follow-up visit. The NTM sputum culture results at the 12-month visit for the 17 subjects are as follows:

- Eleven subjects remained culture negative; nine of these subjects were non-CF subjects with MAC (eight of these nine subjects were off all NTM treatments at this time), one subject was non-CF *M. abscessus,* and one subject was CF *M. abscessus* at the time of study entry (both subjects with *M. abscessus* were on NTM treatments at this time).

- Three non-CF subjects with MAC could not produce sputum despite reasonable attempts. These same subjects were off all NTM treatments at this time. This is consistent with the achievement of treatment success during the follow-up period as the lack of sputum production is indicative of symptom resolution.

- Two non-CF subjects with MAC were broth culture positive only, which may represent contamination (a false positive) or a new infection rather than a relapse.

- One non-CF subject with *M. abscessus* was also broth culture positive only.

- Of those who did not achieve culture conversion, six subjects died. Twenty-eight subjects provided sputum at the 12-month follow-up visit and 12 subjects did not provide sputum. Of those who provided sputum, 22 continued to have positive sputum cultures and six had a negative culture.

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- Of the seven patients who died during the 12-month follow-up phase, six patients had not achieved culture conversion and one patient had achieved culture conversion during the study treatment phases.

During the double-blind phase, the majority of the subjects in both treatment groups experienced at least one treatment-emergent adverse event (TEAE). All of the most common TEAEs, except diarrhea, occurred more frequently in the ARIKAYCE group than in the placebo group. Renal TEAEs were reported infrequently. Audiovestibular TEAEs were reported in similar proportions of subjects in the two treatment groups in the double-blind phase and were reported infrequently in the open-label phase. TEAEs considered related by the investigator were reported more frequently in the ARIKAYCE group than in the placebo group in the double-blind phase (ARIKAYCE: 72.7%, placebo: 37.8%). The overall incidences of adverse events leading to study drug discontinuation and serious adverse events were higher in the ARIKAYCE group than in the placebo group.

During the treatment phases of the study, there were two deaths; one subject died during the double-blind phase of pneumonia and acute respiratory distress syndrome and one subject died during the open-label phase of multi-organ failure, intestinal ischemia, and urosepsis. None of the events in either subject were considered to be related to the study drug by the investigator. All of these events were assessed by the Data Monitoring Committee, with no change in their assessment of the risk benefit of ARIKAYCE. In the double-blind phase, serious adverse events were reported for a greater proportion of subjects in the ARIKAYCE group than in the placebo group (18.2% versus 8.9%, respectively). In the double-blind phase, a greater proportion of subjects in the ARIKAYCE treatment group than in the placebo group reported adverse events leading to study drug discontinuation (ARIKAYCE: 18.2%; placebo: 0%). The most commonly reported TEAEs leading to study drug discontinuation in the ARIKAYCE group were infective exacerbation of underlying bronchiectasis (6.8%) and dyspnea (4.5%). The incidence of adverse events leading to discontinuation did not increase in the ARIKAYCE group with longer exposure to the study drug in the open-label phase compared with the double-blind phase (17.1% and 18.2%, respectively). In the open-label phase, 27.9% of subjects who had received placebo during the double-blind phase of the trial reported adverse events leading to study drug discontinuation.

No clinically significant changes in laboratory values, vital signs, body mass index, and pulmonary function tests were observed over the course of the study. The results discussed above are preliminary findings based on currently available data.

MAA for NTM

We are currently seeking EU approval of ARIKAYCE for the treatment of NTM lung disease caused by MAC in adult patients who have persistent positive sputum cultures despite the use of medically appropriate first-line therapy. Our MAA filing is based on data from the 112 study. We submitted our responses to the CHMP s 120-day questions in December 2015. We received the CHMP s 180-day LOI in the first quarter of 2016 and we recently submitted our responses. In addition to our responses to the 180-day LOI, we have requested an oral explanation meeting with CHMP, which we expect to take place in the second quarter of 2016. The 120-day and 180-day communications are part of CHMPs official review timetable. We expect the CHMP to render an opinion on our MAA around the middle of 2016.

