INSMED Inc
Form 10-Q
November 03, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from to

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

Virginia	**54-1972729**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
10 Finderne Avenue, Building 10 **Bridgewater, New Jersey**	**08807**
(Address of principal executive offices)	(Zip Code)

(908) 977-9900

(Registrant s telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting Company (See the definitions of large accelerated filer, accelerated filer, and small reporting Company in Rule 12b-2 of the Exchange Act).

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

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

As of October 31, 2016, there were 61,877,905 shares of the registrant s common stock, $0.01 par value, outstanding.

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INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2016

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

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except par value and share data)

	As of September 30, 2016 (unaudited)	As of December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 200,518	$ 282,876
Prepaid expenses and other current assets	5,778	5,242
Total current assets	206,296	288,118
In-process research and development	58,200	58,200
Fixed assets, net	10,274	8,092
Other assets	1,874	2,146
Total assets	$ 276,644	$ 356,556
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 8,283	$ 7,468
Accrued expenses	14,528	10,995
Other current liabilities	647	683
Current portion of long-term debt		3,113
Total current liabilities	23,458	22,259
Debt, long-term	34,681	22,027
Other long-term liabilities	676	572
Total liabilities	58,815	44,858
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 61,877,905 and 61,813,995 issued and outstanding shares at September 30, 2016 and December 31, 2015, respectively	619	618
Additional paid-in capital	914,049	900,043
Accumulated deficit	(696,834)	(588,963)
Accumulated other comprehensive (loss)	(5)	
Total shareholders equity	217,829	311,698
Total liabilities and shareholders equity	$ 276,644	$ 356,556

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues	$	$	$	$
Operating expenses:				
Research and development	23,433	19,221	67,851	54,631
General and administrative	13,716	11,024	38,498	30,272
Total operating expenses	37,149	30,245	106,349	84,903
Operating loss	(37,149)	(30,245)	(106,349)	(84,903)
Investment income	138	75	472	166
Interest expense	(769)	(725)	(2,015)	(2,165)
Other income (expense), net	45	(67)	92	(36)
Loss before income taxes	(37,735)	(30,962)	(107,800)	(86,938)
Provision for income taxes	25		71	
Net loss	$ (37,760)	$ (30,962)	$ (107,871)	$ (86,938)
Basic and diluted net loss per share	$ (0.61)	$ (0.50)	$ (1.74)	$ (1.51)
Weighted average basic and diluted common shares outstanding	61,878	61,774	61,871	57,565
Net loss	$ (37,760)	$ (30,962)	$ (107,871)	$ (86,938)
Other comprehensive loss:				
Foreign currency translation loss	(17)		(5)	
Total comprehensive loss	$ (37,777)	$ (30,962)	$ (107,876)	$ (86,938)

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, 2016	2015
Operating activities		
Net loss	$ (107,871)	$ (86,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,756	1,342
Stock based compensation expense	13,879	11,757
Amortization of debt discount and debt issuance costs	250	343
Accrual of the end of term charge on the debt		57
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(230)	(2,616)
Accounts payable	361	1,340
Accrued expenses and other	3,109	1,562
Net cash used in operating activities	(88,746)	(73,153)
Investing activities		
Purchase of fixed assets	(3,428)	(3,047)
Net cash used in investing activities	(3,428)	(3,047)
Financing activities		
Proceeds from exercise of stock options	128	5,001
Proceeds from issuance of debt	10,000	
Payment of debt issuance costs	(308)	
Proceeds from issuance of common stock, net		222,942
Net cash provided by financing activities	9,820	227,943
Effect of exchange rates on cash and cash equivalents	(4)	
Net (decrease) / increase in cash and cash equivalents	(82,358)	151,743
Cash and cash equivalents at beginning of period	282,876	159,226
Cash and cash equivalents at end of period	$ 200,518	$ 310,969
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 2,471	$ 2,230
Cash paid / (received) for income taxes	$ 49	$ (994)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Insmed is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The Company s lead product candidate is ARIKAYCE, or liposomal amikacin for inhalation (LAI), which is in late-stage development for patients with nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and which can be fatal. The Company s earlier clinical-stage pipeline includes INS1007, a novel oral reversible inhibitor of dipeptidyl peptidase 1, and INS1009, an inhaled prodrug formulation of treprostinil.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999 and its principal executive offices are located in Bridgewater, New Jersey. The Company has operations in the United States (US), Ireland, Germany, France, the United Kingdom (UK) and the Netherlands. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

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

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

2. Summary of Significant Accounting Policies

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

Fair Value Measurements - The Company categorizes its financial assets and liabilities measured and reported at fair value in the financial statements on a recurring basis based upon the level of judgments associated with the inputs used to measure their fair value. Hierarchical levels, which are directly related to the amount of subjectivity associated with the inputs used to determine the fair value of financial assets and liabilities, are as follows:

- Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

- Level 2 Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the assets or liability through correlation with market data at the measurement date and for the duration of the instrument s anticipated life.

- Level 3 Inputs reflect management s best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

Each major category of financial assets and liabilities measured at fair value on a recurring basis are categorized based upon the lowest level of significant input to the valuations. The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Financial instruments in Level 1 generally include US treasuries and mutual funds listed in active markets.

The Company s only assets and liabilities which were measured at fair value as of September 30, 2016 and December 31, 2015 were Level 1 and such assets were comprised of cash and cash equivalents of $200.5 million and $282.9 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.

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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, 2016 and 2015, respectively.

As of September 30, 2016 and December 31, 2015, the Company held no securities that were in an unrealized gain or loss position. The Company reviews the status of each security quarterly to determine whether an other-than-temporary impairment has occurred. In making its determination, the Company considers a number of factors, including: (1) the significance of the decline; (2) whether the securities were rated below investment grade; (3) how long the securities have been in an unrealized loss position; and (4) the Company s ability and intent to retain the investment for a sufficient period of time for it to recover.

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

The following table sets forth the reconciliation of the weighted average number of shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2016 and 2015:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands, except per share amounts)			
Numerator:				
Net loss	$ (37,760)	$ (30,962)	$ (107,871)	$ (86,938)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share:	61,878	61,774	61,871	57,565
Effect of dilutive securities:				
Common stock options				
Restricted stock and restricted stock units				
Weighted average common shares outstanding used in calculation of diluted net loss per share	61,878	61,774	61,871	57,565
Net loss per share:				
Basic and diluted	$ (0.61)	$ (0.50)	$ (1.74)	$ (1.51)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of September 30, 2016 and 2015 as their effect would have been anti-dilutive (in thousands):

	2016	2015
Stock options to purchase common stock	7,306	5,241
Unvested restricted stock units	89	44

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

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

3. Identifiable Intangible Asset

The Company believes there are no indicators of impairment relating to its in-process research and development intangible asset as of September 30, 2016.

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4. Accrued Expenses

Accrued expenses consist of the following:

	As of September 30, 2016	As of December 31, 2015
	(in thousands)	
Accrued clinical trial expenses	$ 5,623	$ 4,331
Accrued compensation	6,063	4,302
Accrued professional fees	1,898	1,202
Accrued technical operation expenses	446	702
Accrued interest payable	195	199
Other accrued expenses	303	259
	$ 14,528	$ 10,995

5. Debt

On September 30, 2016, the Company and its domestic subsidiaries, as co-borrowers, entered into an Amended and Restated Loan and Security Agreement (the A&R Loan Agreement) with Hercules Capital, Inc. (Hercules). The A&R Loan Agreement includes a total commitment from Hercules of up to $55.0 million, of which $25.0 million was previously outstanding. The amount of borrowings was initially increased by $10.0 million to an aggregate total of $35.0 million on September 30, 2016. An additional $20.0 million was available at the Company s option through June 30, 2017 subject to certain conditions, including the payment of a facility fee of 0.375%. The Company exercised this option in early October 2016 and borrowed an additional $20.0 million in connection with its upfront payment obligation under the License Agreement with AstraZeneca (see *Note 10 Subsequent Event*). The interest rate for the term is floating and is defined as the greater of (i) 9.25% or (ii) 9.25% plus the sum of the US prime rate minus 4.50%, along with a backend fee of 4.15% of the aggregate principal amount outstanding and an aggregate facility fee of $337,500. The interest-only period extends through May 1, 2018, but can be extended up to 12 months under certain conditions. The maturity date of the loan facility was also extended to October 1, 2020. Pursuant to the A&R Loan Agreement, the Company is required to have consolidated minimum cash liquidity in an amount no less than $25.0 million. Such requirement terminates upon the earlier of the date by which the Company completes an equity financing with at least $75.0 million in proceeds or the date the Company generates and announces data from the CONVERT Phase III study in a manner that could support an NDA filing. In addition, pursuant to the A&R Loan Agreement, Hercules has the right to participate, in an aggregate amount of up to $2.0 million, in a subsequent private financing of equity securities.

