INSMED Inc
Form 10-Q
November 06, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

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 October 31, 2015, there were 61,803,749 shares of the registrant s common stock, $0.01 par value, outstanding.

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INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2015

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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 re 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 September 30, 2015 (unaudited)	As of December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 310,969	$ 159,226
Prepaid expenses and other current assets	8,289	5,488
Total current assets	319,258	164,714
In-process research and development	58,200	58,200
Fixed assets, net	8,052	7,534
Other assets	231	416
Total assets	$ 385,741	$ 230,864
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 10,857	$ 9,249
Accrued expenses	9,903	9,638
Other current liabilities	682	743
Current portion of long-term debt	25,256	
Total current liabilities	46,698	19,630
Other long-term liabilities	44	141
Debt, long-term		24,856
Total liabilities	46,742	44,627
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 61,803,749 and 49,806,131 issued and outstanding shares at September 30, 2015 and December 31, 2014, respectively	618	498
Additional paid-in capital	896,099	656,519
Accumulated deficit	(557,718)	(470,780)
Total shareholders equity	338,999	186,237
Total liabilities and shareholders equity	$ 385,741	$ 230,864

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues	$	$	$	$
Operating expenses:				
Research and development	19,221	15,200	54,631	41,493
General and administrative	11,024	8,204	30,272	22,806
Total operating expenses	30,245	23,404	84,903	64,299
Operating loss	(30,245)	(23,404)	(84,903)	(64,299)
Investment income	75	12	166	41
Interest expense	(725)	(594)	(2,165)	(1,795)
Other (expense) / income, net	(67)	(4)	(36)	152
Loss before income taxes	(30,962)	(23,990)	(86,938)	(65,901)
Benefit from income taxes				(4,389)
Net loss and comprehensive loss	$ (30,962)	$ (23,990)	$ (86,938)	$ (61,512)
Basic and diluted net loss per share	$ (0.50)	$ (0.54)	$ (1.51)	$ (1.50)
Weighted average basic and diluted common shares outstanding	61,774	44,082	57,565	40,882

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (unaudited)

(in thousands)

	Nine months ended September 30,	
	2015	**2014**
Operating activities		
Net loss	$ (86,938)	$ (61,512)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,342	697
Stock based compensation expense	11,757	8,592
Amortization of debt discount and debt issuance costs	343	283
Accrual of the end of term charge on the debt	57	86
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,616)	(1,358)
Accounts payable	1,340	2,546
Accrued expenses and other current liabilities	1,562	(818)
Net cash used in operating activities	(73,153)	(51,484)
Investing activities		
Purchase of fixed assets	(3,047)	(3,814)
Net cash used in investing activities	(3,047)	(3,814)
Financing activities		
Payments on capital lease obligations		(48)
Proceeds from exercise of stock options	5,001	847
Proceeds from issuance of common stock, net	222,942	108,016
Payment of debt issuance costs		(100)
Net cash provided by financing activities	227,943	108,715
Net increase in cash and cash equivalents	151,743	53,417
Cash and cash equivalents at beginning of period	159,226	113,894
Cash and cash equivalents at end of period	$ 310,969	$ 167,311
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 2,230	$ 1,403
Cash received for taxes (proceeds from sales of New Jersey net operating losses)	$ 994	$ 4,389

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 when left untreated. The Company s earlier stage pipeline includes INS1009, a nebulized prodrug formulation of treprostinil that the Company is developing for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs.

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 subsidiaries in a number of countries in Europe in preparation for the commercialization of ARIKAYCE, upon approval in the European Union, and to support its global tax structure. The Company has operations in the United States (U.S.), Ireland, Germany, France, the United Kingdom 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 United States 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 Form 10-K for the year ended December 31, 2014.

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.

Subsequent Events The Company has evaluated all events and transactions since September 30, 2015 and identified no significant events requiring disclosure in or adjustment to these financial statements.

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, 2014:

Foreign currency The Company has operations in the United States, Ireland, Germany, France, the United Kingdom and the Netherlands. The results of its non-U.S. dollar based operations are translated to U.S. dollars at the average exchange rates during the period. Assets and liabilities are translated at the exchange rate prevailing at the balance sheet date. Equity is translated at the prevailing exchange rate at the date of the equity transaction. Translation adjustments, when material, will be reflected in shareholders equity and included as a component of other comprehensive loss.

The Company realizes foreign currency transaction gains/(losses) in the normal course of business based on movements in the applicable exchange rates. These gains/(losses) are included as a component of other (expense) / income, net.

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:

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- 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 U.S. treasuries and mutual funds listed in active markets.

The Company s only assets and liabilities which were measured at fair value as of September 30, 2015 and December 31, 2014 were Level 1 and were comprised of cash and cash equivalents of $311.0 million and $159.2 million, respectively.

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 and nine months ended September 30, 2015 and 2014.

As of September 30, 2015 and December 31, 2014, 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 and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands, except per share amounts)			
Numerator:				
Net loss	$ (30,962)	$ (23,990)	$ (86,938)	$ (61,512)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share	61,774	44,082	57,565	40,882
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	61,774	44,082	57,565	40,882
Net loss per share:				
Basic and diluted net loss per share	$ (0.50)	$ (0.54)	$ (1.51)	$ (1.50)

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The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of September 30, 2015 and 2014 as their effect would have been anti-dilutive (in thousands):

	2015	2014
Stock options to purchase common stock	5,241	4,674
Restricted stock units	44	21

3. *Identifiable Intangible Assets*

The Company believes there are no indicators of impairment relating to its in-process research and development intangible assets as of September 30, 2015.

4. *Accrued Expenses*

Accrued expenses consist of the following:

	As of September 30, 2015	As of December 31, 2014
	(in thousands)	
Accrued clinical trial expenses	$ 4,258	$ 2,113
Accrued compensation	3,208	4,317
Accrued technical operation expenses	1,136	762
Accrued office construction costs		1,500
Accrued professional fees	931	542
Accrued interest payable	193	258
Other accrued expenses	177	146
	$ 9,903	$ 9,638

5. *Debt*

On June 29, 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 originally allowed the Company to borrow up to $20.0 million (Loan Agreement) at an interest rate of 9.25%. On December 15, 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 a total of $25.0 million and the interest-only period was extended through December 31, 2015. In addition, in the event the Company receives at least $90.0 million in cash proceeds from the completion of certain types of equity financings, subordinated debt financings, and/or up-front cash payments from corporate transactions prior to December 31, 2015, the Company has the option to extend the maturity date of the loan to January 1, 2018. If the Company elects to exercise

such option, it must pay Hercules a $250,000 fee. The Company completed an equity financing in April 2015 of $222.9 million which qualifies as a financing event under the Loan Agreement.