NTM Market Opportunity

NTM is a rare and serious disorder associated with increased morbidity and mortality. There is an increasing rate of lung disease caused by NTM and this is an emerging public health concern worldwide. Patients with NTM lung disease may experience a multitude of symptoms such

as fever, weight loss, cough, lack of appetite, night sweats, blood in the sputum, and fatigue. Patients with NTM lung disease frequently require lengthy hospital stays to manage their condition. There are no inhaled antibiotic treatments specifically indicated for the treatment of NTM lung disease in North America, Europe or Japan. Current guideline-based approaches involve multi-drug regimens that may cause severe side effects and treatment can be as long as two years or more.

The prevalence of human disease attributable to NTM has increased over the past two decades. In a decade-long study (1997-2007), researchers found that the prevalence of NTM in the US is increasing at approximately 8% per year and that NTM patients on Medicare over the age of 65 are 40% more likely to die over the period of the study than those who did not have the disease (Adjemian et al., 2012). A 2015 publication from co-authors from several US government departments stated that prior year statistics led to a projected 181,037 national annual cases in 2014 costing the US healthcare system approximately $1.7 billion (Strollo et al., 2015).

Our market research indicates that there are approximately 100,000 patients in the US, the EU5 (France, Germany, Italy, Spain and the United Kingdom), and Japan who have a confirmed diagnosis of NTM lung disease, of which an estimated 10 to 30 percent are refractory to current treatments. 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 of pulmonary disease attributable to NTM in the US in 2011 and that such cases were estimated to be growing at a rate of 10% per year. In 2013, we engaged Clarity Pharma Research to perform a similar chart audit study of NTM in Europe and Japan. Based on results of this study, researchers estimated that there are approximately 20,000

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cases of pulmonary disease attributable to NTM within the EU5 and approximately 30,000 in the 28 countries comprising the EU. In addition, there are nearly 32,000 cases in Japan. Although population-based data on the epidemiology of NTM lung disease are limited, studies worldwide have described an increasing prevalence.

NTM currently includes over 165 species. MAC is the predominant pathogenic species in NTM pulmonary disease in the US, Japan and Europe, followed by *M. abscessus*. Thus far, we have studied ARIKAYCE in both MAC and *M. abscessus*.

We are studying the economic and societal implications of NTM lung infections. We have conducted a burden of illness study in the US with a major medical benefits provider. This study showed that patients with NTM lung infections are costly to healthcare plans and ATS/IDSA guideline-based treatment results in healthcare savings as opposed to suboptimal treatment.

In partnership with one of the nation s largest Medicare insurance providers, we presented the results of three claims-based studies.

- At the Interscience Conference of Antimicrobial Agents and Chemotherapy in September 2015, researchers reported a 36.1% increase in the incidence of NTM lung infections between 2008 and 2013 in US Medicare population of a national managed care health plan, with the greatest incidence increase (56.3%) observed in members 65 to 74 years of age. Following diagnosis with NTM lung infections, over 50% of members were still in the plan after six years (Abraham et al., 2015).

- At the Infectious Disease Week in October 2015, researchers reported that patients with NTM lung infections were using greater healthcare resources than their age and gender-matched controls in the period preceding their initial diagnosis. Ordering mycobacterial testing of sputum earlier may help in preventing a misdiagnosis or delaying a diagnosis (Holt et al., 2015).

- At the Academy of Managed Care Pharmacy conference in October 2015, researchers reported higher resource utilization and costs for patients with NTM lung infections than their age and gender-matched controls both pre- and post-diagnosis. Patients who received treatment regimens conforming to the 2007 ATS/IDSA guidelines showed lower healthcare resource utilization and total medical costs than patients who received suboptimal treatment. These data suggest that healthcare plans should consider mechanisms to identify and appropriately treat patients with NTM lung disease (Abraham et al., 2015).

