INSMED Inc
Form 10-Q
May 03, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o
	Emerging growth 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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

As of April 28, 2017, there were 62,090,141 shares of the registrant s common stock, $0.01 par value, outstanding.

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INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2017

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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. ARIKAYCE, INSMED and CONVERT are trademarks of Insmed Incorporated. This Form 10-Q also contains trademarks of third parties. Each trademark of another company appearing in this Form 10-Q is the property of its owner.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except par value and share data)

	As of March 31, 2017 (unaudited)	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 125,839	$ 162,591
Prepaid expenses and other current assets	5,785	5,816
Total current assets	131,624	168,407
In-process research and development	58,200	58,200
Fixed assets, net	9,807	10,020
Other assets	1,028	1,329
Total assets	$ 200,659	$ 237,956
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 8,454	$ 10,439
Accrued expenses	14,143	16,822
Other current liabilities	674	728
Total current liabilities	23,271	27,989
Debt, long-term	54,993	54,791
Other long-term liabilities	711	693
Total liabilities	78,975	83,473
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 62,087,828 and 62,019,889 issued and outstanding shares at March 31, 2017 and December 31, 2016, respectively	621	620
Additional paid-in capital	923,760	919,164
Accumulated deficit	(802,650)	(765,236)
Accumulated other comprehensive loss	(47)	(65)
Total shareholders equity	121,684	154,483
Total liabilities and shareholders equity	$ 200,659	$ 237,956

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands, except per share data)

	Three Months ended March 31,	
	2017	**2016**
Revenues	$	$
Operating expenses:		
Research and development	22,254	20,547
General and administrative	13,715	12,520
Total operating expenses	35,969	33,067
Operating loss	(35,969)	(33,067)
Investment income	154	170
Interest expense	(1,474)	(622)
Other (expense) income, net	(95)	15
Loss before income taxes	(37,384)	(33,504)
Provision for income taxes	30	28
Net loss	$ (37,414)	$ (33,532)
Basic and diluted net loss per share	$ (0.60)	$ (0.54)
Weighted average basic and diluted common shares outstanding	62,041	61,858
Net loss	$ (37,414)	$ (33,532)
Other comprehensive income (loss):		
Foreign currency translation gains (losses)	18	(3)
Total comprehensive loss	$ (37,396)	$ (33,535)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (unaudited)

(in thousands)

	Three months ended March 31,	
	2017	**2016**
Operating activities		
Net loss	$ (37,414)	$ (33,532)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	716	514
Stock based compensation expense	4,032	4,219
Amortization of debt discount and debt issuance costs	31	38
Accrual of backend fee on debt	171	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	352	(316)
Accounts payable	(2,026)	527
Accrued expenses and other	(2,774)	(978)
Net cash used in operating activities	(36,912)	(29,528)
Investing activities		
Purchase of fixed assets	(417)	(588)
Net cash used in investing activities	(417)	(588)
Financing activities		
Proceeds from exercise of stock options	565	81
Net cash provided by financing activities	565	81
Effect of exchange rates on cash and cash equivalents	12	31
Net decrease in cash and cash equivalents	(36,752)	(30,004)
Cash and cash equivalents at beginning of period	162,591	282,876
Cash and cash equivalents at end of period	$ 125,839	$ 252,872
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,273	$ 975
Cash paid for income taxes	$ 17	$

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 adult patients with treatment refractory nontuberculous mycobacteria (NTM) lung disease caused by *Mycobacterium avium* complex (MAC), a rare and often chronic infection that can cause 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 treprostinil prodrug nanoparticle formulation.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999 and its principal executive offices are in Bridgewater, New Jersey. The Company has legal entities in the United States (US), Ireland, Germany, France, the United Kingdom (UK) and the Netherlands. 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, 2016.

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, 2016:

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

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

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

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

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

The Company s only assets and liabilities which were measured at fair value as of March 31, 2017 and December 31, 2016 were Level 1 and such assets were comprised of cash and cash equivalents of $125.8 million and $162.6 million, respectively.

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

The Company recognizes transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no transfers in or out of Level 1, Level 2 or Level 3 during the three months ended March 31, 2017 and 2016, respectively.