The following table presents the components of the Company s debt balance as of September 30, 2015 (in thousands):

Debt:		
Notes payable	$	25,000
Accretion of end of term charge		371
Issuance fees paid to lender		(77)
Discount from warrant		(38)
Current portion of long-term debt		(25,256)
Long-term debt	$	

As of September 30, 2015, future principal repayments of the debt for each of the years ending December 31, 2015 and 2016 were as follows (in thousands):

Year Ending in December 31:		
2015	$	
2016 (due in full January 1, 2016)		25,000
	$	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 September 30, 2015 approximates the carrying amount.

6. *Shareholders Equity*

Common Stock As of September 30, 2015, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 61,803,749 shares of common stock issued and outstanding. In addition, as of September 30, 2015, the Company had reserved 5,240,590 shares of common stock for issuance upon the exercise of outstanding common stock options and 43,798 for issuance upon the vesting of restricted stock units.

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.

On August 18, 2014, the Company completed an underwritten public offering of 10,235,000 shares of the Company s common stock, which included the underwriter s exercise in full of its over-allotment option of 1,335,000 shares, at a price to the public of $11.25 per share. The Company s net proceeds from the sale of the shares, after deducting the underwriter s discount and offering expenses of $7.1 million, were $108.0 million.

Preferred Stock As of September 30, 2015 and December 31, 2014, 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 September 30, 2015, there were 4,338,355 shares remaining 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. During the nine months ended September 30, 2015, the Company granted 227,000 inducement stock options to new employees.

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Volatility	78.1%-79.1%	84.1%-85.4%	78.1%-82.3%	83.1%-85.5%
Risk-free interest rate	1.49%-1.72%	1.62%-1.83%	1.31%-1.72%	1.46%-1.83%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term (in years)	6.25	6.25	6.25	6.25
Weighted average fair value of stock options granted	$17.32	$10.10	$14.38	$11.74

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 on December 1, 2010. The expected life was determined using the simplified method as described in ASC Topic 718, Accounting for Stock Compensation , which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield in effect at the date of grant. Forfeitures are based on

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the actual percentage of option forfeitures since the closing of the Company s merger with Transave on December 1, 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 September 30, 2015 the Company had performance options totaling 168,334 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.

The following table summarizes the Company s aggregate stock option activity for the nine months ended September 30, 2015:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2014	4,400,106	$ 10.59		
Granted	1,740,150	$ 20.68		
Exercised	(471,138)	$ 10.61		
Forfeited or expired	(428,528)	$ 14.93		
Options outstanding at September 30, 2015	5,240,590	$ 13.59	8.27	$ 56,828
Vested and expected to vest at September 30, 2015	5,002,447	$ 13.38	8.23	$ 55,303
Exercisable at September 30, 2015	1,787,295	$ 8.48	7.42	$ 28,484

The total intrinsic value of stock options exercised during the three months ended September 30, 2015 and 2014 was $0.7 million and $0.8 million, respectively, and during the nine months ended September 30, 2015 and 2014 was $4.6 million and $1.5 million, respectively.

As of September 30, 2015, there was $30.5 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.6 years. Included above in unrecognized compensation expense was $1.4 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 September 30, 2015			Exercisable as of September 30, 2015	
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	3.29	153,878	6.26	3.05	128,915	3.05
3.40	3.40	708,314	6.95	3.40	531,236	3.40
3.60	6.90	584,572	7.20	6.01	343,412	5.95
6.96	12.44	702,620	7.66	11.34	351,382	11.23
12.58	13.94	545,475	8.66	12.77	131,828	12.78

14.04	16.07	808,650	8.75	15.34	120,324	14.43
16.19	20.49	646,581	8.59	19.53	174,573	19.65
20.92	22.14	107,300	9.40	21.54	5,625	21.54
22.76	22.76	823,700	9.65	22.76		
22.84	27.38	159,500	9.68	23.80		

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 nine months ended September 30, 2015:

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	Number of RSUs	Weighted Average Grant Price
Outstanding at December 31, 2014	20,502	$ 19.47
Granted	49,776	16.07
Released	(26,480)	18.72
Outstanding at September 30, 2015	43,798	$ 16.06
Expected to vest	43,798	$ 16.06

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 and nine months ended September 30, 2015 and 2014:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
	(in millions)		(in millions)	
Research and development expenses	$ 0.8	$ 1.4	$ 3.1	$ 3.6
General and administrative expenses	3.0	1.8	8.7	5.0
Total	$ 3.8	$ 3.2	$ 11.8	$ 8.6

8. Income Taxes

The benefit for income taxes was $0 and $4.4 million for the nine months ended September 30, 2015 and 2014, respectively. The benefit for income taxes recorded for the nine months ended September 30, 2014 solely reflects the reversal of a valuation allowance previously recorded against the Company s New Jersey State net operating losses (NOLs) that resulted from the Company s sale of a portion of its New Jersey State NOLs under the State of New Jersey s Technology Business Tax Certificate Transfer Program (the Program) for cash of $4.4 million, net of commissions. The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits for cash.

The Company is subject to U.S. federal, 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 U.S. 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 would be subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. The Company s policy is to recognize interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company has recorded no such expense. As of September 30, 2015 and December 31, 2014, 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.

At December 31, 2014, the Company had federal net operating loss carryforwards for income tax purposes of approximately $461.8 million. Due to the limitation on NOLs as more fully discussed below, $283.5 million of the NOLs are available to offset future taxable income, if any. The NOL carryovers and general business tax credits expire in various years beginning in 2018. For state tax purposes, the Company has approximately $63 million of New Jersey NOLs available to offset against future taxable income or to be sold as part of the New Jersey Transfer Program. The Company also has California and Virginia NOLs that are entirely limited due to Section 382 (as discussed below), in addition to changing state apportionment allocations, as the Company is now 100% resident in New Jersey.