We plan to repeat this type of research globally in support of our overall disease awareness and education efforts.

The FDA has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a QIDP for NTM lung disease. Orphan designation features seven years of post-approval market exclusivity, and QIDP features an additional five years of post-approval exclusivity. A QIDP-designated product is eligible for fast track and priority review designations. A priority review designation for a drug means the FDA s goal is to take action on the NDA within six months as compared to 10 months under a standard review.

INS1009

INS1009 is an investigational sustained-release nebulized treprostinil prodrug that has the potential to address certain of the current limitations of existing inhaled prostanoid therapies. We believe that INS1009 prolongs duration of effect and may provide greater consistency in pulmonary arterial pressure reduction over time. Current inhaled prostanoid therapies must be dosed four to nine times per day for the treatment of PAH. Reducing dose frequency has the potential to ease patient burden and improve compliance. Additionally, we believe that INS1009 may be associated with fewer side effects, including elevated heart rate, low blood pressure, and severity and/or frequency of cough, associated with high initial drug levels and local upper airway exposure when using current inhaled prostanoid therapies. We believe INS1009 may have therapeutic potential in PAH, IPF, sarcoidosis, and severe refractory asthma.

In late 2014, we had a pre-investigational new drug (pre-IND) meeting with the FDA for INS1009 and clarified that, subject to final review of the preclinical data, INS1009 could be eligible for an approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) (505(b)(2) approval). Like a traditional NDA that is submitted under Section 505(b)(1) of the FDCA, a 505(b)(2) NDA must establish that the drug is safe and effective, but unlike a traditional NDA the applicant may rely at least in part on studies not conducted by or for the applicant and for which the applicant does not have a right of reference. The ability to rely on existing third-party data to support safety and/or effectiveness can reduce the time and cost associated with traditional NDAs.

In the fourth quarter of 2015, we submitted an IND application and recently completed a phase 1 study of INS1009. The phase 1 study was a randomized, double-blind, placebo-controlled single ascending dose study of INS1009 for inhalation to determine its safety, tolerability, and pharmacokinetics in healthy volunteers. We have submitted the results for presentation at a medical meeting in the second half of 2016.

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PAH

PAH is a serious, progressive rare disease. There is no cure for PAH. Research has estimated PAH prevalence in Europe at 15 to 52 per million (Peacock et al., 2007). Claims-based research has estimated a higher PAH prevalence in the US at 109 per million for the privately insured (under age 65) population and 451 per million for the Medicare population (Kirson et al., 2011). PAH ultimately leads to heart failure and the disease has a 15% one-year mortality rate (Kirson et al., 2011; Kane et al., 2011; and Thenappan et al., 2007). Several medications are used to treat PAH. Non-specific treatments such as anticoagulants, diuretics, and oxygen may be used. These drugs are not specifically approved for the treatment of PAH, but are commonly utilized. In specific circumstances, drugs such as digoxin or calcium channel blockers may also be used to treat PAH. Several drugs are approved specifically for the treatment of PAH. These drugs address three target pathophysiologic pathways: the endothelin pathway; the nitric oxide pathway; and the prostacyclin pathway. They may be used alone or in combination.

IPF

IPF is a rare, chronic, progressive, interstitial lung disease of unknown etiology that affects around five million patients worldwide. Patients with IPF are generally middle-aged or older at the time of diagnosis. Disease progression is variable but progressive fibrosis (scarring) leads ultimately to death, with a median survival of three to five years after diagnosis. Symptoms often include shortness of breath, dry cough, unintended weight loss, fatigue, and clubbing of the fingers and toes. Over time, IPF can lead to a debilitating loss of physical ability. The prevalence of IPF in the US ranges from between 90,000 and 190,000 patients, a range similar to that reported in Europe (Lee et al., 2014).