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As of March 31, 2017 and December 31, 2016, 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 and restricted stock units (RSUs) would be antidilutive as the Company incurred a net loss. Potentially dilutive common shares resulting from the assumed exercise of outstanding stock options are determined based on the treasury stock method.

The following table sets forth the reconciliation of the weighted average number of shares used to compute basic and diluted net loss per share for the three months ended March 31, 2017 and 2016:

	Three Months Ended March 31,	
	2017	**2016**
Numerator:		
Net loss	$ (37,414)	$ (33,532)
Denominator:		
Weighted average common shares used in calculation of basic net loss per share	62,041	61,858
Effect of dilutive securities:		
Stock options to purchase common stock		
RSUs		
Weighted average common shares outstanding used in calculation of diluted net loss per share	62,041	61,858
Net loss per share:		
Basic and diluted net loss per share	$ (0.60)	$ (0.54)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of March 31, 2017 and 2016 as their effect would have been anti-dilutive (in thousands):

	2017	**2016**
Stock options to purchase common stock	7,719	6,221
Unvested RSUs	89	

Recently Adopted Accounting Pronouncements - In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*, which defines

management s responsibility to perform interim and annual assessments of an entity s ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The new standard was effective for the annual period ending after December 15, 2016, and for interim periods thereafter. The Company adopted ASU 2014-15 in the fourth quarter of 2016, which had no impact on the Company s consolidated financial statements. The interim assessment during the first quarter of 2017 did not have an impact on the consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, *Compensation Stock Compensation*. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. The Company adopted ASU 2016-09 in the first quarter of 2017 and impact of the adoption was not material to the consolidated financial statements as of and for the quarter ended March 31, 2017.

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3. Identifiable Intangible Asset

The Company believes there are no indicators of impairment relating to its in-process research and development intangible asset as of March 31, 2017.

4. Accrued Expenses

Accrued expenses consist of the following:

	As of March 31, 2017	As of December 31, 2016
	(in thousands)	
Accrued clinical trial expenses	$ 7,842	$ 7,071
Accrued compensation	2,674	6,937
Accrued professional fees	2,290	1,604
Accrued technical operation expenses	534	591
Accrued interest payable	438	438
Other accrued expenses	365	181
	$ 14,143	$ 16,822

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 included a total commitment from Hercules of up to $55.0 million, of which $25.0 million was previously outstanding. The amount of borrowings was 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 AB. The interest rate for the term is floating and is calculated 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. Upon entry into the A&R Loan Agreement, the interest-only period was extended through November 1, 2018, and it could be extended up to six additional 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 study in a manner that could support the filing of a new drug application. 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 that involves the issuance of our 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 is being 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 March 31, 2017 (in thousands):

Debt:		
Notes payable	$	55,000
Accretion of backend fee		342
Debt issuance costs, unamortized		(349)
Debt, long-term	$	54,993

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As of March 31, 2017, future principal repayments of the debt for each of the fiscal years through maturity were as follows (in thousands):

Year Ending in December 31:	
2017	$
2018	3,271
2019	20,753
2020	30,976
	$ 55,000

The estimated fair value of the debt (categorized as a Level 2 liability for fair value measurement purposes) is determined using current market factors and the ability of the Company to obtain debt at comparable terms to those that are currently in place. The Company believes the estimated fair value at March 31, 2017 approximates the carrying amount.

6. *Shareholders Equity*

Common Stock As of March 31, 2017, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 62,087,828 shares of common stock issued and outstanding. In addition, as of March 31, 2017, the Company had reserved 7,718,990 shares of common stock for issuance upon the exercise of outstanding common stock options and 89,194 shares of common stock for issuance upon the vesting of RSUs.

Preferred Stock As of March 31, 2017, 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 2015 Annual Meeting of Shareholders. 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. The Company has 5,000,000 shares of common stock authorized for issuance under the 2015 Incentive Plan and, as of March 31, 2017, there were 1,596,242 shares remaining for future grants (or issuances) of stock options, stock appreciation rights, restricted stock, restricted stock units and incentive bonuses thereunder. The 2015 Incentive Plan will terminate on April 9, 2025 unless it is extended or terminated earlier pursuant to its terms. The Company has submitted a proposal to its shareholders to approve a new equity compensation plan, the 2017 Incentive Plan, at the 2017 Annual Meeting of Shareholders. The

2017 Incentive Plan, if approved, will provide for the issuance of 5,000,000 shares, plus any shares that were subject to outstanding awards under the 2015 Incentive Plan and the 2013 Incentive Plan, as of the effective date of the 2017 Incentive Plan, that are cancelled, terminate unearned, expire, are forfeited, lapse for any reason or are settled in cash without the delivery of shares. If approved, no additional awards will be granted under the 2015 Incentive Plan. 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.