During 2014, the Company completed an Internal Revenue Code Section 382 (Section 382) analysis in order to determine the amount of losses that are currently available for potential offset against future taxable income, if any. It was determined that the utilization of the Company s NOL and general business tax credit carryforwards generated in tax periods up to and including December 2010 (the December 2010 and prior NOLs) were subject to substantial limitations under Section 382 due to ownership changes that occurred at various points from the Company s original organization through December 2010. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company s formation, it has raised capital through the issuance of common stock on several occasions which, combined with the purchasing shareholders subsequent

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disposition of those shares, resulted in multiple changes in ownership, as defined by Section 382 since the Company s formation in 1999. These ownership changes resulted in substantial limitations on the use of the Company s NOLs and general business tax credit carryforwards up to and including December 2010. The Company continues to track all of its NOLs and tax credit carryforwards but has provided a full valuation allowance to offset those amounts.

9. Commitments and Contingencies

Commitments

The Company has an operating lease for office and laboratory space located in Bridgewater, NJ, its corporate headquarters, that terminates in November 2019. Future minimum rental payments under this lease are $3.1 million. The Company also holds a lease that expires in October 2016 for office space in Richmond, VA, the Company s former corporate headquarters. Future minimum rental payments under this lease total approximately $0.5 million. During 2011, the Company recorded a net present value charge of $1.2 million in general and administrative expenses associated with vacating the Richmond facility. The remaining accrual for this charge was $0.2 million as of September 30, 2015. In December 2014, the Company entered into an agreement to sublet this space for the remainder of the lease term.

Rent expense charged to operations was $0.2 million and $0.4 million for the three months ended September 30, 2015 and 2014, respectively, and $0.6 million and $1.0 million for the nine months ended September 30, 2015 and 2014, respectively. Future minimum rental payments (net of sublease) required under the Company s operating leases for the period from October 1, 2015 to December 31, 2015 and for each of the next five years are as follows (in thousands):

Year Ending December 31:

2015 (remaining)	$	303
2016		1,144
2017		741
2018		762
2019		718
2020		
	$	3,668

On September 15, 2015, the Company entered into a Commercial Fill/Finish Services Agreement (the Fill/Finish Agreement) with Ajinomoto Althea, Inc., a Delaware corporation (Althea), for Althea to produce, on a non-exclusive basis, ARIKAYCE in finished dosage form. Under the Fill/Finish Agreement, the Company is obligated to pay a minimum of $2.7 million for the batches of ARIKAYCE produced each calendar year during the term of the Fill/Finish Agreement. The Fill/Finish Agreement is effective as of January 1, 2015, has an initial term that ends on December 31, 2017 and may be extended for additional two year periods upon mutual written agreement of the Company and Althea at least one year prior to the expiration of its then-current term.

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 include, but are not limited to: failure or delay of European Medicines Agency, Health Canada, United States Food and Drug Administration and other regulatory reviews and approvals; competitive developments affecting the Company s product candidates; delays in product development or clinical trials or other studies; patent disputes and other intellectual property developments relating to the Company s product candidates; unexpected regulatory actions, delays or requests; the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations; the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in Company s prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies; the inability to successfully develop the Company s product candidates or receive necessary regulatory approvals; inability to make product candidates commercially successful; changes in anticipated expenses; changes in the Company s financing requirements or ability to raise additional capital; our ability to complete development of, receive regulatory approval for, and successfully commercialize ARIKAYCE or INS1009; our estimates of expenses and future revenues and profitability; our plans to develop and market new products and the timing of these development programs; our estimates of the size of the potential markets for our product candidates; our selection and licensing of product candidates; our ability to attract third parties with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate license agreements and other third party efforts, including those relating to the development and commercialization of our product candidates; the degree of protection afforded to us by our intellectual 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 and amount of reimbursement for our product candidates; the success of other competing therapies that may become available; and the availability of adequate supply and manufacturing capacity and quality for our product candidates.

Forward-looking statements are based upon our current expectations and beliefs, and involve known and unknown 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, 2014 filed with the Securities and Exchange Commission (SEC) on February 27, 2015 and on our subsequent quarterly reports on Form 10-Q filed in 2015. 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, 2014.

OVERVIEW

Insmed is 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 which can be fatal when left untreated. Our earlier stage pipeline includes INS1009, a nebulized prodrug formulation of treprostinil that we are developing for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs.

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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 pulmonary disease in the U.S., Japan and Europe. In February 2015 the European Medicines Agency (EMA) validated our Marketing Authorization Application (MAA) for ARIKAYCE for NTM lung infections, as well as cystic fibrosis (CF) patients with *Pseudomonas* lung infections. In the third quarter of 2015, the EMA adopted our request to withdraw the *Pseudomonas* indication from our MAA. We will only seek approval of ARIKAYCE for the treatment of patients with refractory NTM lung infections caused by MAC. We chose to withdraw this indication after receiving a request from EMA for additional information with respect to the similarity of ARIKAYCE to the TobiPodhaler given this product s orphan designation. While it is our view that ARIKAYCE is not similar to the TobiPodhaler, a comprehensive response to the EMA s request would require us to divert significant resources from and potentially delay the regulatory advancement of the NTM indication. Given the significant need for approved medications for patients with NTM lung disease, we concluded the most appropriate near-term course of action for ARIKAYCE was to focus exclusively on advancing the regulatory review process for the NTM indication.

We recently submitted an Investigational New Drug application (IND) for INS1009 and expect to begin a phase 1 study in healthy subjects later this year. In addition to INS1009 our research team is evaluating other preclinical projects including additional formulations of treprostinil for use in a metered dose inhaler or delivered via subcutaneous injection. To complement our internal research, we are evaluating in-licensing and acquisition opportunities for a broad range of rare diseases.