In connection with the A&R Loan Agreement, the Company granted Hercules a first position lien on all of the Company s assets, excluding intellectual property. Prepayment of the loans made pursuant to the A&R Loan Agreement is subject to penalty. The backend fee of 4.15% on the aggregate outstanding principal balance will be charged to interest expense (and accreted to the debt) using the effective interest method over the original life of the A&R Loan Agreement. Debt issuance fees paid to Hercules were recorded as a discount on the debt and are being amortized to interest expense using the effective interest method over the life of the A&R Loan Agreement.

The following table presents the components of the Company s debt balance as of September 30, 2016 (in thousands):

Debt:		
Notes payable	$	35,000
Debt issuance costs		(319)
Current portion of long-term debt		
Debt, long-term	$	34,681

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

Year Ending in December 31:		
2016	$	
2017		
2018		8,527
2019		13,837
2020		12,636
	$	35,000

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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, 2016 approximates the carrying amount.

6. *Shareholders Equity*

Common Stock As of September 30, 2016, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 61,877,905 shares of common stock issued and outstanding. In addition, as of September 30, 2016, the Company had reserved 7,306,178 shares of common stock for issuance upon the exercise of outstanding common stock options.

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

Preferred Stock As of September 30, 2016 and December 31, 2015, the Company had 200,000,000 shares of preferred stock authorized with a par value of $0.01 and no shares of preferred stock were issued and outstanding.

7. Stock-Based Compensation

The Company s current equity compensation plan, the 2015 Incentive Plan, was approved by shareholders at the Company s Annual Meeting of Shareholders on May 21, 2015. The 2015 Incentive Plan is administered by the Compensation Committee and the Board of Directors of the Company. Under the terms of the 2015 Incentive Plan, the Company is authorized to grant a variety of incentive awards based on its common stock, including stock options (both incentive stock options and non-qualified stock options), performance options/shares and other stock awards, as well as the payment of incentive bonuses to all employees and non-employee directors. On May 21, 2015, 5,000,000 shares of the Company s common stock were authorized and as of September 30, 2016, there were 2,130,917 shares available for future grants (or issuances) of stock options, stock appreciation rights, restricted stock, restricted stock units and incentive bonuses under the 2015 Incentive Plan. The 2015 Incentive Plan will terminate on April 9, 2025 unless it is extended or terminated earlier pursuant to its terms. In addition, from time to time, the Company makes inducement grants of stock options. These awards are made pursuant to the Nasdaq inducement grant exception as a component of new hires employment compensation in connection with the Company s equity grant program.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Volatility	75%-76%	78%-79%	75%-77%	78%-82%
Risk-free interest rate	1.00%-1.18%	1.49%-1.72%	1.00%-1.73%	1.31%-1.72%
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	$7.79	$17.32	$8.74	$14.38

For all periods presented, the volatility factor was based on the Company s historical volatility since the closing of the Company s merger with Transave in December 2010. The expected life was determined using the simplified method as described in ASC Topic 718, Accounting for Stock Compensation, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the US Treasury yield in effect at the date of grant. Forfeitures are based on the actual percentage of option forfeitures since the closing of the Company s merger with Transave in December 2010, and this is the basis for future forfeiture expectations.

From time to time, the Company grants performance-condition options to certain of the Company s employees. Vesting of these options is subject to the Company achieving certain performance criteria established at the date of grant and the individuals fulfilling a service condition (continued employment). As of September 30, 2016, the Company had performance options totaling 158,334 shares outstanding which have not met the recognition criteria to date. For the nine months ended September 30, 2015, $1.5 million of non-cash compensation expense was recorded related to certain performance based options as the recognition criteria was

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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, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2015	5,273,722	$ 13.64		
Granted	2,406,165	$ 12.89		
Exercised	(20,356)	$ 6.32		
Forfeited or expired	(353,353)	$ 16.29		
Options outstanding at September 30, 2016	7,306,178	$ 13.29	7.85	$ 22,537
Vested and expected to vest at September 30, 2016	6,998,262	$ 13.23	7.80	$ 21,995
Exercisable at September 30, 2016	3,062,677	$ 10.81	6.58	$ 15,758

The total intrinsic value of stock options exercised during the three months ended September 30, 2015 was $0.7 million and during the nine months ended September 30, 2016 and 2015 was $0.1 million and $4.6 million, respectively. There were no stock options exercised during the three months ended September 30, 2016.

As of September 30, 2016, there was $29.2 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.8 years. Included in unrecognized compensation expense was $1.2 million related to outstanding performance-based options. The following table summarizes the range of exercise prices and the number of stock options outstanding and exercisable:

		Outstanding as of September 30, 2016			Exercisable as of September 30, 2016	
Range of Exercise Prices ($)		Number of Options	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price ($)	Number of Options	Weighted Average Exercise Price ($)
3.03	3.40	850,137	5.83	3.34	850,137	3.34
3.60	6.96	673,847	6.20	6.14	563,814	6.00
8.77	10.85	1,186,595	9.56	10.84	3,000	8.77
11.14	12.44	791,505	7.37	12.00	388,892	12.05
12.45	14.24	822,857	7.59	13.28	402,074	13.35
14.32	16.09	509,512	7.86	15.90	207,570	15.85
16.16	16.16	766,650	9.07	16.16	10,250	16.16
16.19	20.92	754,750	7.51	19.38	366,013	19.58
21.20	22.14	51,800	4.94	21.62	30,075	21.77
22.76	27.38	898,525	8.38	22.92	240,852	22.93

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 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, 2016:

	Number of RSUs	Weighted Average Grant Price ($)
Outstanding at December 31, 2015	43,554	16.07
Granted	89,194	10.85
Released	(43,554)	16.07
Outstanding at September 30, 2016	89,194	10.85

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The following table summarizes the aggregate stock-based compensation recorded in the Consolidated Statements of Comprehensive Loss related to stock options and RSUs during the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
	(in millions)		(in millions)	
Research and development expenses	$ 1.7	$ 0.8	$ 4.6	$ 3.1
General and administrative expenses	3.4	3.0	9.3	8.7
Total	$ 5.1	$ 3.8	$ 13.9	$ 11.8

8. Income Taxes

The Company s provision for income taxes was $25,000 and $71,000 for the three and nine months ended September 30, 2016, respectively. The current year provision was a result of certain of the Company s subsidiaries in Europe, which had taxable income during the three and nine months ended September 30, 2016. In jurisdictions where the Company has net losses, there was a full valuation allowance recorded against the Company s deferred tax assets and therefore no tax benefit was recorded. The Company is subject to US federal, US state and foreign income taxes. The statute of limitations for tax audit is open for the US federal tax returns for the years ended 2013 and later and is generally open for certain states for the years 2012 and later. The Company s US federal tax return for the year ended December 31, 2013 is currently under audit by the Internal Revenue Service. The Company has incurred net operating losses since inception, with the exception of 2009. Such loss carryforwards are subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. As of September 30, 2016 and December 31, 2015, the Company has recorded no reserves for unrecognized income tax benefits, nor has it recorded any accrued interest or penalties related to uncertain tax positions. The Company does not anticipate any material changes in the amount of unrecognized tax positions over the next twelve months.

9. Commitments and Contingencies

Commitments

The Company has an operating lease for office and laboratory space located in Bridgewater, NJ, its corporate headquarters, for which the initial lease term expires in November 2019. Future minimum rental payments under this lease are $3.2 million. In July 2016, the Company signed an operating lease for additional laboratory space located in Bridgewater, NJ for which the initial lease term expires in September 2021. Future minimum rental payments under this lease are $2.1 million.

Rent expense charged to operations was $0.4 million and $0.2 million for the three months ended September 30, 2016 and 2015, respectively, and $0.9 million and $0.6 million for the nine months ended September 30, 2016 and 2015, respectively. Future minimum rental payments required under the Company s operating leases for the period from October 1, 2016 to December 31, 2016 and for each of the next five years are as follows (in thousands):

Year Ending December 31:		
2016 (remaining)	$	340
2017		1,395
2018		1,433
2019		1,390
2020		444
2021		423
	$	5,425

Legal Proceedings

On July 15, 2016, a purported class action lawsuit was filed in the U.S. District Court for the District of New Jersey against the Company and certain of its executive officers: Hoey v. Insmed Incorporated, et al, No. 3:16-cv-04323-FLW-TJB (D.N.J. July 15, 2016). The complaint alleges that from March 18, 2013 through June 8, 2016, the Company and certain of our executive officers made material misstatements or omissions concerning the likelihood of the EMA approving the Company s European MAA for use of ARIKAYCE in the treatment of NTM lung disease and the likelihood of commercialization of ARIKAYCE in Europe. The complaint alleges violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. The complaint seeks unspecified damages. On October 25, 2016, the Court issued an order appointing Bucks County Employees Retirement Funds as lead plaintiff for the putative class. A consolidated amended complaint has not yet been filed. The Company believes that the allegations in the complaint are without merit and intends to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of the lawsuit.

