INSMED Inc
Form 10-Q
August 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 June 30, 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 July 31, 2017, there were 62,377,916 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 JUNE 30, 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 June 30, 2017 (unaudited)	As of December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 91,064	$ 162,591
Prepaid expenses and other current assets	5,470	5,816
Total current assets	96,534	168,407
In-process research and development	58,200	58,200
Fixed assets, net	9,234	10,020
Other assets	1,672	1,329
Total assets	$ 165,640	$ 237,956
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 11,030	$ 10,439
Accrued expenses	14,548	16,822
Other current liabilities	694	728
Total current liabilities	26,272	27,989
Debt, long-term	55,194	54,791
Other long-term liabilities	729	693
Total liabilities	82,195	83,473
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 62,376,416 and 62,019,889 issued and outstanding shares at June 30, 2017 and December 31, 2016, respectively	624	620
Additional paid-in capital	930,185	919,164
Accumulated deficit	(847,322)	(765,236)
Accumulated other comprehensive loss	(42)	(65)
Total shareholders equity	83,445	154,483
Total liabilities and shareholders equity	$ 165,640	$ 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 June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenues	$	$	$	$
Operating expenses:				
Research and development	26,871	23,871	49,125	44,418
General and administrative	16,644	12,262	30,359	24,782
Total operating expenses	43,515	36,133	79,484	69,200
Operating loss	(43,515)	(36,133)	(79,484)	(69,200)
Investment income	169	164	323	334
Interest expense	(1,489)	(624)	(2,963)	(1,246)
Other income, net	200	32	105	47
Loss before income taxes	(44,635)	(36,561)	(82,019)	(70,065)
Provision for income taxes	37	18	67	46
Net loss	$ (44,672)	$ (36,579)	$ (82,086)	$ (70,111)
Basic and diluted net loss per share	$ (0.72)	$ (0.59)	$ (1.32)	$ (1.13)
Weighted average basic and diluted common shares outstanding	62,209	61,878	62,126	61,868
Net loss	$ (44,672)	$ (36,579)	$ (82,086)	$ (70,111)
Other comprehensive income:				
Foreign currency translation gains	5	15	23	12
Total comprehensive loss	$ (44,667)	$ (36,564)	$ (82,063)	$ (70,099)

See accompanying notes to consolidated financial statements

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INSMED INCORPORATED

Consolidated Statements of Cash Flows (unaudited)

(in thousands)

	Six Months Ended June 30,	
	2017	**2016**
Operating activities		
Net loss	$ (82,086)	$ (70,111)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,454	1,082
Stock-based compensation expense	8,591	8,834
Amortization of debt discount and debt issuance costs	61	75
Accretion of backend fee on debt	342	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	128	(1,176)
Accounts payable	767	1,222
Accrued expenses and other	(2,415)	2,309
Net cash used in operating activities	(73,158)	(57,765)
Investing activities		
Purchase of fixed assets	(854)	(2,128)
Net cash used in investing activities	(854)	(2,128)
Financing activities		
Proceeds from exercise of stock options	2,434	128
Net cash provided by financing activities	2,434	128
Effect of exchange rates on cash and cash equivalents	51	(2)
Net decrease in cash and cash equivalents	(71,527)	(59,767)
Cash and cash equivalents at beginning of period	162,591	282,876
Cash and cash equivalents at end of period	$ 91,064	$ 223,109
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 2,574	$ 1,572
Cash paid for income taxes	$ 41	$ 26

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 amikacin liposome inhalation suspension (ALIS) (formerly known as liposomal amikacin for inhalation, or 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 judgment 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 June 30, 2017 and December 31, 2016 were Level 1 and such assets were comprised of cash and cash equivalents of $91.1 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 and six months ended June 30, 2017 and 2016, respectively.

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As of June 30, 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 and six months ended June 30, 2017 and 2016:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands, except per share amounts)			
Numerator:				
Net loss	$ (44,672)	$ (36,579)	$ (82,086)	$ (70,111)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share:	62,209	61,878	62,126	61,868
Effect of dilutive securities:				
Common stock options				
RSUs				
Weighted average common shares outstanding used in calculation of diluted net loss per share	62,209	61,878	62,126	61,868
Net loss per share:				
Basic and Diluted	$ (0.72)	$ (0.59)	$ (1.32)	$ (1.13)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of June 30, 2017 and 2016 as their effect would have been anti-dilutive (in thousands):

	2017	2016
Stock options to purchase common stock	8,621	7,508
Unvested RSUs	47	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 and second quarters of 2017 did not have an impact on the consolidated financial statements.