Sarcoidosis

Sarcoidosis is a granulomatous inflammatory disease that is induced by unknown antigen(s) in a genetically susceptible host (Mortaz et al., 2014). This rare, chronic systemic disease most commonly affects the lung. Several features of sarcoidosis tend to obscure the diagnosis, leading to an under-appreciation of the potential impact of the disease on the health care system and society as a whole. Sarcoidosis frequently presents with non-specific complaints, ranging from fatigue and depression, asthma symptoms (wheezing, cough), to arthritis and muscle pain or weakness. As such, sarcoidosis can mimic other diseases, leading to misdiagnosis and inappropriate treatments (Erdal et al., 2012).

Severe refractory asthma

Severe refractory asthma is characterized by a difficulty to achieve disease control despite high-intensity treatment. Prevalence figures of severe refractory asthma are lacking, whereas longstanding estimates vary between five and 10% of all asthmatic patients. To make a reliable estimate of the prevalence of severe refractory asthma as defined by the Innovative Medicine Initiative consensus, Hekking et al. analyzed prescription data from 65 Dutch pharmacy databases, representing 500,500 adult inhabitants. Of asthmatic adults, 3.6% qualified for a diagnosis of severe refractory asthma; therefore, the prevalence of severe refractory asthma might be lower than estimated by expert opinion, which implies that currently recognized severe asthma phenotypes could meet the criteria of rare disease (Hekking et al., October 2014).

Our Strategy

Our strategy focuses on the needs of patients with rare diseases. We are currently focused on the development and commercialization of ARIKAYCE. There are currently no inhaled products specifically indicated to treat NTM lung disease in North America, Europe or Japan. While we believe that ARIKAYCE has the potential to treat many different diseases, we are prioritizing securing regulatory approval of ARIKAYCE in NTM lung disease caused by MAC. We are also advancing earlier-stage programs in other rare disorders.

Our current priorities are as follows:

- Enrolling the global CONVERT study;
- Securing approval of our MAA for ARIKAYCE in the EU for the treatment of MAC lung disease in adult patients who have persistent positive sputum cultures despite the use of medically appropriate first-line therapy;
- Preparing our US NDA submission, which will be based on the results of the CONVERT study;
- Ensuring our product supply chain will support the clinical development and if approved, commercialization of ARIKAYCE;
- Preparing for potential commercialization of ARIKAYCE in certain European countries and the US;
- Defining further research and lifecycle management strategies for ARIKAYCE, including investigator-initiated studies;

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- Presenting the results of the phase 1 study of INS1009, our nebulized treprostinil prodrug, and investigating its use in other indications;
- Presenting preclinical findings from our earlier-stage program(s); and
- Expanding our rare disease pipeline through corporate development.

Corporate Development

We plan to develop, acquire, in license or co-promote other products that address rare diseases. We are focused broadly on rare disease therapeutics and prioritizing those areas that best align with our core competencies and current therapeutic focus in the fields of pulmonology and infectious disease.

Manufacturing

ARIKAYCE is manufactured by Ajinimoto Althea, Inc. (Althea) in the US at a 50 liter scale. In September 2015, we entered into a commercial fill/finish services agreement with Althea to produce ARIKAYCE. Althea has the right to terminate this agreement upon written notice for our uncured material breach, if we are the subject of specified bankruptcy or liquidation events, or without cause with 24 months prior written notice. In February 2014, we entered into a contract manufacturing agreement with Therapure Biopharma Inc. (Therapure) for the manufacture of ARIKAYCE at a 200 liter scale which we believe will be necessary to support commercialization. We have also identified certain second source suppliers for our supply chain, and plan to implement supply and quality agreements in preparation for commercialization of ARIKAYCE. In July 2014, we entered into a commercialization agreement with PARI Pharma GmbH (PARI), the manufacturer of our drug delivery nebulizer, to address our commercial supply needs. We currently produce INS1009, our investigational nebulized treprostinil prodrug, and plan to utilize third parties to manufacture INS1009 at a larger scale and the drug delivery device.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenues

In 2015, the French National Agency for Medicines and Health Products Safety granted LAI several nominative Temporary Authorization for Use (Autorisation Temporaire d Utilisation or ATU). Pursuant to this program, we shipped ARIKAYCE to pharmacies after receiving requests from physicians for patients in France. For the three months ended March 31, 2016, the revenue recorded from the ATU program was immaterial to disclose and is included as a component of other income, net. In February 2016, the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte or BfArM) granted LAI a compassionate use program (CUP) for use in adult patients with MAC pulmonary disease who do not achieve culture conversion despite initial treatment. Pursuant to this non-reimbursed CUP, we have started to enroll patients in this program based on individual requests by their treating physicians in Germany. We may initiate expanded access programs (EAPs) in

other select territories in Europe, some of which may be fully reimbursed. EAPs are intended to make products available before they are commercially available in accordance with local regulations. Besides the ATU revenue in France, we currently do not recognize any revenue from product sales or other sources.

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. Expenses also include other internal operating expenses, the cost of manufacturing our drug candidate for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. Our expenses related to manufacturing our drug candidate for clinical study are primarily related to activities at contract manufacturing organizations that manufacture ARIKAYCE 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 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. In 2015, we commenced the CONVERT study for ARIKAYCE for patients with NTM lung disease. In 2015, we also completed an open-label extension study in which CF patients that completed our phase 3 trial received ARIKAYCE for a period of two years. The majority of our research and development expenses have been for our

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ARIKAYCE development programs. Our development efforts in 2015 and 2016 principally relate to the development of ARIKAYCE in the NTM indication and, to a lesser extent, for INS1009.

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, pre-commercial, corporate development, information technology, program management and human resource functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, insurance, board of director fees, tax and accounting services. We expect that our general and administrative expenses will increase in order to support increased levels of development activities and preparation for commercialization activities for our product candidates, specifically in Europe.

Debt Issuance Costs

Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Our balance sheet reflects debt net of debt issuance costs paid to the lender and reflects debt issuance costs paid to other third parties as other assets.

Investment Income and Interest Expense

Investment income consists of interest and dividend income earned on our cash and cash equivalents. Interest expense consists primarily of interest costs related to our debt.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2016 and 2015

Net Loss

Net loss for the quarter ended March 31, 2016 was $33.5 million, or ($0.54) per common share basic and diluted, compared with a net loss of $27.4 million, or ($0.55) per common share basic and diluted, for the quarter ended March 31, 2015. The $6.2 million increase in our net loss for the quarter ended March 31, 2016 as compared to the same period in 2015 was primarily due to:

- Increased research and development expenses of $3.4 million primarily resulting from an increase in clinical trial expenses related to the CONVERT study and higher compensation and related expenses due to an increase in headcount compared to the prior year period. These increases were partially offset by a decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015; and

- Increased general and administrative expenses of $3.0 million primarily resulting from an increase in pre-commercial activities in Europe and higher compensation and related expenses due to an increase in headcount as compared to the prior year period.

Research and Development Expenses

Research and development expenses for the quarters ended March 31, 2016 and 2015 were comprised of the following (in thousands):

	Quarters Ended March 31,		Increase (decrease)	
	2016	2015	$	%
External Expenses				
Clinical development & research	$ 8,206	$ 5,883	$ 2,323	39.5%
Manufacturing	3,464	4,352	(888)	-20.4%
Regulatory and quality assurance	234	627	(393)	-62.7%
Subtotal external expenses	$ 11,904	$ 10,862	$ 1,042	9.6%
Internal Expenses				
Compensation and related expenses	$ 6,552	$ 4,770	$ 1,782	37.4%
Other internal operating expenses	2,091	1,532	559	36.5%
Subtotal internal expenses	$ 8,643	$ 6,302	$ 2,341	37.1%
Total	$ 20,547	$ 17,164	$ 3,383	19.7%

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Research and development expenses increased to $20.5 million during the quarter ended March 31, 2016 from $17.2 million in the same period in 2015. The $3.4 million increase was primarily due to a $2.3 million increase in external clinical development expenses related to the CONVERT study and a $1.8 million increase in compensation and related expenses. These increases were partially offset by a $0.9 million decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015. We expect research and development expenses to increase in 2016 as compared to 2015 due primarily to the clinical trial activity related to the CONVERT study.