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10. Subsequent Event

License Agreement

AstraZeneca On October 4, 2016, the Company entered into a license agreement (the License Agreement) with AstraZeneca AB, a Swedish corporation (AstraZeneca). Pursuant to the terms of the License Agreement, AstraZeneca granted the Company global exclusive rights for the purpose of developing and commercializing AZD7986 (renamed INS1007 by the Company). INS1007 is a novel oral inhibitor of dipeptidyl peptidase 1 (DPP1). DPP1 is an enzyme that catalyzes the activation of neutrophil serine proteases, which play a key role in pulmonary diseases such as non-cystic fibrosis bronchiectasis.

In consideration of the licenses and other rights granted by AstraZeneca, the Company paid an upfront payment of $30.0 million in early November 2016, which will be included as research and development expense in the fourth quarter of 2016. In connection with the upfront payment obligation in the License Agreement, the Company borrowed an additional $20.0 million under the A&R Loan Agreement in early October 2016, as further described in *Note 5 - Debt*. The Company will make a series of contingent milestone payments totaling up to an additional $85.0 million upon the achievement of clinical development and regulatory filing milestones. If the Company elects to develop INS1007 for a second indication, the Company will make an additional series of contingent milestone payments equal to half of the contingent milestone payments in the preceding sentence. No additional milestone payments are due for any indications beyond the first and second indications. In addition, the Company will pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teen on net sales of any approved product based on INS1007 and one additional payment of $35.0 million upon the first achievement of $1 billion in annual net sales. The License Agreement provides AstraZeneca with the option to negotiate a future agreement with the Company for commercialization of INS1007 in chronic obstructive pulmonary disease or asthma.

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

Cautionary Note Regarding Forward Looking Statements

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

Forward-looking statements are based upon our current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such factors include, among others, the factors discussed in Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the Securities and Exchange Commission (SEC) on February 25, 2016, our subsequent quarterly reports on Form 10-Q filed in 2016, and the following: the ability to complete development of, receive regulatory approval for, and successfully commercialize ARIKAYCE, or liposomal amikacin for inhalation, INS1007, an oral reversible inhibitor of dipeptidyl peptidase, and INS1009, an inhaled treprostinil prodrug; the number of patients enrolled and the timing of patient enrollment in the Company s global phase 3 clinical study of ARIKAYCE; estimates of expenses and future revenues and profitability; plans to develop and market new products and the timing of these development programs; status, timing, and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the sufficiency of preclinical and clinical data in obtaining regulatory approval for the Company s product candidates; the timing of responses to information and data requests from the US Food and Drug Administration, the European Medicines Agency, and other regulatory authorities; clinical development of product candidates; the ability to obtain and maintain regulatory approval for product candidates; expectation as to the timing of regulatory review and approval; estimates regarding capital requirements, including milestone payments due to AstraZeneca, and the needs for additional financing; the ability to repay our existing indebtedness; estimates of the size of the potential markets for product candidates; selection and licensing of product candidates; 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 product candidates; the degree of protection afforded to the Company by its intellectual property portfolio; the safety and efficacy of 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; the ability to create an effective direct sales and marketing infrastructure for products the Company elects to market and sell directly; the rate and degree of market acceptance of product candidates; the impact of any litigation the Company is a party to, including, without limitation, the class action lawsuit filed against the Company; the timing, scope and rate of reimbursement for product candidates; the success of other competing therapies that may become available; and the availability of adequate supply and manufacturing capacity and quality for product candidates.

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

The following discussion should be read in conjunction with our consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and related notes thereto in our Annual Report on Form 10-K for the year ended December 31, 2015.

OVERVIEW

We are a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. Our lead product candidate is ARIKAYCE, or liposomal amikacin for inhalation (LAI), which is in late-stage development for patients with nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. Our earlier clinical-stage pipeline includes INS1007 and INS1009. INS1007 is a novel oral reversible inhibitor of dipeptidyl peptidase 1 (DPP1), an enzyme responsible for activating neutrophil serine proteases, which are implicated in the pathology of chronic inflammatory lung diseases, such as non-cystic fibrosis (non-CF) bronchiectasis. INS1009 is our inhaled treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders, including pulmonary arterial hypertension (PAH).

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We are conducting a global phase 3 clinical study of ARIKAYCE (the 212 or CONVERT study) in adult patients with treatment refractory NTM lung disease caused by *Mycobacterium avium* complex (MAC), which is the predominant infective species in NTM lung disease in the United States (US), Europe, and Japan.

In October 2016, we acquired the global exclusive rights to INS1007 (formerly known as AZD7986) from AstraZeneca and we are finalizing our plans for a phase 2 study in our lead indication, non-CF bronchiectasis. In a phase 1 study of healthy volunteers, AZD7986 was well tolerated and demonstrated inhibition of the activity of the neutrophil serine protease neutrophil elastase in a dose and concentration dependent manner. In preclinical studies, AZD7986 was shown to effectively and reversibly inhibit DPP1 and the activation of neutrophil serine proteases within maturing neutrophils.

We have completed a phase 1 study of INS1009 in healthy subjects and the results were presented at the European Respiratory Society international congress in September 2016. This first-in-human study of INS1009 determined the maximum-tolerated dose of a single dose of INS1009 and characterized a pharmacokinetic profile that supports once- or twice-daily dosing. The longer half-life of treprostinil associated with INS1009 was likely due to a sustained pulmonary release.

Our earlier-stage pipeline includes preclinical compounds that we are evaluating in multiple rare diseases of unmet medical need, including methicillin-resistant staph aureus (MRSA), NTM, and sarcoidosis. To complement our internal research and development, we actively evaluate in-licensing and acquisition opportunities for a broad range of rare diseases.

The following table summarizes the current status of and anticipated milestones for ARIKAYCE, INS1007, and INS1009:

Product Candidate/Target Indications	**Status**	**Next Expected Milestones**
ARIKAYCE for adult patients with treatment refractory NTM lung infections caused by MAC	• We are advancing the CONVERT study, a randomized, open-label global phase 3 clinical study of ARIKAYCE in adult patients with treatment refractory NTM lung disease caused by MAC. • The US Food and Drug Administration (FDA) has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP). Breakthrough therapy features intensive guidance on efficient drug development and offers the potential for a rolling review. A QIDP-designated product qualifies	• We have achieved our enrollment objective for the CONVERT study. We expect to report top-line results for the Month 6 primary endpoint in 2017. • If the CONVERT study meets its primary endpoint, we intend to seek accelerated marketing approval for ARIKAYCE in the US. We intend to seek marketing approvals for ARIKAYCE in certain countries outside the US, when sufficient data are available. If approved, we expect ARIKAYCE would be the first inhaled antibiotic specifically indicated for the treatment of NTM

	for the same benefits as fast track designation and is typically eligible for priority review. • The European Commission granted an orphan designation for ARIKAYCE for the treatment of NTM lung disease.	lung infections in North America, Europe, and Japan. • If approved, we plan to commercialize ARIKAYCE in the US, certain countries in Europe, Japan and certain other countries.
INS1007 (oral reversible inhibitor of dipeptidyl peptidase 1)	• In October 2016, we entered into a licensing agreement with AstraZeneca for the global exclusive rights to AZD7986. We renamed the compound INS1007 and plan to pursue an initial indication of non-CF bronchiectasis.	• We plan to submit an Investigational New Drug (IND) application with FDA and subsequently commence a phase 2 clinical study of INS1007 in non-CF bronchiectasis. The study is expected to begin in 2017.
INS1009 (inhaled treprostinil prodrug) for rare pulmonary disorders	• The results of our phase 1 study of INS1009 were presented at the European Respiratory Society international congress in September 2016. • The phase 1 study was a randomized, double-blind, placebo-controlled single ascending dose study of INS1009 for inhalation to determine its safety, tolerability, and pharmacokinetics in healthy volunteers.	• We have additional preclinical studies reading out later this year, which will help inform our clinical development strategy for INS1009.

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Product Pipeline

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

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

The CONVERT study

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

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

At Month 8, after all sputum culture results are known up to and including Month 6, subjects will be assessed as converters or non-converters for the primary efficacy endpoint. All converters will continue on their randomized treatment regimen for 12 months beginning from the first negative culture that defined culture conversion. All converters will return for off-treatment follow-up visits. A 12-month off-treatment study visit will be the last visit for the CONVERT study. All non-converters, as determined at the Month 8 visit, may be eligible to enter a separate 12-month open-label study (the 312 study). The primary objective of the 312 study is to evaluate the long-term safety and tolerability of ARIKAYCE in combination with a standard multi-drug regimen. The secondary endpoints of the 312 study include evaluating the proportion of subjects achieving culture conversion (three consecutive monthly negative sputum cultures) by Month 6 and the proportion of subjects achieving culture conversion by Month 12 (end of treatment).