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

	Three Months Ended March 31,	
	2017	**2016**
Volatility	73%-74%	77%
Risk-free interest rate	1.86%-1.99%	1.16%-1.73%
Dividend yield	0.0%	0.0%
Expected option term (in years)	6.25	6.25
Weighted average fair value of stock options granted	$9.18	$10.68

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For each period 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. Estimated forfeitures are based on the actual percentage of option forfeitures since the closing of the Company s merger with Transave in December 2010.

From time to time, the Company grants performance-condition options to certain of its employees. Vesting of these options is subject to the Company achieving certain performance criteria established at the date of grant and the grantees fulfilling a service condition (continued employment). As of March 31, 2017, the Company had performance options totaling 133,334 shares outstanding which had not yet met the recognition criteria.

The following table summarizes the Company s aggregate stock option activity for the three months ended March 31, 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2016	7,116,706	$ 13.30		
Granted	940,060	$ 13.77		
Exercised	(67,939)	$ 8.58		
Forfeited or expired	(269,837)	$ 14.50		
Options outstanding at March 31, 2017	7,718,990	$ 13.36	7.58	$ 37,828
Vested and expected to vest at March 31, 2017	7,418,298	$ 13.32	7.52	$ 36,705
Exercisable at March 31, 2017	3,436,957	$ 11.80	6.17	$ 22,276

The total intrinsic value of stock options exercised during the three months ended March 31, 2017 and 2016 was $0.5 million and $0.1 million, respectively.

As of March 31, 2017, there was $28.4 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.7 years. Included in unrecognized compensation expense was $1.1 million related to outstanding performance-based options. The following table summarizes the range of exercise prices and the number of stock options outstanding and exercisable:

		Outstanding as of March 31, 2017			Exercisable as of March 31, 2017	
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	841,850	5.34	3.34	841,850	3.34
3.60	6.90	452,003	4.25	5.82	414,503	5.72
6.96	10.85	1,096,296	9.05	10.76	23,751	6.96
11.14	12.58	1,121,225	6.79	12.18	664,466	12.21

12.66	13.58	187,880	8.17	13.24	68,887	13.30
13.67	13.67	880,750	9.77	13.67		
13.94	16.07	867,990	7.47	15.18	467,219	15.13
16.09	16.54	775,528	8.55	16.18	215,355	16.17
17.14	22.76	1,427,631	7.54	21.27	714,903	21.00
22.84	27.38	67,837	8.13	23.78	26,023	23.79

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Restricted Stock and Restricted Stock Units The Company may grant Restricted Stock (RS) and RSUs to eligible employees, including its executives, and non-employee directors. Each share of RS vests upon, and each RSU represents a right to receive one share of the Company s common stock upon the completion of a specific period of continued service or achievement of a certain milestone. 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 three months ended March 31, 2017:

	Number of RSUs	Weighted Average Grant Price ($)
Outstanding at December 31, 2016	89,194	10.85
Granted		
Released		
Outstanding at March 31, 2017	89,194	10.85

The following table summarizes the aggregate stock-based compensation recorded in the Consolidated Statements of Comprehensive Loss related to stock options and RSUs during the three months ended March 31, 2017 and 2016:

	Three months ended March 31,	
	2017	2016
	(in millions)	
Research and development expenses	$ 1.5	$ 1.4
General and administrative expenses	2.5	2.8
Total	$ 4.0	$ 4.2

8. Income Taxes

The Company s provision for income taxes was $30,000 and $28,000 for the three months ended March 31, 2017 and 2016, respectively. The provision for income taxes in both periods was a result of certain of the Company s subsidiaries in Europe, which had taxable income during the three months ended March 31, 2017 and 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 Company s 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, except for 2009. Such loss carryforwards are subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. As of March 31, 2017 and December 31, 2016, the Company had recorded no reserves for unrecognized income tax benefits, nor had 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 $2.7 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 $2.2 million.