General and Administrative Expenses

General and administrative expenses for the quarters ended March 31, 2016 and 2015 were comprised of the following (in thousands):

	Quarters Ended March 31,		Increase (decrease)	
	2016	2015	$	%
General & administrative	$ 9,025	$ 7,766	$ 1,259	16.2%
Pre-commercial expenses	3,495	1,776	1,719	96.8%
Total general & administrative expenses	$ 12,520	$ 9,542	$ 2,978	31.2%

General and administrative expenses increased to $12.5 million during the quarter ended March 31, 2016 from $9.5 million in the same period in 2015. The $3.0 million increase was primarily due to an increase of $1.2 million in expenses related to the build out of our European operations and an increase of $1.0 million related to an increase in headcount. We expect general and administrative expenses to increase in 2016 as compared to 2015 due, in part, to an increase in expenses related to activities in certain European markets.

Interest Expense

Interest expense was $0.6 million during the quarter ended March 31, 2016 as compared to $0.7 million in the same period in 2015. The $0.1 million decrease in interest expense in 2016 relates to a decrease in the amortization of our debt issuance costs in 2016.

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 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 both in our US and certain international entities, as we plan to fund research and development activities and commercial launch activities.

We believe we currently have sufficient funds to meet our financial needs for at least the next twelve months. We may opportunistically raise additional capital and may do so 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 other technologies, to commercialize our product candidates or to purchase other products. 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. During the remainder of 2016, we plan to continue to fund further clinical development of ARIKAYCE and INS1009, support efforts to obtain regulatory approvals and prepare for commercialization in certain European countries. Our cash requirements in 2016 will be impacted by a number of factors, the most significant of which, being the enrollment rates and other expenses related to the CONVERT study.

Cash Flows

As of March 31, 2016, we had total cash and cash equivalents of $252.9 million, as compared with $282.9 million as of December 31, 2015. The $30.0 million decrease was due primarily to the use of cash in operating activities. Our working capital was $232.9 million as of March 31, 2016 as compared with $265.9 million as of December 31, 2015.

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Net cash used in operating activities was $29.5 million and $24.9 million for the three months ended March 31, 2016 and 2015, respectively. The net cash used in operating activities during 2016 and 2015 was primarily for the clinical, manufacturing and pre-commercial activities related to ARIKAYCE, as well as general and administrative expenses.

Net cash used in investing activities was $0.6 million and $1.3 million for the three months ended March 31, 2016 and 2015, respectively. The net cash used in investing activities during 2016 was primarily related to payments for the build out of our headquarters and lab facility in Bridgewater, New Jersey.

Net cash provided by financing activities was $0.1 million and $1.5 million for the three months ended March 31, 2016 and 2015, respectively. Net cash provided by financing activities in 2016 and 2015 was cash proceeds received from stock option exercises.

Contractual Obligations

In June 2012, we and our domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement with Hercules that allowed us to borrow up to $20.0 million (Loan Agreement) at an interest rate of 9.25%. The interest rate for the term is floating and is defined as the greater of (i) 9.25% or (ii) 9.25% plus the sum of the US prime rate minus 4.50%. In December 2014, we entered into a third amendment (the Third Amendment) to the Loan Agreement with Hercules. In connection with the Third Amendment, we paid a commitment fee of $25,000, and at the closing, paid a facility fee of $125,000. Under the Third Amendment, the amount of borrowings was increased by an additional $5.0 million to an aggregate total of $25.0 million and the interest-only period was extended through December 31, 2015. In December 2015, we entered into a fifth amendment (the Fifth Amendment) to the Loan Agreement to exercise an option to extend the maturity date of the loan to January 1, 2018 with a payment to Hercules of $250,000. The Fifth Amendment extends the interest-only period, with principal repayments beginning in October 2016.