The protocol for the CONVERT study incorporates feedback from the FDA and the European Medicines Agency (EMA) via its scientific advice working party process, as well as local health authorities in other countries, including Japan s Pharmaceuticals and Medical Devices Agency. If the CONVERT study meets the primary endpoint of culture conversion by 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, if successful, will suffice to meet this commitment. The CONVERT study is taking place in North America, Europe, Australia, New Zealand and Asia. The CONVERT study is designed to enroll enough subjects to ensure at least 261 patients are evaluable for the primary endpoint.

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*

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abscessus (*M. abscessus*) that was refractory to guideline-based therapy. The study included an 84-day double-blind phase in which subjects were randomized 1:1 either to ARIKAYCE once-daily plus a multi-drug regimen or to placebo once-daily plus the same multi-drug regimen. After completing the 84-day double-blind phase, subjects had the option of continuing in an 84-day open-label phase during which all subjects received ARIKAYCE plus the same multi-drug regimen. The study also included 28-day and 12-month off-ARIKAYCE follow-up assessments.

Eighty-nine (89) subjects were randomized and dosed in the study. Of the 80 subjects who completed the 84-day double-blind phase, 78 subjects entered the open-label phase and received ARIKAYCE plus the same multi-drug regimen for an additional 84 days. Seventy-six (76) percent (59/78) of subjects who entered the open-label phase of the study completed the open-label study.

The primary efficacy endpoint of the study was the change from baseline (day 1) to the end of the double-blind phase of the trial (day 84) in a semi-quantitative measurement of mycobacterial density on a seven-point scale. ARIKAYCE did not meet the pre-specified level for statistical significance although there was a positive trend (p=0.072) in favor of ARIKAYCE. The p-value for the key secondary endpoint of culture conversion to negative at Day 84 was 0.003, in favor of ARIKAYCE. A shorter time to first negative sputum culture was also observed with ARIKAYCE relative to placebo during the double-blind phase (p=0.013).

The microbiologic outcomes from the 112 study were also explored post hoc using a more stringent definition of culture conversion, which is defined as at least three consecutive monthly sputum samples that test negative for NTM. This definition of culture conversion is in the guidelines and used in clinical practice.

Twenty-three (23) subjects achieved at least three consecutive negative monthly sputum samples by the 28-day follow-up assessment, of which four started to convert at baseline prior to administration of study drug. For the 19 patients who achieved culture conversion, 17 achieved culture conversion after receiving ARIKAYCE, 10 who were randomized to ARIKAYCE in the double-blind phase and seven after entering the open-label phase. Two patients achieved culture conversion while receiving placebo in the double-blind phase.

The majority of subjects who achieved culture conversion (three consecutive negative monthly sputum samples) during the double-blind phase continued to have negative cultures through the open-label and follow-up phases.

At the end of the double-blind phase, the ARIKAYCE group improved from baseline in mean distance walked in the six-minute walk test. At the end of the open-label phase, patients in the ARIKAYCE group continued to improve in the mean distance walked in the six-minute walk test while the patients who previously received placebo in the double-blind phase and subsequently received ARIKAYCE in the open-label phase demonstrated a reduced rate of decline from baseline.

The majority (90 percent) of patients in both treatment groups experienced at least one treatment-emergent adverse event with most events either mild or moderate in severity. During the double-blind phase a greater percentage of patients treated with ARIKAYCE experienced dysphonia, bronchiectasis exacerbation, cough, oropharyngeal pain, fatigue, chest discomfort, wheezing, and infective pulmonary exacerbation of cystic

fibrosis. No clinically relevant changes were detected in laboratory values and vital signs.

In October 2016, the phase 2 study was published online in the *American Journal of Respiratory and Critical Care Medicine* (Olivier et al. 2016).

ARIKAYCE for NTM in the EU

We previously filed a marketing authorization application (MAA) with the EMA for ARIKAYCE as a treatment for NTM lung disease. The filing was based on data from our phase 2 study. In May 2016, we participated in an oral explanation meeting with the EMA s Committee for Medicinal Products for Human Use (CHMP). After the oral explanation meeting, the CHMP concluded that the data submitted did not provide enough evidence to support an approval. In June 2016, we withdrew our MAA. We intend to resubmit our MAA when sufficient clinical data from our ongoing global CONVERT study are available.

NTM Market Opportunity

NTM is a rare and serious disorder associated with increased morbidity and mortality. There is an increasing rate of lung disease caused by NTM and this is an emerging public health concern worldwide. Patients with NTM lung disease may experience a multitude of symptoms such as fever, weight loss, cough, lack of appetite, night sweats, blood in the sputum, and fatigue. Patients with NTM lung disease frequently require lengthy, and repeat, hospital stays to manage their condition. There are no inhaled antibiotic treatments specifically indicated for the treatment of NTM lung disease in North America, Europe or Japan. Current guideline-based approaches involve multi-drug regimens that may cause severe side effects and treatment can be as long as two years or more.

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

Our market research indicates that there are approximately 100,000 patients in the US, the EU5 (France, Germany, Italy, Spain and the United Kingdom), and Japan who have a confirmed diagnosis of NTM lung disease, of which an estimated 10 to 30 percent are refractory to current treatments. In 2012, in collaboration with the NIH, we funded a study performed by Clarity Pharma Research that showed there were an estimated 50,000 cases of pulmonary disease attributable to NTM in the US in 2011 and that such cases were estimated to be growing at a rate of 10% per year. In 2013, we engaged Clarity Pharma Research to perform a similar chart audit study of NTM in Europe and Japan. Based on results of this study, researchers estimated that there are approximately 20,000 cases of pulmonary disease attributable to NTM within the EU5 and approximately 30,000 in the 28 countries comprising the EU. In addition, there are nearly 32,000 cases in Japan. Although population-based data on the epidemiology of NTM lung disease are limited, and determining the true prevalence and incidence of rare diseases can be challenging, studies worldwide have described an increasing prevalence.

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

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

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

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

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

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

We plan to repeat this type of research globally in support of our overall disease awareness and education efforts. Results from an EU burden of illness study were recently presented at the International Society of Pharmacoeconomic and Outcomes Research annual European congress.

The FDA has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a QIDP for NTM lung disease. Orphan designation features seven years of post-approval market exclusivity, and QIDP features an additional five years of post-approval exclusivity. A QIDP-designated product is eligible for fast track and priority review designations. A priority review designation for a drug means the FDA s goal is to take action on the NDA within six months of the 60-day filing date, as compared to 10 months of the 60-day filing date under a standard review.

INS1007

INS1007 is a small molecule, oral reversible inhibitor of DPP1, an enzyme responsible for activating neutrophil serine proteases in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. Neutrophils contain three neutrophil serine proteases, neutrophil elastase, proteinase 3, and cathepsin G, that have been implicated in a variety of inflammatory diseases. In chronic

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inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active neutrophil serine proteases that cause lung destruction and inflammation. INS1007 may decrease the damaging effects of inflammatory diseases, such as non-CF bronchiectasis, by inhibiting DPP1 and its activation of neutrophil serine proteases.

Non-CF bronchiectasis

Non-CF bronchiectasis is a rare, progressive pulmonary disorder in which the bronchi become permanently dilated due to chronic inflammation and infection. Neutrophils play a key role in the pathologic inflammatory process. Symptoms include chronic cough, excessive sputum production, shortness of breath, and repeated respiratory infections, which can worsen the underlying condition. There is currently no cure for non-CF bronchiectasis.

Bronchiectasis increases susceptibility to NTM lung disease, and up to 50 percent of patients with bronchiectasis may also have an active NTM infection. We have completed a phase 2 study of ARIKAYCE for the treatment of chronic *Pseudomonas aeruginosa* infection in patients with non-CF bronchiectasis.

INS1009

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

In late 2014, we had a pre-investigational new drug (pre-IND) meeting with the FDA for INS1009 and clarified that, subject to final review of the preclinical data, INS1009 could be eligible for an approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) (505(b)(2) approval). Like a traditional NDA that is submitted under Section 505(b)(1) of the FDCA, a 505(b)(2) NDA must establish that the drug is safe and effective, but unlike a traditional NDA the applicant may rely at least in part on studies not conducted by or for the applicant and for which the applicant does not have a right of reference. The ability to rely on existing third-party data to support safety and/or effectiveness can reduce the time and cost associated with traditional NDAs. We have completed a phase 1 study of INS1009. The phase 1 study was a randomized, double-blind, placebo-controlled single ascending dose study of INS1009 for inhalation to determine its safety, tolerability, and pharmacokinetics in healthy volunteers. The pharmacokinetic characteristics supported once- or twice-daily whereas existing inhaled therapies are dosed four to nine times per day. The adverse event profile was consistent with other inhaled prostanoids.

Twenty-four (24) subjects were enrolled and received INS1009 with cohorts of eight subjects receiving doses of 85 mcg, 170 mcg, 340 mcg or placebo. Participants in the first cohort (8 patients) received a single dose of open label treprostinil (Tyvaso) at 54 mcg 24 hours prior to receiving INS1009 at 85 mcg. The 85 mcg dose of INS1009 provides an equivalent amount of treprostinil on a molar basis as the 54 mcg dose of Tyvaso. The peak serum concentration was approximately 90% lower for treprostinil after INS1009 administration compared with Tyvaso,

which could indicate a reduced future adverse event (AE) profile. The pharmacokinetic characteristics also supported once- or twice-daily dosing. The longer half-life of treprostinil for INS1009 was likely due to a sustained pulmonary release. The AE profile was consistent with other inhaled prostanoids. These data were presented at the European Respiratory Society international congress in September 2016.