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Rent expense charged to operations was $0.4 million and $0.2 million for the three months ended March 31, 2017 and 2016, respectively. Future minimum rental payments required under the Company s operating leases for the period from April 1, 2017 to December 31, 2017 and for each of the five years thereafter are as follows (in thousands):

Year Ending December 31:		
2017 (remaining)	$	1,107
2018		1,515
2019		1,421
2020		477
2021		498
2022		
	$	5,018

Legal Proceedings

On July 15, 2016, a lawsuit captioned Hoey v. Insmed Incorporated, et al, No. 3:16-cv-04323-FLW-TJB (D.N.J. July 15, 2016) was filed in the US District Court for the District of New Jersey on behalf of a putative class of investors who purchased the Company s common stock from March 18, 2013 through June 8, 2016. The complaint alleged that the Company and certain of its executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (Exchange Act) by misrepresenting and/or omitting 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.

On October 25, 2016, the Court issued an order appointing Bucks County Employees Retirement Fund as lead plaintiff for the putative class. On December 15, 2016, lead plaintiff filed an amended complaint that shortens the putative class period for the Exchange Act claims to March 26, 2014 through June 8, 2016 and adds claims under Sections 11, 12, and 15 of the Securities Act on behalf of a putative class of investors who purchased common stock in or traceable to the Company s March 31, 2015 public offering. The amended complaint names as defendants in the Securities Act claims the Company, certain directors and officers, and the investment banks who served as underwriters in connection with the secondary offering. The amended complaint alleges defendants violated the Securities Act by using a purportedly misleading definition of culture conversion and supposedly failing to disclose in the offering materials purported flaws in its Phase 2 study that made the secondary offering risky or speculative. The amended complaint seeks damages in an unspecified amount. The Company moved to dismiss the amended complaint on March 1, 2017. The lead plaintiff s opposition to the motion is currently due by May 17, 2017. The Company believes that the allegations in the complaints are without merit and intends to defend the lawsuit vigorously; however, there can be no assurance regarding the ultimate outcome of the lawsuit.

From time to time, the Company is a party to various other lawsuits, claims and other legal proceedings that arise in the ordinary course of business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company s consolidated financial position, results of operations or cash flows.

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

Cautionary Note Regarding Forward Looking Statements

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

Forward-looking statements are based on 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 following:

- *uncertainties in the research and development of our existing product candidates, including due to delays in patient enrollment or failure of our preclinical studies or clinical trials to satisfy pre-established endpoints;*

- *failure to develop, or to license for development, additional product candidates, including a failure to attract experienced third party collaborators;*

- *failure to obtain, or delays in obtaining, regulatory approval from the United States (US) Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other regulatory authorities for our product candidates or their delivery devices, including due to insufficient clinical data or selection of endpoints that are not satisfactory to regulators;*

- *failure of third parties on which we are dependent to conduct our clinical trials and to manufacture sufficient quantities of our product candidates for clinical or commercial needs;*

- *failure to comply with license agreements that are critical for our product development, including our license agreements with PARI Pharma GmbH (PARI) and AstraZeneca AB (AstraZeneca);*

- *lack of safety and efficacy of our product candidates;*

- *inaccuracies in our estimate of the size of the potential markets for our product candidates;*

- *failure to maintain regulatory approval for our product candidates, once received, due to a failure to satisfy post-approval regulatory requirements, such as the need for post-clinical trials;*

- *uncertainties in the rate and degree of market acceptance of product candidates, if approved;*

- *uncertainties in the timing, scope and rate of reimbursement for our product candidates;*

- *competitive developments affecting our product candidates;*

- *inaccurate estimates regarding our future capital requirements, including those necessary to fund milestone payments or royalties owed to third parties;*

- *inability to repay our existing indebtedness or to obtain additional financing when needed;*

- *failure to obtain, protect and enforce our patents and other intellectual property;*

- *inability to create an effective direct sales and marketing infrastructure or to partner with a third party that offers such an infrastructure for distribution of our product candidates;*

- *the cost and potential reputational damage resulting from litigation to which we are a party, including, without limitation, the class action lawsuit pending against us;*

- *failure to comply with the laws and regulations that impact our business;*

- *loss of key personnel; and*

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- *changes in laws and regulations applicable to our business, including those related to pricing and reimbursement of our product candidates.*

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. More information on factors that could cause actual results to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, particularly under the caption Risk Factors. 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, 2016.