We have an operating lease for office and laboratory space located in Bridgewater, NJ, our corporate headquarters, for which the initial lease term expires in November 2019. Future minimum rental payments under this lease total approximately $3.7 million.

As of March 31, 2016, future payments under our long-term debt agreements, capital leases, minimum future payments under non-cancellable operating leases and minimum future payment obligations are as follows:

	As of March 31, 2016 Payments Due By Period				
	Total	Less than 1 year	1 - 3 Years	4 - 5 Years	After 5 Years
			(In thousands)		
Debt obligations					
Debt maturities	$ 25,000	$ 5,818	$ 19,182	$	$
Contractual interest	3,383	2,234	1,149		

Operating leases	4,022	1,281	2,037	704	
Purchase obligations	4,725	2,700	2,025		
Total contractual obligations	$ 37,130	$ 12,033	$ 24,393	$ 704	$

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; (c) contracts that are entered into in the ordinary course of business which are not material in the aggregate in any period presented above; or (d) any payments related to the agreements mentioned below.

We currently have a licensing agreement with PARI for the use of the optimized eFlow Nebulizer System for delivery of ARIKAYCE in treating patients with NTM infections, CF and bronchiectasis. We have rights to several US and foreign issued patents, and patent applications involving improvements to the optimized eFlow Nebulizer System. Under the licensing agreement, PARI is entitled to receive payments either in cash, qualified stock or a combination of both, at PARI s discretion, based on achievement of certain milestone events including phase 3 trial initiation (which occurred in 2012), first acceptance of MAA submission (or equivalent) in the US of ARIKAYCE and the device, first receipt of marketing approval in the US for ARIKAYCE and the device, and first receipt of marketing approval in a major EU country for ARIKAYCE and the device. In addition, PARI is entitled to receive royalty payments in the mid-single digits on commercial net sales of ARIKAYCE pursuant to the licensing agreement, subject to certain specified annual minimum royalties. In July 2014, we entered into a Commercialization Agreement (the PARI Agreement) with PARI for the manufacture and supply of eFlow nebulizer systems and related accessories (the Device) as optimized for use with our proprietary liposomal amikacin for inhalation. The PARI Agreement has an initial term of fifteen years from the first commercial sale of ARIKAYCE pursuant to the licensing agreement (the Initial Term). The term of the PARI Agreement may be

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extended by us for an additional five years by providing written notice to PARI at the least one year prior to the expiration of the Initial Term.

In 2004 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 ARIKAYCE. If ARIKAYCE 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 global sales milestones are met within five years of the drug commercialization, we would owe an additional $3.9 million in additional payments. Since there is significant development risk associated with ARIKAYCE, we have not accrued these obligations.

In February 2014, we entered into a contract manufacturing agreement with Therapure for the manufacture of ARIKAYCE at the larger scales necessary to support commercialization. Pursuant to the agreement, we collaborated with Therapure to construct a production area for the manufacture of ARIKAYCE in Therapure s existing manufacturing facility in Canada. We paid Therapure approximately $12 million for the build out of the construction area and related manufacturing costs. Therapure manufactures ARIKAYCE for us on a non-exclusive basis. The agreement has an initial term of five years from the first date on which Therapure delivers ARIKAYCE to us after we obtain permits related to the manufacture of ARIKAYCE. Under the agreement, we are obligated to pay certain minimum amounts for the batches of ARIKAYCE produced each calendar year.