Our Strategy

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

Our current priorities are as follows:

- Advancing the global CONVERT study;
- Preparing our US NDA submission, which will be based on the primary endpoint of the CONVERT study;

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- Ensuring our product supply chain will support the clinical development and, if approved, commercialization of ARIKAYCE;
- Preparing for potential commercialization of ARIKAYCE in the US, Europe, Japan, and certain other countries;
- Supporting further research and lifecycle management strategies for ARIKAYCE, including investigator-initiated studies;
- Developing the core value dossier to support the global reimbursement of ARIKAYCE;
- Filing an IND with FDA and starting a phase 2 study of INS1007 in non-CF bronchiectasis;
- Generating preclinical findings from our earlier-stage program(s); and
- Expanding our rare disease pipeline through corporate development.

Corporate Development

We plan to develop, acquire, in license or co-promote complementary 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 area of rare pulmonary diseases.

Manufacturing

ARIKAYCE is manufactured by Therapure Biopharma Inc. (Therapure) in Canada at a 200 liter scale and by Ajinimoto Althea, Inc. (Althea) in the US at a 50 liter scale. In September 2015, we entered into a commercial fill/finish services agreement with Althea to produce ARIKAYCE. Althea has the right to terminate this agreement upon written notice for our uncured material breach, if we are the subject of specified bankruptcy or liquidation events, or without cause with 24 months prior written notice. In February 2014, we entered into a contract manufacturing agreement with Therapure for the manufacture of ARIKAYCE. 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, the manufacturer of our drug delivery nebulizer, to address our commercial supply needs. We expect to enter into a commercial supply agreement with AstraZeneca related to certain short-term production needs for INS1007. In addition, we expect our future requirements for INS1007 will be manufactured by a contract manufacturing organization. We currently produce INS1009, our investigational inhaled treprostinil prodrug, and plan to utilize third parties to manufacture INS1009 at a larger scale and the drug delivery device.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Revenues

In 2015, the French National Agency for Medicines and Health Products Safety granted LAI several nominative Temporary Authorization for Use (Autorisation Temporaire d Utilisation or ATU). Pursuant to this program, we shipped ARIKAYCE to pharmacies after receiving requests from physicians for patients in France. In 2016, the revenue recorded from the ATU program was immaterial to disclose and is included as a component of other income (expense), net Other than the ATU revenue in France, we currently do not recognize any revenue from product sales or other sources.

Research and Development Expenses

Research and development expenses consist primarily of salaries, benefits and other related costs, including stock based compensation, for personnel serving in our research and development functions. Expenses also include other internal operating expenses, the cost of manufacturing our drug candidate for clinical study, the cost of conducting clinical studies, and the cost of conducting preclinical and research activities. Our expenses related to manufacturing our drug candidate for clinical study are primarily related to activities at contract manufacturing organizations that manufacture ARIKAYCE for our use. Our expenses related to clinical trials are primarily related to activities at contract research organizations that conduct and manage clinical trials on our behalf. These contracts set forth the scope of work to be completed at a fixed fee or amount per patient enrolled. Payments under these contracts primarily depend on performance criteria such as the successful enrollment of patients or the completion of clinical trial milestones as well as time-based fees. Expenses are accrued based on contracted amounts applied to the level of patient enrollment and to activity according to the clinical trial protocol. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Since 2011, we have focused our development activities principally on our proprietary, advanced liposomal technology designed specifically for inhalation lung delivery. In 2015, we commenced the CONVERT study for ARIKAYCE for patients with NTM lung disease. In 2015, we also completed an open-label extension study in which CF patients that completed our phase 3 trial

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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 and 2016 principally relate to the development of ARIKAYCE in the NTM indication.

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.

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. Unamortized debt issuance costs associated with extinguished debt are expensed in the period of the extinguishment.

Investment Income and Interest Expense

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

RESULTS OF OPERATIONS

Comparison of the Three Months Ended September 30, 2016 and 2015

Net Loss

Net loss for the quarter ended September 30, 2016 was $37.8 million, or ($0.61) per common share basic and diluted, compared with a net loss of $31.0 million, or ($0.50) per common share basic and diluted, for the quarter ended September 30, 2015. The $6.8 million increase in our net loss for the quarter ended September 30, 2016 as compared to the same period in 2015 was primarily due to:

- Increased research and development expenses of $4.2 million resulting from higher compensation and related expenses due to an increase in headcount compared to the prior year period and in increase in clinical trial expenses primarily related to the CONVERT study. These increases were partially offset by a decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015; and

- Increased general and administrative expenses of $2.7 million primarily resulting from an increase in pre-commercial activities and higher compensation and related expenses due to an increase in headcount as compared to the prior year period.

Research and Development Expenses

Research and development expenses for the quarters ended September 30, 2016 and 2015 were comprised of the following (in thousands):

	Quarters Ended September 30,		Increase (decrease)	
	2016	2015	$	%
External Expenses				
Clinical development & research	$ 9,628	$ 6,515	$ 3,113	47.8%
Manufacturing	2,967	5,713	(2,746)	-48.1%
Regulatory and quality assurance	401	956	(555)	-58.1%
Subtotal external expenses	$ 12,996	$ 13,184	$ (188)	-1.4%
Internal Expenses				
Compensation and related expenses	$ 8,086	$ 4,464	$ 3,622	81.1%
Other internal operating expenses	2,351	1,573	778	49.5%
Subtotal internal expenses	$ 10,437	$ 6,037	$ 4,400	72.9%
Total	$ 23,433	$ 19,221	$ 4,212	21.9%

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Research and development expenses increased to $23.4 million during the quarter ended September 30, 2016 from $19.2 million in the same period in 2015. The $4.2 million increase was due to a $3.1 million increase in external clinical development expenses primarily related to the CONVERT study and a $3.6 million increase in compensation and related expenses, including stock-based compensation, due to an increase in headcount. These increases were partially offset by a $2.7 million decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015. We expect research and development expenses to increase in 2016 as compared to 2015 due primarily to the clinical trial activity related to the CONVERT study.

General and Administrative Expenses

General and administrative expenses for the quarters ended September 30, 2016 and 2015 were comprised of the following (in thousands):

	Quarters Ended September 30,		Increase (decrease)	
	2016	2015	$	%
General & administrative	$ 9,097	$ 7,508	$ 1,589	21.2%
Pre-commercial expenses	4,619	3,516	1,103	31.4%
Total general & administrative expenses	$ 13,716	$ 11,024	$ 2,692	24.4%

Total general and administrative expenses increased to $13.7 million during the quarter ended September 30, 2016 from $11.0 million in the same period in 2015. The $2.7 million increase was primarily due to an increase of $1.4 million in consulting expenses related to pre-commercial marketing activities and legal expenses and an increase of $1.4 million due to higher compensation, including stock-based compensation, related to an increase in headcount.

Interest Expense

Interest expense was $0.8 million during the quarter ended September 30, 2016 as compared to $0.7 million in the same period in 2015. The $0.1 million increase in interest expense in 2016 was due to expenses for debt issuance costs related to our previous loan agreement with Hercules.

Comparison of the Nine Months Ended September 30, 2016 and 2015

Net Loss

Net loss for the nine months ended September 30, 2016 was $107.9 million, or ($1.74) per common share basic and diluted, compared with a net loss of $86.9 million, or ($1.51) per common share basic and diluted, for the nine months ended September 30, 2015. The $20.9 million increase

in our net loss for the nine months ended September 30, 2016 as compared to the same period in 2015 was primarily due to:

- Increased research and development expenses of $13.2 million resulting from an increase in clinical trial expenses primarily related to the CONVERT study and higher compensation and related expenses due to an increase in headcount compared to the prior year period. These increases were partially offset by a decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015; and

- Increased general and administrative expenses of $8.2 million primarily resulting from an increase in pre-commercial activities and higher compensation and related expenses due to an increase in headcount as compared to the prior year period.