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

Product Candidate/Target Indications	**Status**	**Next Expected Milestones**
ARIKAYCE for patients with refractory nontuberculous mycobacteria (NTM) lung infections caused by MAC	• We are advancing the CONVERT study, which is designed to confirm the culture conversion results seen in our phase 2 clinical trial. The CONVERT study is investigating ARIKAYCE in adult non-CF patients with NTM lung infections caused by MAC that are refractory to treatment. • In February 2015 the EMA validated our MAA for ARIKAYCE. We have received the EMA s 120-day questions and are preparing our responses. • We reported top-line clinical results from our phase 2 clinical trial in which ARIKAYCE did not meet the pre-specified level for statistical significance with respect to the primary endpoint, but demonstrated clearance of the	• We expect to complete enrollment in the CONVERT study in approximately eighteen to twenty-four months from the initiation of the trial. • We anticipate responding to the EMA s 120-day questions before the end of 2015. • If approved, we expect ARIKAYCE would be the first approved inhaled antibiotic treatment specifically indicated for NTM lung infections in the U.S., Europe and Canada. • We are developing plans to commercialize ARIKAYCE, if approved, in certain countries in Europe and in the U.S., and eventually Canada, Japan and certain other countries.

infecting mycobacterial organism in the sputum with regard to the secondary endpoint of NTM culture conversion to negative.

- The FDA has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP) for NTM lung disease. Breakthrough therapy features intensive guidance on efficient drug development and allows for a rolling review. An application for a QIDP designated product is eligible for priority review.

- The Committee for Orphan Medicinal Products of the EMA has issued a

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	positive opinion for orphan designation for ARIKAYCE.	
INS1009 (nebulized treprostinil prodrug) *for pulmonary arterial hypertension (PAH)*	• We recently submitted an IND to the FDA and plan to begin a phase 1 study of INS1009.	• We expect to commence a phase 1 single ascending dose study of INS1009 in healthy subjects in the fourth quarter of 2015.

Product Pipeline

ARIKAYCE

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 infections, a rare and often chronic infection that is capable of causing irreversible lung damage and which can be fatal when left untreated. Amikacin solution for parenteral administration is an established drug that is effective 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 pulmonary 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 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 phase 3 randomized, open-label, global 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-CF patients 18 years and older with a NTM lung infection caused by MAC that is refractory to a stable multi-drug regimen for at least six months with treatment either ongoing or completed within 12 months of screening. This subgroup of patients responded particularly well to treatment with ARIKAYCE in our completed phase 2 study. We believe this clinical trial will confirm the culture conversions seen in the phase 2 study and provide the basis for submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). After a screening period of approximately 10 weeks, eligible subjects will be randomized 2:1 to once-daily ARIKAYCE plus a multi-drug regimen or a multi-drug regimen alone. The primary efficacy endpoint is the proportion of patients who achieve culture conversion at month 6 (defined as 3 consecutive negative sputum cultures collected monthly) in the ARIKAYCE plus multi-drug regimen arm compared to the arm in which patients receive a multi-drug regimen alone. Key secondary and exploratory endpoints include the change from baseline in the six-minute walk test; comprehensive pharmacokinetic sampling conducted in lieu of a separate local pharmacokinetic study in Japanese patients; and off-treatment assessments to evaluate durability of effect.

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At month 8, after all sputum culture results are known up to and including month 6, patients will be assessed as converters or non-converters for the primary efficacy endpoint. A converter is defined as a patient with three consecutive monthly sputum samples at month 6 that test negative for the presence of MAC NTM bacteria. All non-converters in the study will be eligible to enter a separate open-label study known as the INS-312 study. 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 months off-treatment study visit will be the last study visit for the CONVERT study.

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, including Japan s Pharmaceuticals and Medical Devices Agency, and was approved in the U.S. by a central Institutional Review Board (IRB). We initiated the global trial in early 2015 and expect to complete enrollment in approximately eighteen to twenty-four months from the initiation of the trial. 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 expect to conduct CONVERT at over 100 sites in the United States, Europe, Australia, Asia and Canada. The CONVERT study is designed to enroll enough subjects to ensure at least 261 patients are evaluable for the primary endpoint at month 6.

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. 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 safety and durability of effect.

Eighty-nine patients were randomized and dosed in the study. Of the 80 patients who completed 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 (76) percent (59/78) of patients who elected to continue in the open-label phase of the study completed the open-label study.

The primary efficacy endpoint of the study was a semi-quantitative measurement of the change in mycobacterial density on a seven-point scale from baseline (day 1) to the end of the randomized portion of the trial (day 84). ARIKAYCE did not meet the pre-specified level for statistical significance although there was a positive trend (p=0.148) in favor of ARIKAYCE. The p-value for the key secondary endpoint of culture conversion to negative at Day 84 was 0.01, in favor of ARIKAYCE.

After establishing the primary endpoint for the phase 3 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 commonly 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 during the 168-day treatment phase of the study.

- Three additional patients achieved culture conversion by the 28-day off-ARIKAYCE follow-up assessment.

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

- Eleven patients remained culture negative; nine of these patients were non-CF MAC and 2 were CF *M. abscessus* at the time of study entry.

- Three non-CF MAC patients could not produce sputum despite reasonable attempts.

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

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

In contrast, of the patients who did not achieve culture conversion:

- Twenty eight patients provided sputum at the 12-month follow up visit, of which 6 patients had a negative culture.

- One patient could not produce sputum.

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.

During the double-blind phase, the majority of the patients 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 patients 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%). However, in the open-label phase, the overall incidence of treatment-related adverse events was lower in the ARIKAYCE group than in the placebo group (ARIKAYCE: 48.6%, placebo: 60.5%).

One patient died during the double-blind phase of pneumonia and acute respiratory distress syndrome and one patient died during the open-label phase of multi-organ failure, intestinal ischemia, and urosepsis. None of the events in either patient were considered to be related to the study drug by the investigator. In the double-blind phase, serious adverse events were reported for a greater proportion of patients in the ARIKAYCE group than in the placebo group (18.2% versus 8.9%, respectively). In the double-blind phase, a greater proportion of patients 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 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 patients in the placebo group reported adverse events leading to study drug discontinuation.

No clinically significant changes in laboratory values, vital signs, BMI, 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

In the fourth quarter of 2014, we filed an MAA with the EMA seeking approval of ARIKAYCE for the treatment of NTM lung infections, as well as *Pseudomonas* lung infections in CF patients. The EMA s review of the MAA is ongoing. We have received the EMA s 120-day questions and we anticipate responding before the end of 2015. In the third quarter of 2015, the EMA adopted our request to withdraw the *Pseudomonas* indication from our MAA. We will only seek approval of ARIKAYCE for the treatment of patients with refractory NTM lung infections caused by MAC. We chose to withdraw this indication after receiving a request from EMA for additional information with respect to the similarity of ARIKAYCE to the TobiPodhaler given this product s orphan designation. While it is our view that ARIKAYCE is not similar to the TobiPodhaler, a comprehensive response to the EMA s request would require us to divert significant resources from and potentially delay the regulatory advancement of the NTM indication. Given the significant need for approved medications for patients with NTM lung disease, we concluded the most appropriate near-term course of action for ARIKAYCE was to focus exclusively on advancing the regulatory review process for the NTM indication.