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 adult patients with treatment refractory nontuberculous mycobacteria (NTM) lung disease caused by *Mycobacterium avium* complex (MAC), a rare and often chronic infection that can cause 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 an inhaled nanoparticle formulation of a treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders, including pulmonary arterial hypertension (PAH).

The table below summarizes the current status and anticipated milestones for our principal product candidates: ARIKAYCE, INS1007, and INS1009.

Product Candidate/Target Indications	Status	Next Expected Milestones
ARIKAYCE (LAI) for adult patients with treatment refractory NTM lung infections caused by MAC	• We are advancing the CONVERT (or 212) study, a randomized, open-label global phase 3 clinical study of ARIKAYCE in adult patients with treatment refractory NTM lung disease caused by MAC. We have achieved our enrollment objective for the CONVERT study.	• We expect to report top-line results for the Month 6 primary endpoint in the second half of 2017. • If the CONVERT study meets its primary endpoint, we intend to seek accelerated marketing approval for

	• The US Food and Drug Administration (FDA) has designated ARIKAYCE as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP). • The European Commission has granted an orphan designation for ARIKAYCE for the treatment of NTM lung disease.	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 refractory NTM lung infections caused by MAC 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.

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Product Candidate/Target Indications	Status	Next Expected Milestones
INS1007 (oral reversible inhibitor of dipeptidyl peptidase 1) for non-CF bronchiectasis	• In October 2016, we entered into a license agreement with AstraZeneca for the exclusive global rights for the purpose of developing and commercializing AZD7986 (AZ License Agreement). We renamed the compound INS1007 and plan to pursue an initial indication in non-CF bronchiectasis. • We are defining our regulatory strategies to potentially secure US and EU orphan drug designations and expedite the development and regulatory review of INS1007 through programs such as US fast track designation and breakthrough therapy.	• We plan to submit an Investigational New Drug (IND) application with the FDA for non-CF bronchiectasis and subsequently commence a phase 2 clinical study of INS1007. The study is expected to begin in the second half of 2017.
INS1009 (inhaled nanoparticle formulation of a 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 believe INS1009 may offer a differentiated product profile for rare pulmonary disorders, including PAH, and we are currently evaluating our options to advance its development.

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) and NTM. To complement our internal research and development, we actively evaluate in-licensing and acquisition opportunities for a broad range of rare diseases.

Our Strategy

Our strategy focuses on the needs of patients with rare diseases. We are currently focused on the development and commercialization of ARIKAYCE. We are not aware of any inhaled products specifically indicated to treat refractory NTM lung disease in North America, Europe or Japan. While we believe that ARIKAYCE has the potential to treat a number of different bacterial infections, we are prioritizing securing US regulatory approval of ARIKAYCE for adult patients with refractory NTM lung disease caused by MAC. We are also advancing earlier-stage programs in other rare pulmonary disorders.

Our current priorities are as follows:

- Completing the CONVERT study;

- Preparing a New Drug Application (NDA) for submission to the FDA for ARIKAYCE, which we plan to base on the primary endpoint of the CONVERT study;

- Ensuring our product supply chain will support the clinical development and, if approved, commercialization of ARIKAYCE;

- Preparing for potential commercialization of ARIKAYCE in the US, certain countries in Europe, Japan, and certain other countries;

- Developing the core value dossier to support the global reimbursement of ARIKAYCE;

- Supporting further research and lifecycle management strategies for ARIKAYCE;

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- Filing an investigational new drug (IND) application with the 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.

Product Pipeline

ARIKAYCE for patients with NTM lung disease

Our lead product candidate is ARIKAYCE, or LAI, a novel, once-daily liposomal formulation of amikacin that is in late-stage clinical development for adult patients with treatment refractory NTM lung disease caused by MAC, a rare and often chronic infection that can cause irreversible lung damage and which can be fatal. Amikacin solution for parenteral administration is an established drug that has activity against a variety of NTM; however, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function (Peloquin et al., 2004). Unlike intravenous amikacin, 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 technology 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 a portable aerosol delivery system, via an optimized, investigational eFlow® Nebulizer System manufactured by PARI.