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2016 and 2015 were comprised of the following (in thousands):

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	Nine Months Ended September 30,		Increase (decrease)	
	2016	2015	$	%
External Expenses				
Clinical development & research	$ 26,266	$ 18,393	$ 7,873	42.8%
Manufacturing	12,243	16,141	(3,898)	-24.1%
Regulatory and quality assurance	1,366	1,897	(531)	-28.0%
Subtotal external expenses	$ 39,875	$ 36,431	$ 3,444	9.5%
Internal Expenses				
Compensation and related expenses	$ 21,463	$ 13,795	$ 7,668	55.6%
Other internal operating expenses	6,513	4,405	2,108	47.9%
Subtotal internal expenses	$ 27,976	$ 18,200	$ 9,776	53.7%
Total	$ 67,851	$ 54,631	$ 13,220	24.2%

Research and development expenses increased to $67.9 million during the nine months ended September 30, 2016 from $54.6 million in the same period in 2015. The $13.2 million increase was due to a $7.9 million increase in external clinical development expenses primarily related to the CONVERT study and a $7.7 million increase in compensation and related expenses, including stock-based compensation, due to an increase in headcount. These increases were partially offset by a $3.9 million decrease in manufacturing expenses primarily due to the completion of the build-out of our production area at Therapure s facility in 2015. We expect research and development expenses to increase in 2016 as compared to 2015 due primarily to the clinical trial activity related to the CONVERT study.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2016 and 2015 were comprised of the following (in thousands):

	Nine Months Ended September 30,		Increase (decrease)	
	2016	2015	$	%
General & administrative	$ 26,789	$ 22,840	$ 3,949	17.3%
Pre-commercial expenses	11,709	7,432	4,277	57.5%
Total general & administrative expenses	$ 38,498	$ 30,272	$ 8,226	27.2%

General and administrative expenses increased to $38.5 million during the nine months ended September 30, 2016 from $30.3 million in the same period in 2015. The $8.2 million increase was primarily due to an increase of $4.6 million in consulting fees relating to pre-commercial marketing activities and legal and consulting expenses and an increase of $3.6 million due to higher compensation costs, including stock-based compensation, related to an increase in headcount.

Interest Expense

Interest expense was $2.0 million during the nine months ended September 30, 2016 as compared to $2.2 million in the same period in 2015. The $0.2 million decrease in interest expense relates to a decrease in the amortization of our debt issuance costs in 2016.

LIQUIDITY AND CAPITAL RESOURCES

Overview

There is considerable time and cost associated with developing a potential drug or pharmaceutical product to the point of regulatory approval and commercialization. In recent years, we have funded our operations through public and private placements of equity securities and through debt financing. We expect to continue to incur losses both in our US and certain international entities, as we plan to fund research and development activities and commercial launch activities.

We believe we currently have sufficient funds to meet our financial needs for at least the next twelve months. We will 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

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be forced to delay, restrict or eliminate all or a portion of our research or development programs, dispose of assets or technology or cease operations. During the remainder of 2016 and 2017, we plan to continue to fund further clinical development of ARIKAYCE and INS1007, support efforts to obtain regulatory approvals, and prepare for commercialization of ARIKAYCE. Our cash requirements in 2016 and 2017 will be impacted by a number of factors, the most significant of which, being expenses related to the CONVERT study, and to a lesser extent, research and clinical expenses related to INS1007.

Cash Flows

As of September 30, 2016, we had total cash and cash equivalents of $200.5 million, as compared with $282.9 million as of December 31, 2015. The $82.4 million decrease was due primarily to the use of cash in operating activities. Our working capital was $182.8 million as of September 30, 2016 as compared with $265.9 million as of December 31, 2015.

Net cash used in operating activities was $88.7 million and $73.2 million for the nine months ended September 30, 2016 and 2015, respectively. The net cash used in operating activities during 2016 and 2015 was primarily for the clinical, manufacturing and pre-commercial activities related to ARIKAYCE, as well as general and administrative expenses.

Net cash used in investing activities was $3.4 million and $3.0 million for the nine months ended September 30, 2016 and 2015, respectively. The net cash used in investing activities during 2016 was primarily related to payments for the expansion of our headquarters and lab facility in Bridgewater, New Jersey. 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 $9.8 million and $227.9 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash provided by financing activities in 2016 was cash proceeds of $9.7 million from the issuance of debt (net of $0.3 million of debt issuance costs) and cash proceeds received from stock option exercises. 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 cash proceeds of $5.0 million received from stock option exercises.

Contractual Obligations

On September 30, 2016, we and our domestic subsidiaries, as co-borrowers, entered into an Amended and Restated Loan and Security Agreement (the A&R Loan Agreement) with Hercules. The A&R Loan Agreement includes a total commitment from Hercules of up to $55.0 million, of which $25.0 million was previously outstanding. The amount of borrowings was initially increased by $10.0 million to an aggregate total of $35.0 million on September 30, 2016. An additional $20.0 million was available at our option through June 30, 2017 subject to certain conditions, including the payment of a facility fee of 0.375%. We exercised this option in early October 2016 and borrowed an additional $20.0 million in connection with our upfront payment obligation under the License Agreement with AstraZeneca. The interest rate for the term is floating and is defined as the greater of (i) 9.25% or (ii) 9.25% plus the sum of the US prime rate minus 4.50%, along with a backend fee of 4.15% of the aggregate principal amount outstanding and an aggregate facility fee of $337,500. The interest-only period extends through May 1, 2018, but can be extended up to 12 months under certain conditions. The maturity date of the loan facility was also extended to October 1, 2020.

Pursuant to the A&R Loan Agreement, we are required to have a consolidated minimum cash liquidity in an amount no less than $25.0 million. Such requirement terminates upon the earlier of the date by which we complete an equity financing with at least $75.0 million in proceeds or the date we generate and announce data from the CONVERT Phase III study in a manner that could support an NDA filing. In addition, pursuant to the A&R Loan Agreement, Hercules has the right to participate, in an aggregate amount of up to $2.0 million, in a subsequent private financing of equity securities.

In connection with the A&R Loan Agreement, we granted the lender a first position lien on all of our assets, excluding intellectual property. Prepayment of the loans made pursuant to the A&R Loan Agreement is subject to penalty. The backend fee of 4.15% on the aggregate outstanding principal balance will be charged to interest expense (and accreted to the debt) using the effective interest method over the original life of the A&R Loan Agreement. Debt issuance fees paid to the lender were recorded as a discount on the debt and are being amortized to interest expense using the effective interest method over the life of the A&R Loan Agreement.

We have an operating lease for office and laboratory space located in Bridgewater, NJ, our corporate headquarters, for which the initial lease term expires in November 2019. Future minimum rental payments under this lease total approximately $3.2 million. In July 2016, we signed an operating lease for additional laboratory space located in Bridgewater, NJ for which the initial lease term expires in September 2021. Future minimum rental payments under this lease are $2.1 million.

As of September 30, 2016, future payments under our long-term debt agreement, capital leases, minimum future payments under non-cancellable operating leases and minimum future payment obligations are as follows:

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	As of September 30, 2016 Payments Due By Period				
	Total	Less than 1 year	1 - 3 Years	4 - 5 Years	After 5 Years
			(in thousands)		
Debt obligations					
Debt maturities	$ 35,000	$	$ 18,782	$ 16,218	$
Contractual interest	10,981	3,208	5,415	2,358	
Operating leases	5,425	1,383	2,888	1,075	79
Purchase obligations	3,375	2,700	675		
Total contractual obligations	$ 54,781	$ 7,291	$ 27,760	$ 19,651	$ 79

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 for ARIKAYCE and the device, first receipt of marketing approval in the US for ARIKAYCE and the device, and first receipt of marketing approval in a major EU country for ARIKAYCE and the device. In addition, PARI is entitled to receive royalty payments in the mid-single digits on commercial net sales of ARIKAYCE pursuant to the licensing agreement, subject to certain specified annual minimum royalties. In July 2014, we entered into a Commercialization Agreement (the PARI Agreement) with PARI for the manufacture and supply of eFlow nebulizer systems and related accessories (the Device) as optimized for use with our proprietary liposomal amikacin for inhalation. The PARI Agreement has an initial term of fifteen years from the first commercial sale of ARIKAYCE pursuant to the licensing agreement (the Initial Term). The term of the PARI Agreement may be extended by us for an additional five years by providing written notice to PARI at 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 patients with CF in the US, we will owe a payment to CFFT of up to $13.4 million that is payable over a three-year period after approval as a commercialized drug in the US. Furthermore, if certain global sales milestones are met within five years of the drug commercialization, we would owe an additional $3.9 million in additional payments. Since there is significant development risk associated with ARIKAYCE, we have not accrued these obligations.

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

In December 2014, we entered into a services agreement with SynteractHCR, Inc. (Synteract) pursuant to which we retained Synteract to perform implementation and management services in connection with the 212 study. We anticipate that aggregate costs relating to all work orders for the 212 study will be approximately $40 million over the period of the study. In April 2015, we entered into a work order with Synteract to perform implementation and management services for the 312 study. We anticipate that aggregate costs relating to all work orders for the 312 study will be approximately $20 million over the period of the study.