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 lethargy. Patients with NTM lung disease frequently require lengthy hospital stays to manage their condition. There are no products specifically

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indicated for the treatment of NTM lung disease in the U.S., Europe and Canada. 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 U.S. is increasing at approximately 8% per year and that those Medicare part B NTM patients 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 U.S., 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 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 U.S. in 2011 and that such cases were estimated to be growing at a rate of 10% per year. NTM is four to five times more prevalent than tuberculosis (TB) in the U.S. (Incidence of TB from Center for Disease Control and Prevention Morbidity and Mortality Weekly Report, March 2012). 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 cases of pulmonary disease attributable to NTM within the EU5 and a total of 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 infections in Europe are limited, consistent with U.S. prevalence trends, recent published studies concur that prevalence in Europe is increasing and, according to a study published in the Japanese journal Kekkaku in 2011, Japan has one of the world s highest NTM disease rates.

NTM currently includes over 150 species. MAC is the predominant pathogenic species in NTM pulmonary disease in the U.S., Japan and Europe, followed by *M. abscessus*. Thus far, we have studied ARIKAYCE in two of the most common pathogenic species, 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 U.S. 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 recently 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 ($p<0.001$) in the incidence of NTM infections between 2008 and 2013 with the greatest incidence (56.3%) for those members 65 to 74 years of age. Following diagnosis with NTM infection, over 50% of members were still in the plan after six years (Abraham et al.).

- At Infectious Disease Week in October 2015 researchers reported that patients with NTM are using significantly greater healthcare resources in the period preceding their diagnosis. Ordering mycobacterial testing of sputum earlier may help in preventing or delaying a diagnosis (Holt et al.).

- At the Academy of Managed Care Pharmacy conference in October 2015, researchers reported significantly higher resource utilization and cost patterns for patients with NTM lung infections than their matched controls both pre- and post-diagnosis. Patients who received optimal treatment based on 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.).

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 qualified infectious disease product (QIDP) for NTM lung disease. Orphan designation features seven years of post-approval market exclusivity and QIDP features five years of post-approval exclusivity. In addition, an NDA for a QIDP designated product is also eligible for priority review designation

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by FDA. A priority review designation means FDA s goal is to take action on the NDA within six months of FDA s accepting the application as filed 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 in PAH. We believe that INS1009 may prolong 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. Reducing dose frequency therefore has the potential to ease patient burden and to positively impact compliance. Additionally, we believe that INS1009 over time may reduce 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. In addition to INS1009, our research team is evaluating other preclinical projects including additional formulations of treprostinil for use in a metered dose inhaler or delivered via subcutaneous injection.

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 include full safety and effectiveness reports, but unlike a traditional NDA the applicant may rely at least in part on studies not conducted by or for the applicant. The ability to rely on existing data to support safety and/or effectiveness can reduce the time and cost associated with traditional NDAs. We recently submitted an IND application and plan to commence a phase 1 trial before the end of 2015.

Market Opportunity

There is no cure for PAH. PAH is a serious, progressive rare disease affecting approximately 100,000 patients globally, including approximately 25,000 treated patients in the United States (Yang et al., 2006; Peacock et al. 2007; and Humbert et al. 2006). PAH ultimately leads to heart failure and the disease has a 15% one-year mortality rate (Kane et al., 2011). 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.

The long term outcomes of medically treated patients remain uncertain, and transplantation remains an option for patients who fail on drug therapy. Prostanoid formulations used to treat PAH include intravenous epoprostenol (prostacyclin), intravenous treprostinil (a prostacyclin analog), subcutaneous treprostinil, inhaled treprostinil, oral treprostinil and inhaled iloprost. All prostanoid compounds have the limitation of a short half-life in the body, including treprostinil.

For subcutaneous or intravenous administered treprostinil, continuous infusion is required and patients often experience injection site pain and increased risk of infection, respectively. Oral and inhaled forms of treprostinil require multiple dosing sessions per day with high and low cycling in blood levels. The initial high levels of drug and the local delivery of the drug may cause tolerability issues (cough, laryngeal irritation, emesis, hypotension and headache) and at the subsequent low levels of drug there may be reduced therapeutic benefit, especially in the overnight hours.

Our Strategy

Our strategy is to focus on the needs of patients with rare diseases. We are currently focused on the development and commercialization of ARIKAYCE, or LAI. There are currently no products indicated to treat NTM lung disease in North America or Europe. While we believe that ARIKAYCE has the potential to treat many different diseases, our initial focus is on securing regulatory approval and commercialization preparation for ARIKAYCE in NTM lung disease. Our earlier stage pipeline includes INS1009, a prodrug formulation of treprostinil.

Our current priorities are as follows:

- Continue conducting clinical trials to generate additional data supporting the safety and effectiveness of ARIKAYCE for the treatment of patients with NTM lung disease;

- Actively pursue approvals of ARIKAYCE to treat NTM lung disease through the submission of country-specific marketing authorizations to applicable regulatory bodies in the U.S., Europe, Canada, Japan and certain other countries;

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- Expand our product supply chain in support of clinical development and if approved, commercialization;

- Prepare for commercial launch of ARIKAYCE in Europe and the U.S., and eventually Canada, Japan and certain other countries;

- Advance the clinical development of INS1009, our nebulized treprostinil prodrug for PAH;

- Attempt to develop, acquire, in-license or co-promote promising late stage or commercial products that we believe are complementary to ARIKAYCE and our core competencies; and

- Continue to develop novel formulations of existing therapies, where such reformulation could materially improve the treatment paradigm for the underlying disease or enable pursuit of new indications.

Corporate Development

We also 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. Our current primary development focus is to obtain regulatory approval for ARIKAYCE in the EU, complete our global phase 3 CONVERT study, and prepare for commercialization, assuming regulatory approval in Europe, the U.S., Canada, Japan and certain other countries. We intend to file a New Drug Submission (NDS) application with Health Canada after we have approval for ARIKAYCE in the U.S. We anticipate that, if approved, ARIKAYCE would be the first once-a-day inhaled antibiotic treatment option available for the NTM indication in North America and Europe.