In December 2014, we entered into Work Order 1 (the Work Order), pursuant to a Master Agreement for Services with SynteractHCR, Inc. (Synteract) dated as of August 27, 2014, as amended on December 23, 2014, pursuant to which we retained Synteract to perform implementation and management services in connection with certain clinical trials pursuant to a specific protocol of pharmaceutical products under development by us or under our control. Synteract is providing comprehensive services for protocol INS-212, a randomized, open-label, multicenter study of liposomal amikacin for inhalation in adult patients with NTM lung infections caused by MAC complex that are refractory to treatment. Prior to the execution of the Work Order, Synteract was providing such services pursuant to a Letter of Intent, dated August 25, 2014. We anticipate that aggregate costs relating to all work orders for the 212 study will be approximately $40 million over the period of the study. In April 2015, we entered into a work order with Synteract to perform implementation and management services for protocol INS-312, a study in which all non-converters from the INS-212 study will be eligible to enter a separate open-label study. We anticipate that aggregate costs relating to all work orders for the 312 study will be approximately $20 million over the period of the study.

Future Funding Requirements

We may need to raise additional capital to fund our operations, to develop and commercialize ARIKAYCE, to develop INS1009, and to develop, acquire, in-license or co-promote other products that address orphan or rare diseases. Our future capital requirements may be substantial and will depend on many factors, including:

- the timing and cost of our anticipated clinical trials of ARIKAYCE for the treatment of patients with NTM lung infections;

- the decisions of the FDA and EMA with respect to our applications for marketing approval of ARIKAYCE in the US and Europe; the costs of activities related to the regulatory approval process; and the timing of approvals, if received;

- the cost of putting in place the sales and marketing capabilities necessary to be prepared for a potential commercial launch of ARIKAYCE, if approved;

- the cost of filing, prosecuting and enforcing patent claims;

- the costs of our manufacturing-related activities;

- the costs associated with commercializing ARIKAYCE if we receive marketing approval; and

- subject to receipt of marketing approval, the levels, timing and collection of revenue received from sales of approved products, if any, in the future.

In April 2015, we generated net proceeds of $222.9 million from the issuance of 11.5 million shares of common stock. We believe we currently have sufficient funds to meet our financial needs for the next twelve months. 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. 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

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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.

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

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, stock-based compensation, identifiable 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. There have been no material changes to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015. For the required interim updates of our accounting policies see Note 2 to our Consolidated Financial Statements Summary of Significant Accounting Policies in this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of March 31, 2016, 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 March 31, 2016, we had $25.0 million of fixed rate borrowings that bear interest at 9.25% outstanding under a Loan and Security Agreement we entered into in June 2012 and amended most recently in December 2015. If a 10% change in interest rates was to have occurred on March 31, 2016, this change would not have had a material effect on the fair value of our debt as of that date, nor would it have had a

material effect on our future earnings or cash flows.

The majority of our business is conducted in US dollars. However, we do conduct certain transactions in other currencies, including Euros, British Pounds, and Japanese Yen. Historically, fluctuations in foreign currency exchange rates have not materially affected our results of operations and during the three months ended March 31, 2016 and 2015, our results of operations were not materially affected by fluctuations in foreign currency exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2016. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the periodic reports that we file or submit with the SEC is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation as of March 31, 2016, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2016 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

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. Management does not expect that the ultimate costs to resolve these matters will materially adversely affect our business, financial position, or results of operations.

ITEM 1A. RISK FACTORS

Except for the historical information in this report on Form 10-Q, 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, 2015. 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, 2015.

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

There were no unregistered sales of the Company s equity securities during the quarter ended March 31, 2016.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. **OTHER INFORMATION**

None.

ITEM 6. **EXHIBITS**

A list of exhibits filed herewith is included on the Exhibit Index, which 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: May 5, 2016

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

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EXHIBIT INDEX

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 The following materials from Insmed Incorporated s quarterly report on Form 10-Q for the quarter ended March 31, 2016 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2016 and 2015, (iii) Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015, and (iv) Notes to the Unaudited Consolidated Financial Statements.