On October 4, 2016, we entered into a license agreement (License Agreement) with AstraZeneca AB, a Swedish corporation (AstraZeneca). Pursuant to the terms of the License Agreement, AstraZeneca granted to us global exclusive rights for the purpose of developing and commercializing AZD7986 (renamed INS 1007). INS1007 is a novel oral inhibitor of dipeptidyl peptidase 1 (DPP1). DPP1 is an enzyme that catalyzes the activation of neutrophil serine proteases, which play a key role in pulmonary diseases such as non-CF bronchiectasis. In consideration of the licenses and other rights granted by AstraZeneca, we paid an upfront payment of $30.0 million in early November 2016, which will be included as research and development expense in the fourth quarter of 2016. In connection with the upfront payment obligation in the License Agreement, we borrowed an additional $20.0 million under the A&R

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Loan Agreement in early October 2016. We are also obligated to make a series of contingent milestone payments totaling up to an additional $85.0 million upon the achievement of clinical development and regulatory filing milestones. If we elect to develop INS1007 for a second indication, we will be obligated to make an additional series of contingent milestone payments equal to half of the contingent milestone payments in the preceding sentence. No additional milestone payments are due for any indications beyond the first and second indications. In addition, we will pay AstraZeneca tiered royalties ranging from a high single-digit to mid-teen on net sales of any approved product based on INS1007 and one additional payment of $35.0 million upon the first achievement of $1 billion in annual net sales. The License Agreement provides AstraZeneca with the option to negotiate a future agreement with us for commercialization of INS1007 in chronic obstructive pulmonary disease or asthma.

Future Funding Requirements

We will need to raise additional capital to fund our operations, to develop and commercialize ARIKAYCE, to develop INS1007 and INS1009, and to develop, acquire, in-license or co-promote other products that address orphan or rare diseases. Our future capital requirements may be substantial and will depend on many factors, including:

- the timing and cost of our anticipated clinical trials of ARIKAYCE for the treatment of patients with NTM lung infections;
- the decisions of the FDA and EMA with respect to our applications for marketing approval of ARIKAYCE in the US and Europe; the costs of activities related to the regulatory approval process; and the timing of approvals, if received;
- the cost of putting in place the sales and marketing capabilities necessary to be prepared for a potential commercial launch of ARIKAYCE, if approved;
- the cost of filing, prosecuting, defending and enforcing patent claims;
- the timing and cost of our anticipated clinical trials, including INS1007 and the related milestone payments due to AstraZeneca;
- 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. On September 30, 2016, we received a commitment of $55.0 million pursuant to the A&R Loan Agreement with Hercules, of which $25.0 million was previously outstanding. We believe we currently have sufficient funds to meet our financial needs for the next twelve months. However, our business strategy will 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 will 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 material revenue from ARIKAYCE and we do not know when, or if, we will generate material revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and secure reimbursement of and commercialize, ARIKAYCE.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, other than operating leases, that have or are reasonably likely to have a current or future material effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We do not have any interest in special purpose entities, structured finance entities or other variable interest entities.

CRITICAL ACCOUNTING POLICIES

Preparation of financial statements in accordance with generally accepted accounting principles in the US requires us to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expenses and the disclosures of contingent assets and liabilities. We use our historical experience and other relevant factors when developing our estimates and assumptions. We continually evaluate these estimates and assumptions. The amounts of assets and liabilities reported in our consolidated balance sheets and the amounts of revenue reported in our consolidated statements of comprehensive loss are effected by

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estimates and assumptions, which are used for, but not limited to, the accounting for research and development, stock-based compensation, identifiable intangible assets, and accrued expenses. The accounting policies discussed below are considered critical to an understanding of our consolidated financial statements because their application places the most significant demands on our judgment. Actual results could differ from our estimates. There have been no material changes to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015. For the required interim updates of our accounting policies see Note 2 to our Consolidated Financial Statements Summary of Significant Accounting Policies in this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of September 30, 2016, our cash and cash equivalents were in cash accounts or were invested in money market funds. Such accounts or investments are not insured by the federal government.

As of September 30, 2016, we had $35.0 million of fixed rate borrowings that bear interest at 9.25% outstanding under the A&R Loan Agreement with Hercules. If a 10% change in interest rates was to have occurred on September 30, 2016, this change would not have had a material effect on the fair value of our debt as of that date, nor would it have had a material effect on our future earnings or cash flows.

The majority of our business is conducted in US dollars. However, we do conduct certain transactions in other currencies, including Euros, British Pounds, and Japanese Yen. Historically, fluctuations in foreign currency exchange rates have not materially affected our results of operations and during the three and nine months ended September 30, 2016 and 2015, our results of operations were not materially affected by fluctuations in foreign currency exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934, as amended (the Exchange Act), means controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the periodic reports that we file or submit with the SEC is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation as of September 30, 2016, 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

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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 15, 2016, a purported class action lawsuit was filed in the U.S. District Court for the District of New Jersey against us and certain of our executive officers: Hoey v. Insmed Incorporated, et al, No. 3:16-cv-04323-FLW-TJB (D.N.J. July 15, 2016). The complaint alleges that from March 18, 2013 through June 8, 2016, we and certain of our executive officers made material misstatements or omissions concerning the likelihood of the EMA approving our European MAA for use of ARIKAYCE in the treatment of NTM lung disease and the likelihood of commercialization of ARIKAYCE in Europe. The complaint alleges violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. The complaint seeks unspecified damages. On October 25, 2016, the Court issued an order appointing Bucks County Employees Retirement Funds as lead plaintiff for the putative class. A consolidated amended complaint has not yet been filed. We believe that the allegations in the complaint are without merit and intend to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of the lawsuit.

ITEM 1A. RISK FACTORS

Except for the historical information in this report on Form 10-Q, the matters contained in this report include forward-looking statements that involve risks and uncertainties. Our operating results and financial condition have varied in the past and may in the future vary significantly depending on a number of factors. These factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this report and presented elsewhere by management from time to time. Such factors may have a material adverse effect upon our business, results of operations and financial condition.

You should consider carefully the risk factors, together with all of the other information included in our Annual Report on Form 10-K for the year ended December 31, 2015. Each of these risk factors could adversely affect our business, results of operations and financial condition, as well as adversely affect the value of an investment in our common stock. There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Report on Form 10-Q for the three months ended June 30, 2016, except for the following updates:

Risks Related to Development and Commercialization of our Product Candidates

We may not have, or may be unable to obtain, sufficient quantities of our product candidates to meet our required supply for clinical studies or commercialization requirements.

We do not have any in-house manufacturing capability other than for development and characterization and depend completely on a small number of third-party manufacturers and suppliers for the manufacture of our product candidates on a clinical or commercial scale. In September 2015, we entered into a Commercial Fill/Finish Services Agreement with Althea to produce ARIKAYCE on a non-exclusive basis.

Althea currently manufactures ARIKAYCE at a relatively small scale. In order to meet potential commercial demand, we have constructed a manufacturing operation at Therapure in Canada as an alternate site of manufacture that operates at a larger scale. In February 2014, we entered into a contract manufacturing agreement with Therapure for the manufacture of ARIKAYCE. Our supply of the active pharmaceutical ingredient for INS1009 is dependent on a single supplier. We expect to enter into a commercial supply agreement with AstraZeneca related to certain short-term production needs for INS1007. In addition, we expect our future requirements for INS1007 will be manufactured by a contract manufacturing organization. The inability of a supplier to fulfill our supply requirements could materially adversely affect our ability to obtain and maintain regulatory approvals and future operating results. A change in the relationship with any supplier, or an adverse change in their business, could materially adversely affect our future operating results.

We are dependent upon Althea and Therapure being able to provide an adequate supply of ARIKAYCE both for our clinical trials and for commercial sale in the event ARIKAYCE receives marketing approval. We intend to work closely with Althea and Therapure to coordinate efforts regarding regulatory requirements and our supply needs.

We are dependent upon PARI being able to provide an adequate supply of nebulizers both for our clinical trials and for commercial sale in the event ARIKAYCE receives marketing approval. PARI is the sole manufacturer of the eFlow nebulizer system. These nebulizers must be in good working order and meet specific performance characteristics. We intend to work closely with PARI to coordinate efforts regarding regulatory requirements.

We do not have long-term commercial agreements with all of our suppliers and if any of our suppliers are unable or unwilling to perform for any reason, we may not be able to locate suppliers or enter into favorable agreements with them. Any

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inability to acquire sufficient quantities of our components in a timely manner from these third parties could delay clinical trials or commercialization and prevent us from developing and distributing our products in a cost-effective manner or on a timely basis.

In addition, manufacturers of our components are subject to cGMP and similar standards and we do not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA, as well as other regulatory authorities in jurisdictions outside the US, will not grant approval and may institute restrictions on the marketing or sale of our products. We are reliant on third-party manufacturers and suppliers to meet our clinical supply demands and any future commercial products. Delays in receipt of materials, scheduling, release, custom s control and regulatory compliance issues may adversely impact our ability to initiate, maintain or complete clinical trials that we are sponsoring or may adversely impact commercialization. Issues arising from scale-up, facility construction, environmental controls, equipment requirements, local and federal permits and allowances or other factors may have an adverse impact on our ability to manufacture our product candidates.

We may not be able to enroll enough patients to complete our clinical trials.