Manufacturing

We currently manufacture ARIKAYCE at Ajinimoto Althea (Althea) in the U.S. and increased the scale of manufacturing at this location during the last 12 months. In February 2014, we entered into a contract manufacturing agreement with Therapure Biopharma Inc. (Therapure) for the manufacture of ARIKAYCE at the larger scales necessary to support commercialization. We expect this location to be fully operational by the end of 2015. 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 recently filed an IND with the FDA for INS1009, our investigational nebulized treprostinil prodrug for use in the treatment of PAH, and plan to manufacture INS1009 at third party locations.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenues

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, and other internal operating expenses, the cost of manufacturing our drug candidates 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 candidates for clinical study are primarily related to activities at contract manufacturing organizations that manufacture ARIKAYCE and INS1009 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.

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Since 2011, we have focused our development activities principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. In 2013, we completed a phase 3 trial in Europe and Canada in which we evaluated ARIKAYCE in CF patients with *Pseudomonas* lung infections. In 2014, we completed a phase 2 clinical trial in the U.S. and Canada of ARIKAYCE in patients with NTM lung disease. In 2015, we commenced a global phase 3 trial 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 ARIKAYCE development programs. Our development efforts in 2015 principally relate to the development of ARIKAYCE in the NTM indication and, to a lesser extent, for INS1009 for PAH.

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

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

Our clinical trials may be subject to delays, particularly if we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our clinical trials. Moreover, all of our product candidates must overcome significant regulatory, technological, manufacturing and marketing challenges before they can be successfully commercialized. Any significant delays that occur or additional expenses that we incur may have a material adverse effect on our financial position and may require us to raise additional capital sooner or in larger amounts than is presently expected. In addition, as a result of the risks and uncertainties related to the development and approval of our product candidates and the additional uncertainties related to our ability to market and sell these products once approved for commercial sale, we are unable to provide a meaningful prediction regarding when, if at all, we will generate positive cash flow from these projects.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance and accounting, legal, 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.

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RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2015 and 2014

Net Loss

Net loss for the quarter ended September 30, 2015 was $31.0 million, or ($0.50) per common share basic and diluted, compared with a net loss of $24.0 million, or ($0.54) per common share basic and diluted, for the quarter ended September 30, 2014. The $7.0 million increase in our net loss for the quarter ended September 30, 2015 as compared to the same period in 2014 was primarily due to:

- Increased research and development expenses of $4.0 million primarily resulting from an increase in clinical trial expenses related to the ARIKAYCE phase 3 CONVERT study and expenses related to research activities for INS1009, our treprostinil prodrug candidate for PAH; and

- Increased general and administrative expenses of $2.8 million primarily resulting from an increase in pre-commercial activities in Europe and an increase in noncash stock-based compensation as compared to the prior year period.

Research and Development Expenses

Research and development expenses for the quarters ended September 30, 2015 and 2014 were comprised of the following:

	Quarters Ended September 30,		Increase (decrease)	
	2015	2014	$	%
External Expenses				
Clinical development & research	$ 6,515	$ 3,226	$ 3,289	102.0%
Manufacturing	5,713	4,706	1,007	21.4%
Regulatory and quality assurance	956	1,245	(289)	-23.2%
Subtotal external expenses	$ 13,184	$ 9,177	$ 4,007	43.7%
Internal Expenses				
Compensation and related expenses	$ 4,464	$ 4,687	$ (223)	-4.8%
	1,573	1,336	237	17.7%

Other internal operating expenses				
Subtotal internal expenses	$ 6,037	$ 6,023	$ 14	0.2%
Total	$ 19,221	$ 15,200	$ 4,021	26.5%

Research and development expenses increased to $19.2 million during the quarter ended September 30, 2015 from $15.2 million in the same period in 2014. The $4.0 million increase was primarily due to a $3.3 million increase in external clinical development and research expenses related to the ARIKAYCE phase 3 CONVERT study and expenses pertaining to research activities for INS1009. We expect research and development expenses to increase in 2015 as compared to 2014 due primarily to the clinical trial activity related to the ARIKAYCE phase 3 CONVERT study and also for research expenses related to the INS1009 program.

General and Administrative Expenses

General and administrative expenses for the quarters ended September 30, 2015 and 2014 were comprised of the following:

	Quarters Ended September 30,		Increase (decrease)	
	2015	**2014**	**$**	**%**
General & administrative	$ 7,508	$ 6,489	$ 1,019	15.7%
Pre-commercial expenses	3,516	1,715	1,801	105.0%
Total general & administrative expenses	$ 11,024	$ 8,204	$ 2,820	34.4%

General and administrative expenses increased to $11.0 million during the quarter ended September 30, 2015 from $8.2 million in the same period in 2014. The $2.8 million increase was primarily due to pre-commercial expenses related to the build out of our European operations and an increase in noncash stock-based compensation expense. We expect general and administrative expenses to increase in 2015 as compared to 2014 due, in part, to an increase in expenditures related to pre-commercial activities in certain European markets.

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Interest Expense

Interest expense was $0.7 million during the quarter ended September 30, 2015 as compared to $0.6 million in the same period in 2014. The $0.1 million increase in interest expense in 2015 relates to an increase in our borrowings from Hercules. In December 2014, we entered into a third amendment to the Loan and Security Agreement with Hercules which increased our borrowings $5.0 million to a total of $25.0 million.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Net Loss

Net loss for the nine months ended September 30, 2015 was $86.9 million, or ($1.51) per common share basic and diluted, compared with a net loss of $61.5 million, or ($1.50) per common share basic and diluted, for the nine months ended September 30, 2014. The $25.4 million increase in our net loss for the nine months ended September 30, 2015 as compared to the same period in 2014 was primarily due to:

- Increased research and development expenses of $13.1 million primarily resulting from an increase in clinical trial expenses related to the ARIKAYCE phase 3 CONVERT study and expenses related to research activities for INS1009; and

- Increased general and administrative expenses of $7.5 million resulting from an increase in compensation expenses, including an increase in noncash stock-based compensation related to the vesting of certain performance-based stock options, an increase in pre-commercial expenses in Europe and fees and expenses related to the build-out of our European operations and global tax infrastructure.