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. As a result, ARIKAYCE would have 12 years of post-approval marketing exclusivity in the US, if approved. A QIDP-designated product is eligible for fast track status and is often granted priority review status. A priority review designation for a drug means the FDA s goal is to take action on the NDA within six months following the 60-day filing date, as compared to within 10 months following the 60-day filing date under a standard review.

The CONVERT study

ARIKAYCE is currently being evaluated in a phase 3 randomized, open-label clinical study taking place in North America, Europe, Australia, New Zealand and Asia that is designed to confirm the culture conversion results seen in our phase 2 clinical trial, which we expect will provide the basis for submitting an NDA to the FDA. Because the highest response to ARIKAYCE treatment in our phase 2 study was observed in the subgroup of non-CF patients with NTM lung infection caused by MAC, the CONVERT 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 interrupted within 12 months of screening. The CONVERT study excludes patients whose susceptibility scores indicate that

their MAC lung infection may be resistant to amikacin. We achieved our enrollment objective for the CONVERT study in the fourth quarter of 2016.

After a screening period of approximately 10 weeks, eligible patients were randomized 2:1 to once-daily ARIKAYCE plus a multi-drug regimen or a multi-drug regimen without ARIKAYCE. The first analysis, after the last patient has completed Month 6, will be based on the primary efficacy endpoint comparing the proportion of patients who achieve culture conversion (three consecutive monthly negative sputum cultures) by Month 6 in the ARIKAYCE plus multi-drug regimen arm compared to the arm in which patients receive a multi-drug regimen without ARIKAYCE. The study s key secondary endpoint in the first analysis includes the change from baseline in the six-minute walk test. We expect to report top-line results for the Month 6 primary endpoint during the second half of 2017. A subsequent analysis will examine off-treatment assessments to evaluate the durability of the anti-mycobacterial effect on sputum culture at 3 months off all treatment, in patients that achieve conversion. The study also includes a comprehensive pharmacokinetic sub-study in Japanese patients 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, patients will be assessed as converters (those achieving culture conversion by Month 6) or non-converters for the primary efficacy endpoint. All converters will continue on their randomized treatment regimen for an additional 12 months. 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, single-arm, 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 patients achieving culture conversion (three consecutive monthly negative sputum cultures) by Month 6 and the proportion of patients achieving culture conversion by Month 12 (end of treatment).

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The protocol for the CONVERT study incorporates feedback from the FDA and the EMA via its scientific advice working party process, as well as local health authorities in other countries, including Japan s Pharmaceuticals and Medical Devices Agency. If the CONVERT study meets the primary endpoint of culture conversion by Month 6, we believe we would be eligible to submit an NDA pursuant to 21 C.F.R. Part 314 Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses), which permits the FDA to approve a drug based on a surrogate or intermediate endpoint, provided the sponsor commits to study the drug further to verify and describe the confirmatory data of the drug s clinical benefit. We believe that efficacy data from the CONVERT study after Month 6 in combination with the durability data, if successful, will suffice to meet both the accelerated and confirmatory data requirements.

Phase 2 Study (or 112 Study)

Our completed phase 2 study (or 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 *M. abscessus* that was refractory to guideline-based therapy. In October 2016, the results from the phase 2 study were published online in the *American Journal of Respiratory and Critical Care Medicine* (Olivier et al. 2016).

The study included an 84-day double-blind phase in which patients were randomized 1:1 either to ARIKAYCE once-daily plus a multi-drug regimen or to placebo once-daily plus a multi-drug regimen. After completing the 84-day double-blind phase, patients had the option of continuing in an 84-day open-label phase during which all patients received ARIKAYCE plus the same multi-drug regimen. The study also included 28-day and 12-month off-ARIKAYCE follow-up assessments. Eighty-nine (89) patients were randomized and dosed in the study. Of the 80 patients who completed the 84-day double-blind phase, 78 patients 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 patients 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 was defined as at least three consecutive monthly sputum samples that test negative for NTM, consistent with the definition of culture conversion in the guidelines and in clinical practice. Twenty-three (23) patients 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 other 19 patients who achieved culture conversion, 17 achieved culture conversion after receiving ARIKAYCE (10 during the double-blind phase and seven after entering the open-label phase, of which six received ARIKAYCE for the first time in the open-label phase). Two patients achieved culture conversion while receiving placebo during the double-blind phase. The majority of patients 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.