The completion rate of our global phase 3 clinical study of ARIKAYCE for NTM and other future clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- Investigator identification and recruitment;
- Regulatory approvals to initiate study sites;
- Patient population size;
- The nature of the protocol to be used in the trial;
- Patient proximity to clinical sites;
- Eligibility criteria for the study;
- The patients willingness to participate in the study;
- Competition from other companies potential clinical studies for the same patient population; and
- Ability to obtain any necessary comparator drug or medical device.

Delays in patient enrollment for future clinical trials could increase costs and delay ultimate commercialization and sales, if any, of our products.

If any of our products meet the criteria for approval pursuant to Subpart H (accelerated approval), such approval will be subject to our carrying out, with due diligence, adequate and well-controlled post market studies to verify and describe their clinical benefit. If we fail to complete such studies with due diligence, or if the results of such studies fail to demonstrate clinical benefit, FDA may, following a hearing, withdraw product approval.

Risks Related to Regulatory Matters

We may not be able to obtain regulatory approvals for ARIKAYCE or any other products we develop in the US, Europe or other countries. If we fail to obtain such approvals, we will not be able to commercialize our products.

We are required to obtain various regulatory approvals prior to studying our products in humans and then again before we market and distribute our products. The regulatory review and approval processes in both the US and Europe require evaluation of preclinical studies and clinical studies, as well as the evaluation of our manufacturing process. These processes are complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products requires the submission of much more extensive preclinical and clinical data, manufacturing information regarding the process and facility, scientific data characterizing our product and other supporting data to the regulatory authorities in order to establish its safety and effectiveness. This process also is complex, lengthy, expensive, resource intensive and uncertain. We have limited experience in submitting and pursuing applications necessary to gain these regulatory approvals.

Data submitted to the regulators is subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a product and the period required for review of any application for regulatory agency approval of a particular product. For example, FDA has designated ARIKAYCE for Fast Track, Breakthrough Therapy and QIDP status, all programs intended to expedite or streamline the development and regulatory review of the drug. If we were to lose the current designation under one or more of those programs, we could face delays in the FDA review and approval process. Even with these designations, there is no guarantee we will receive approval for ARIKAYCE on a timely basis, or at all.

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The Generating Antibiotic Incentives Now (GAIN) Act established incentives for the development of new therapies for serious and life-threatening infections by making streamlined priority review and fast track processes available for drugs which the FDA designates as QIDPs. To qualify for designation as a QIDP according to the criteria established in the GAIN Act, a product must be an antibacterial or anti-fungal drug for human use intended to treat serious or life-threatening infections, including: those caused by an anti-fungal resistant pathogen, including novel or emerging infectious pathogens; or caused by qualifying pathogens listed by the FDA in accordance with the GAIN Act. Under the fast track program generally, the sponsor of an IND may request FDA to designate the drug candidate as a fast track drug if it is intended to treat a serious condition and fulfill an unmet medical need. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor s request. Once FDA designates a drug as a fast track candidate, it is required to facilitate the development and expedite the review of that drug by providing more frequent communication with and guidance to the sponsor.

Delays in obtaining regulatory agency approvals could adversely affect the development and marketing of any drugs that we or any third parties develop. Resolving such delays could force us or third parties to incur significant costs, could limit our allowed activities or the allowed activities of third parties, could diminish any competitive advantages that we or our third parties may attain or could adversely affect our ability to receive royalties, any of which could materially adversely affect our business, financial condition, results of operations or prospects.

To market our products outside of the US and Europe we, and any potential third parties, must comply with numerous and varying regulatory requirements of other countries. The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in these other territories might differ from that required to obtain FDA or EMA approval. The regulatory approval process in these other territories includes at least all of the risks associated with obtaining FDA and EMA approval detailed above.

Specifically related to INS1009, we believe that this product could be eligible for approval under Section 505(b)(2) of the FDCA. Like a traditional NDA that is submitted under Section 505(b)(1) of the FDCA, a 505(b)(2) NDA must establish that the drug is safe and effective, but unlike a traditional NDA the applicant may rely at least in part on studies not conducted by or for the applicant and for which the applicant does not have a right of reference. The ability to rely on existing data to support safety and/or effectiveness can reduce the time and cost associated with traditional NDAs. We cannot be sure that we will obtain approval for INS1009 under the 505(b)(2) pathway.

We plan to submit an IND application with the FDA and subsequently commence a phase 2 study of INS1007 in non-CF bronchiectasis. We anticipate an initial NDA submission under Section 505(b)(1) of the FDCA for the treatment of non-CF bronchiectasis. We are defining our regulatory strategies to potentially expedite the development and regulatory review of INS1007 through programs such as US fast track designation, breakthrough therapy, and US and EU orphan drug designations. We cannot be sure that we will obtain approval for INS1007 under the 505(b)(1) pathway and there is no guarantee INS1007 will be eligible to receive such regulatory designations.

Approval by the FDA or the EMA does not ensure approval by the regulatory authorities of other countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. In addition, we may be subject to fines, suspension or withdrawal of marketing approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable US and foreign regulatory requirements. If we fail to comply with regulatory requirements or to obtain and maintain required approvals, our target market may be reduced and our ability to realize the full market potential of our product candidates may be harmed. The failure to obtain such approvals may materially adversely affect our business, financial condition, results of operations and our prospects.

Risks Related to Our Intellectual Property

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts, prevent us from commercializing our products or increase the costs of commercializing our products.

Third parties may claim that we have infringed upon or misappropriated their proprietary rights. Third parties may attempt to obtain patent protection relating to the production and use of our product candidates. We cannot assure you that any existing third-party patents, or patents that may later issue to third parties, would not negatively affect our commercialization of ARIKAYCE, INS1007, INS1009 or any other product. We cannot assure you that such patents can be avoided or invalidated or would be licensed to us at commercially reasonable rates or at all. We cannot assure you that we will be successful in any intellectual property litigation that may arise or that such litigation would not have an adverse effect on our business, financial condition, results of operation or prospects. In the event of a successful claim against us for infringement or misappropriation of a third party s proprietary rights, we may be required to take actions including, but not limited to, the following:

- Pay damages, including up to treble damages, and the other party s attorneys fees, which may be substantial;
- Cease the development, manufacture, marketing and sale of products or use of processes that infringe the proprietary rights of others;

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- Expend significant resources to redesign our products or our processes so that they do not infringe the proprietary rights of others, which may not be possible;

- Redesign our products or processes to avoid third-party proprietary rights, which means we may suffer significant regulatory delays associated with conducting additional clinical trials or other steps to obtain regulatory approval; and/or

- Obtain one or more licenses arising out of a settlement of litigation or otherwise from third parties which license(s) may not be available to us on acceptable terms or at all.

Furthermore, litigation with any third party, even if the allegations are without merit, would likely be expensive and time-consuming and divert management s attention.

In particular, PAH is a competitive indication with established products, including other formulations of treprostinil. Our supply of the active pharmaceutical ingredient for INS1009 is dependent upon a single supplier. The supplier owns patents on its manufacturing process and we have filed patent applications for INS1009. A competitor in the PAH indication may claim that we or our supplier have infringed upon or misappropriated their proprietary rights. We cannot be sure that we or our supplier will be successful in any intellectual property litigation that may arise or that such litigation would not have an adverse effect on our business, financial condition, results of operation or prospects.

If we fail to comply with our obligations in the agreements under which we license rights to technology from third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

On October 4, 2016, we entered into a License Agreement with AstraZeneca. Pursuant to the terms of the License Agreement, AstraZeneca granted us global exclusive rights for the purpose of developing and commercializing INS1007. If we fail to comply with our obligations under our agreements with AstraZeneca (including, among other things, if we fail to use commercially reasonable efforts to develop and commercialize a product based on INS1007, or we are subject to a bankruptcy or insolvency), AstraZeneca may have the right to terminate the license. Termination of the License Agreement or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms and may materially harm our business.

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, 2016.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. **MINE SAFETY DISCLOSURES**

Not applicable.

ITEM 5. **OTHER INFORMATION**

None.

ITEM 6. **EXHIBITS**

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

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSMED INCORPORATED

Date: November 3, 2016

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

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EXHIBIT INDEX

10.1	Amended and Restated Loan and Security Agreement, dated as of September 30, 2016, by and between Insmed Incorporated and its domestic subsidiaries and Hercules Capital, Inc.
10.2	Employment Agreement, effective as of September 27, 2016, between Insmed Incorporated and Roger Adsett.
31.1	Certification of William H. Lewis, Chief Executive Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2	Certification of Andrew T. Drechsler, Chief Financial Officer of Insmed Incorporated, pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1	Certification of William H. Lewis, Chief Executive Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
32.2	Certification of Andrew T. Drechsler, Chief Financial Officer of Insmed Incorporated, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101	The following materials from Insmed Incorporated s quarterly report on Form 10-Q for the quarter ended September 30, 2016 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015, (ii) Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2016 and 2015, (iii) Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015, and (iv) Notes to the Unaudited Consolidated Financial Statements.