In addition, the nine months ended September 30, 2014 included a $4.4 million benefit from income taxes resulting from the sale of a portion of our New Jersey State NOLs under the State of New Jersey s Technology Business Tax Certificate Transfer Program for cash, net of commissions. The reason for the decrease in tax benefit in 2015 was due to timing, as we recognized the full tax benefits of the 2014 sales of NOLs in calendar year 2014, while the 2013 sales of NOLs were recognized in the first quarter of 2014.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2015 and 2014 were comprised of the following:

	Nine Months Ended September 30,		Increase (decrease)	
	2015	2014	$	%
External Expenses				
Clinical development & research	$ 18,393	$ 8,705	$ 9,688	111.3%
Manufacturing	16,141	12,255	3,886	31.7%
Regulatory and quality assurance	1,897	3,763	(1,866)	-49.6%
Subtotal external expenses	$ 36,431	$ 24,723	$ 11,708	47.4%
Internal Expenses				
Compensation and related expenses	$ 13,795	$ 13,131	$ 664	5.1%
Other internal operating expenses	4,405	3,639	766	21.1%
Subtotal internal expenses	$ 18,200	$ 16,770	$ 1,430	8.5%
Total	$ 54,631	$ 41,493	$ 13,138	31.7%

Research and development expenses increased to $54.6 million during the nine months ended September 30, 2015 from $41.5 million in the same period in 2014. The $13.1 million increase was primarily due to a $9.7 million increase in external clinical development and research expenses related to the ARIKAYCE phase 3 CONVERT study and expenses related to research activities for INS1009. In addition manufacturing expenses increased $3.9 million primarily due to an increase in production related to our clinical and research programs. We expect research and development expenses to increase in 2015 as compared to 2014 due primarily to the clinical trial activity related to the ARIKAYCE phase 3 CONVERT study and also for research expenses related to the INS1009 program.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2015 and 2014 were comprised of the following:

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	Nine Months Ended September 30,		Increase (decrease)	
	2015	2014	$	%
General & administrative	$ 22,840	$ 17,096	$ 5,744	33.6%
Pre-commercial expenses	7,432	5,710	1,722	30.2%
Total general & administrative expenses	$ 30,272	$ 22,806	$ 7,466	32.7%

General and administrative expenses increased to $30.3 million during the nine months ended September 30, 2015 from $22.8 million in the same period in 2014. The $7.5 million increase was primarily due to higher compensation related expenses due to an increase in headcount, a $1.5 million increase in noncash stock-based compensation expense related to certain performance based stock options as the recognition criteria was met upon the MAA for ARIKAYCE being accepted for filing by the EMA in February 2015, an increase in pre-commercial expenses in Europe and fees and expenses related to the build-out of our European operations and global tax infrastructure. These increases were partially offset by a decrease in pre-commercial spend in the U.S. We expect general and administrative expenses to increase in 2015 as compared to 2014 due, in part, to an increase in expenditures related to pre-commercial activities in certain European markets.

Interest Expense

Interest expense was $2.2 million during the nine months ended September 30, 2015 as compared to $1.8 million in the same period in 2014. The $0.4 million increase in interest expense in 2015 relates to an increase in our borrowings from Hercules. In December 2014, we entered into a third amendment to the Loan and Security Agreement with Hercules which increased our borrowings $5.0 million to a total of $25.0 million.

Benefit from Income Taxes

The benefit for income taxes was $0 and $4.4 million for the nine months ended September 30, 2015 and 2014, respectively. The benefit for income taxes recorded for the nine months ended September 30, 2014 solely reflects the reversal of a valuation allowance previously recorded against our New Jersey State net operating losses (NOLs) that resulted from the sale of a portion of our New Jersey State NOLs under the State of New Jersey s Technology Business Tax Certificate Transfer Program (the Program) for cash of $4.4 million, net of commissions. The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLs and defined research and development tax credits for cash. The reason for the decrease in tax benefit in 2015 was due to timing, as we recognized the full tax benefits of the 2014 sales of NOLs in calendar year 2014, while the 2013 sales of NOLs were recognized in the first quarter of 2014.

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 because we plan to fund research and development activities and commercial launch activities, and we do not expect material revenues for at least the next two years.

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 2015 and in 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 2015 and 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.

On April 6, 2015, we completed an underwritten public offering of 11.5 million shares of our common stock, which included the underwriter s exercise in full of its over-allotment option of 1.5 million shares, at a price to the public of $20.65 per share. Our 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.

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Cash Flows

As of September 30, 2015, we had total cash and cash equivalents of $311.0 million, as compared with $159.2 million as of December 31, 2014. The $151.7 million increase was due primarily to net proceeds received from the issuance of 11.5 million shares of our common stock in April 2015 offset by the use of cash in operating activities. Our working capital was $272.6 million as of September 30, 2015.

Net cash used in operating activities was $73.2 million and $51.5 million for the nine months ended September 30, 2015 and 2014, respectively. The net cash used in operating activities during 2015 and 2014 was primarily for the clinical, regulatory and pre-commercial activities related to ARIKAYCE.

Net cash used in investing activities was $3.0 million and $3.8 million for the nine months ended September 30, 2015 and 2014, respectively. The net cash used in investing activities during 2015 was primarily related to payments for the build out of our headquarters and lab facility in Bridgewater, New Jersey, as well as investments in an enterprise resource planning system.

Net cash provided by financing activities was $227.9 million and $108.7 million for the nine months ended September 30, 2015 and 2014, respectively. Net cash provided by financing activities in 2015 included net proceeds of $222.9 million received from the issuance of 11.5 million common shares in April 2015 and proceeds of $5.0 million received from stock option exercises. Net cash provided by financing activities in 2014 included $108.0 million from the issuance of common stock and cash received from stock option exercises.

Contractual Obligations

On June 29, 2012, we and our domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement with Hercules that allowed us to borrow up $20.0 million (Loan Agreement) at an interest rate of 9.25%. On December 15, 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 $5.0 million to a total of $25.0 million and the interest-only period was extended through December 31, 2015. In addition, in the event we receive at least $90.0 million in cash proceeds from the completion of certain types of equity financings, subordinated debt financings, and/or up-front cash payments from corporate transactions prior to December 31, 2015, we have the option to extend the maturity date of the loan to January 1, 2018. If we elect to exercise the option, we are required to pay Hercules a $250,000 fee. We completed an equity financing in April 2015 of $222.9 million which qualifies as a financing event under the Loan Agreement.