Ninety (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.

INS1007

INS1007 is a small molecule, oral, reversible inhibitor of DPP1, which we in-licensed from AstraZeneca in October 2016. DPP1 is 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, which play a key role in the pathologic inflammatory process, contain three neutrophil serine proteases, neutrophil elastase, proteinase 3, and cathepsin G, that have been implicated in a variety of inflammatory diseases. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active neutrophil serine proteases that cause lung destruction

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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 is a rare, progressive pulmonary disorder in which the bronchi become permanently dilated due to chronic inflammation and infection.

Phase 1 study results

In a phase 1 study of healthy volunteers, INS1007 (previously 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, it was shown to reversibly inhibit DPP1 and the activation of neutrophil serine proteases within maturing neutrophils.

We plan to submit an IND application with the FDA for INS1007 in non-CF bronchiectasis, and after it becomes effective, to commence a phase 2 clinical study of INS1007 in that indication. We expect the study to begin in the second half of 2017. In addition, we are evaluating INS1007 in other potential indications.

INS1009

INS1009 is an investigational sustained-release inhaled treprostinil prodrug nanoparticle formulation that has the potential to address certain of the current limitations of existing 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, and we are currently evaluating our options to advance its development.

Phase 1 study results

In late 2014, we had a 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. Twenty-four (24) patients were enrolled and received INS1009 with cohorts of eight patients receiving doses of 85 micrograms (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.

KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Research and Development (R&D) Expenses

R&D 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. In addition, our R&D expenses include payments to third parties for the license rights to products in development (prior to marketing approval), such as for INS1007. Our expenses related to manufacturing our drug candidate for clinical study are primarily related to activities at contract manufacturing organizations (CMOs) 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.

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General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for our non-management directors and 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 services, including fees incurred in connection with the securities litigation filed against us and patent-related expenses, consulting services, insurance, board of director fees, tax and accounting services.

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 and amortization of debt issuance costs related to our debt obligations.

Debt Issuance Costs

Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Our balance sheet reflects debt, net of debt issuance costs paid to the lender and other third party costs. Unamortized debt issuance costs associated with extinguished debt are expensed in the period of the extinguishment.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2017 and 2016

Net Loss

Net loss for the quarter ended March 31, 2017 was $37.4 million, or $0.60 per common share basic and diluted, compared with a net loss of $33.5 million, or $0.54 per common share basic and diluted, for the quarter ended March 31, 2016. The $3.9 million increase in our net loss for the quarter ended March 31, 2017 as compared to the same period in 2016 was due to:

- Increased R&D expenses of $1.7 million primarily resulting from higher compensation and related expenses due to an increase in headcount; and

- Increased general and administrative expenses of $1.2 million resulting from an increase in pre-commercial planning activities and higher compensation and related expenses due to an increase in headcount.

In addition, there was a $0.9 million increase in interest expense resulting from the increase in our debt in the second half of 2016.

R&D Expenses

R&D expenses for the quarters ended March 31, 2017 and 2016 were comprised of the following:

	Quarters Ended March 31,		Increase (decrease)	
	2017	2016	$	%
External Expenses				
Clinical development & research	$ 8,475	$ 8,206	$ 269	3.3%
Manufacturing	2,744	3,464	(720)	-20.8%
Regulatory and quality assurance	968	234	734	313.7%
Subtotal external expenses	$ 12,187	$ 11,904	$ 283	2.4%
Internal Expenses				
Compensation and related expenses	$ 7,651	$ 6,552	$ 1,099	16.8%
Other internal operating expenses	2,416	2,091	325	15.5%
Subtotal internal expenses	$ 10,067	$ 8,643	$ 1,424	16.5%
Total	$ 22,254	$ 20,547	$ 1,707	8.3%

R&D expenses increased to $22.3 million during the quarter ended March 31, 2017 from $20.5 million in the same period in 2016. The $1.7 million increase was primarily due to a $1.1 million increase in compensation and related expenses due to an increase in headcount as compared to the prior year period.

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General and Administrative Expenses

General and administrative expenses for the quarter ended March 31, 2017 and 2016 were comprised of the following:

	Quarters Ended March 31,		Increase (decrease)	