The Company had $91.1 million in cash and cash equivalents as of June 30, 2017 and reported a net loss of $82.1 million for the six months ended June 30, 2017. Historically the Company has funded its operations through public offerings of equity securities and debt financings. To date, the Company has not generated material revenue from ALIS. The Company does not expect to generate material revenue unless or until marketing approval is received for ALIS. Accordingly, the Company expects to continue to incur losses while funding research and development (R&D) activities, regulatory submissions, potential commercial launch activities and general and administrative expenses. The Company expects its future cash requirements to be substantial, and the Company will need to raise additional capital to fund operations, to develop and commercialize ALIS, to develop INS1007 and INS1009 and to develop, acquire, in-license or co-promote other products that address orphan or rare diseases.

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ASU 2014-15 requires the Company to evaluate whether it has sufficient resources to fund operations for the next 12 months from the filing date without regard to whether or not it can raise capital in the future. If the Company is unable to obtain sufficient additional capital, the Company believes it currently has sufficient funds to meet its financial needs for at least the next 12 months, if it makes significant reductions in spending. The Company will seek additional capital within the next 12 months and may do so through equity or debt financing(s), strategic transactions or otherwise. The source, timing and availability of any future financing or other transaction will depend principally upon continued progress in the Company s regulatory, development and pre-commercial activities. Any equity or debt financing will also be contingent upon equity and debt market conditions and interest rates at the time. If the Company is unable to obtain sufficient additional funds when required, the Company will be forced to delay, restrict or eliminate all or a portion of its R&D programs, pre-commercialization activities, or dispose of assets or technology.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends Accounting Standards Codification (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 was 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. The impact of the adoption was not material to the 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 June 30, 2017.

4. Accrued Expenses

Accrued expenses consist of the following:

	As of June 30, 2017	As of December 31, 2016
	(in thousands)	
Accrued clinical trial expenses	$ 7,004	$ 7,071
Accrued compensation	4,464	6,937
Accrued professional fees	1,986	1,604
Accrued technical operation expenses	326	591
Accrued interest payable	424	438
Other accrued expenses	344	181
	$ 14,548	$ 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. The interest-only period was extended through November 1, 2018, and it can 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

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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 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 June 30, 2017 (in thousands):

Notes payable	$	55,000
Accretion of backend fee		513
Debt issuance costs, unamortized		(319)
Debt, long-term	$	55,194

As of June 30, 2017, future principal repayments of the debt for each of the fiscal years through maturity were as follows (in thousands):

Year Ending 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 June 30, 2017 approximates the carrying amount.

6. *Shareholders Equity*

Common Stock As of June 30, 2017, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 62,376,416 shares of common stock issued and outstanding. In addition, as of June 30, 2017, the Company had reserved 8,621,451 shares of common stock for issuance upon the exercise of outstanding common stock options and 46,914 shares of common stock for issuance upon the vesting of RSUs.

Preferred Stock As of June 30, 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 2017 Incentive Plan, was approved by shareholders at the Company s Annual Meeting of Shareholders on May 18, 2017. The 2017 Incentive Plan is administered by the Compensation Committee and the Board of Directors of the Company. Under the terms of the 2017 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), RSUs, performance options/shares and other stock awards, as well as pay incentive bonuses to eligible employees and non-employee directors. On May 18, 2017, upon the approval of the 2017 Incentive Plan by shareholders, 5,000,000 shares were authorized for issuance thereunder, plus any shares subject to then-outstanding awards under the 2015 Incentive Plan and the 2013 Incentive Plan that subsequently were cancelled, terminated unearned, expired, were forfeited, lapsed for any reason or were settled in cash without the delivery of shares. As of June 30, 2017, 4,978,554 shares remained for future issuance under the 2017 Incentive Plan. The 2017 Incentive Plan will terminate on April 3, 2027 unless it is extended or terminated earlier pursuant to its terms. In addition, from time to time, the Company makes inducement grants of stock options. These awards are made pursuant to the NASDAQ inducement grant exception as a component of new hires employment compensation in connection with the Company s equity grant program. During the six months ended June 30, 2017, the Company granted 236,370 inducement stock options to new employees.