We have an operating lease for office and laboratory space located in Bridgewater, NJ, our corporate headquarters, that expires in November 2019. Future minimum rental payments under this lease total approximately $3.1 million. We hold a lease that expires in October 2016 for office space in Richmond, VA, the site of our former corporate headquarters. Future minimum rental payments under this lease total approximately $0.5 million. During 2011, we recorded a net present value charge of $1.2 million in general and administrative expenses associated with vacating the Richmond facility. In December 2014, we entered into an agreement to sublet this space for the remainder of the lease term. We expect to collect proceeds from the sublease in the amount of $0.3 million over the remaining term of the lease.

On September 15, 2015, we entered into a Commercial Fill/Finish Services Agreement (the Fill/Finish Agreement) with Ajinomoto Althea, Inc., a Delaware corporation (Althea), for Althea to produce, on a non-exclusive basis, ARIKAYCE in finished dosage form. Under the Fill/Finish Agreement, we are obligated to pay a minimum of $2.7 million for the batches of ARIKAYCE produced each calendar year during the term of the Fill/Finish Agreement. The Fill/Finish Agreement is effective as of January 1, 2015, has an initial term that ends on December 31, 2017 and may be extended for additional two year periods upon mutual written agreement of the Company and Althea at least one year prior to the expiration of its then-current term.

As of September 30, 2015, future payments under our long-term debt agreements, capital leases, minimum future payments under non-cancellable operating leases (net of sublease) and minimum future payment obligations are as follows:

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	As of September 30, 2015 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	$ 25,000	$	$	$
Contractual interest	1,174	1,174			
Capital lease obligations					
Debt maturities					
Contractual interest					
Operating leases	3,668	1,223	1,535	910	
Purchase obligations	5,400	2,025	3,375		
Total contractual obligations	$ 35,242	$ 29,422	$ 4,910	$ 910	$

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 on commercial sales of ARIKAYCE pursuant to the licensing agreement. 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 the Device (the Initial Term). The term of the PARI Agreement may be 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 5 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 2009 and 2012, we entered into a cooperative research and development agreement (CRADA) with the National Institute of Allergy and Infectious Diseases (NIAID) to design and conduct our phase 2 study of ARIKAYCE in patients with NTM. NIAID has also agreed to provide biostatistical advisory input in connection with the phase 2 NTM study. If we decide not to continue with the commercialization of ARIKAYCE in NTM, NIAID will have the right to complete the clinical trial. Further NIAID may elect to pursue its rights to obtain license rights to certain inventions made under the CRADA.

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 are collaborating with Therapure to construct a production area for the manufacture of ARIKAYCE in Therapure s existing manufacturing facility in Mississauga, Ontario, Canada. We expect to pay Therapure approximately $12 million for the build out of the construction area and related manufacturing costs, of which approximately $11 million has been paid as of September 30, 2015. Therapure will manufacture 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.

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. The Work Order covers services related to INS-212 only and any additional study or services will be subject to the negotiation and execution of an additional work order. It is anticipated that aggregate

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costs to us relating to this Work Order will be approximately $33 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.

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 U.S. 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 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 any revenue from ARIKAYCE. We do not know when or if we will generate any revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize, 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

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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, 2014. 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 September 30, 2015, our cash and cash equivalents were in cash accounts or were invested in money market funds. Such accounts or investments are not insured by the federal government.

As of September 30, 2015, 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 originally in June 2012. A hypothetical 10% change in interest rates occurring on September 30, 2015 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 and nine months ended September 30, 2015 and 2014, 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 September 30, 2015. 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 September 30, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

On September 1, 2015 we implemented an enterprise resource planning (ERP) system on a company-wide basis, which is expected to improve the efficiency of certain financial and related transaction processes. The implementation resulted in business and operational changes, which required changes to some of our internal controls over financial reporting that were in place as of June 30, 2015. The controls in place under the new system have been evaluated by management as of September 30, 2015 and management believes that the internal controls are operating effectively. Aside from the implementation of the ERP system, 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 September 30, 2015 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 and 10-K/A for the year ended December 31, 2014 and our subsequent quarterly reports on Form 10-Q. 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, 2014 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2015, except for the following update:

Risks Related to Our Reliance on Third Parties

We rely on Ajinomoto Althea, Inc., a third party manufacturer, to supply ARIKAYCE. Any disruption in the supply of ARIKAYCE could have a material adverse effect on our business.

We are dependent upon Ajinomoto Althea, Inc. (Althea) to provide an adequate supply of ARIKAYCE both for our clinical trials and for commercial sale in the event ARIKAYCE receives marketing approval. On September 15, 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 the event Althea terminates the supply agreement and ceases to supply ARIKAYCE, we cannot be certain that we would be able identify another willing supplier for ARIKAYCE on terms we require or that are favorable to us. A disruption in the supply of ARIKAYCE could delay, impair, or prevent clinical trials, the development and commercialization of ARIKAYCE and adversely affect our business, financial condition, results of operations and prospects.

Althea currently manufactures ARIKAYCE at a relatively small scale. In order to meet potential commercial demand, if ARIKAYCE is approved, we have identified Therapure in Canada as an alternate site of manufacture that operates at a larger scale. Therapure may not be able to successfully transfer the ARIKAYCE manufacturing process to their site, or we may not be able to obtain regulatory approvals for ARIKAYCE produced at Therapure s facility. We may not be able to secure an alternative source of ARIKAYCE at an adequate scale of production.

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

There were no unregistered sales of the Company s equity securities during the quarter ended September 30, 2015.

ITEM 3. **DEFAULTS UPON SENIOR SECURITIES**

None.

ITEM 4. **MINE SAFETY DISCLOSURES**

Not applicable.

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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: November 6, 2015

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

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EXHIBIT INDEX

10.1	Commercial Fill/Finish Services Agreement between Insmed Incorporated and Ajinomoto Althea, Inc., dated as of September 15, 2015.*
31.1	Certification of William H. Lewis, Chief Executive Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of Andrew T. Drechsler, Chief Financial Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification of William H. Lewis, Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
32.2	Certification of Andrew T. Drechsler, Chief Financial Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document

101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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