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

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Volatility	73%	76%-77%	73%-74%	76%-77%
Risk-free interest rate	1.74%-1.88%	1.24%-1.39%	1.74%-1.99%	1.16%-1.73%
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	$11.02	$7.35	$10.20	$8.77

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 June 30, 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 six months ended June 30, 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	2,118,640	$ 15.45		
Exercised	(267,333)	$ 9.10		
Forfeited or expired	(346,562)	$ 15.53		
Options outstanding at June 30, 2017	8,621,451	$ 13.87	7.88	$ 34,487
Vested and expected to vest at June 30, 2017	8,246,653	$ 13.82	7.82	$ 33,565
Exercisable at June 30, 2017	3,699,917	$ 12.10	6.59	$ 21,982

The total intrinsic value of stock options exercised during the three months ended June 30, 2017 and 2016 was $1.6 million and $0.1 million, respectively, and during the six months ended June 30, 2017 and 2016 was $2.1 million and $0.1 million, respectively.

As of June 30, 2017, there was $34.1 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.9 years. Included in unrecognized compensation expense was $1.1 million related to outstanding performance-condition options. The following table summarizes the range of exercise prices and the number of stock options outstanding and exercisable:

Outstanding as of June 30, 2017					Exercisable as of June 30, 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	4.55	1,033,195	5.12	3.56	1,033,195	3.56
6.90	6.90	137,577	5.72	6.90	100,077	6.90
6.96	10.85	1,088,696	8.80	10.76	290,242	10.52
11.14	12.58	1,069,725	6.82	12.17	692,772	12.21
12.66	13.58	185,880	8.01	13.24	75,312	13.28
13.67	13.67	872,520	9.52	13.67		
13.94	16.07	1,164,170	7.98	15.27	500,723	15.05
16.09	17.16	1,567,243	9.18	16.69	209,392	16.18
17.24	22.76	1,441,170	7.64	21.14	770,055	21.17
22.84	27.38	61,275	7.56	23.81	28,149	23.71

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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 six months ended June 30, 2017:

	Number of RSUs	Weighted Average Grant Price ($)
Outstanding at December 31, 2016	89,194	10.85
Granted	46,914	17.16
Released	(89,194)	(10.85)
Outstanding at June 30, 2017	46,914	17.16

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 six months ended June 30, 2017 and 2016:

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	(in millions)			
Research and development expenses	$ 1.5	$ 1.5	$ 3.0	$ 2.9
General and administrative expenses	3.1	3.1	5.6	5.9
Total	$ 4.6	$ 4.6	$ 8.6	$ 8.8

8. Income Taxes

The Company s provision for income taxes was $37,000 and $67,000 for the three and six months ended June 30, 2017, respectively, and $18,000 and $46,000 for the three and six months ended June 30, 2016, respectively. The provision for income taxes in all periods was a result of certain of the Company s subsidiaries in Europe, which had taxable income during the three and six months ended June 30, 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. Loss carryforwards are subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. As of June 30, 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 12

months.

9. ***Commitments and Contingencies***

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 $2.5 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 December 2021. Future minimum rental payments under this lease are $2.1 million.

Rent expense charged to operations was $0.3 million for both the three months ended June 30, 2017 and 2016, and $0.7 million and $0.5 million for the six months ended June 30, 2017 and 2016, respectively. Future minimum rental payments required under the Company s operating leases for the period from July 1, 2017 to December 31, 2017 and for each of the five years thereafter are as follows (in thousands):

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Year Ending December 31:		
2017 (remaining)	$	753
2018		1,519
2019		1,421
2020		477
2021		498
2022		
	$	4,668

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 European Medicines Agency approving the Company s European marketing authorization application for use of ALIS in the treatment of NTM lung disease and the likelihood of commercialization of ALIS 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, the 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 of 1933 (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 opposed the motion on May 17, 2017 and the Company provided its reply brief on July 11, 2017. On July 20, 2017, the plaintiff asked for leave to file a sur-reply in further opposition to the Company s motion to dismiss the amended complaint, which the Company has opposed. 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 data readouts, 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), Japan s Pharmaceuticals and Medical Devices Agency (PMDA), 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, if 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 our ongoing clinical development, regulatory and commercialization efforts as well as 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;*

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

- *loss of key personnel; and*

- *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 amikacin liposome inhalation suspension (ALIS) (formerly known as liposomal amikacin for inhalation, or 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).

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

Product Candidate/Target Indications	Status	Next Expected Milestones
ALIS 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 ALIS in adult patients with treatment refractory NTM lung disease caused by MAC. We achieved our enrollment objective in 2016 and in July 2017, we reported that all remaining patients had progressed beyond the Month 6 visit for the CONVERT study. • The FDA has designated ALIS as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP). • The European Commission has granted an orphan designation for ALIS for the treatment of NTM lung disease.	• We expect to report top-line results for the CONVERT study in September 2017 plus or minus one month. • If the CONVERT study meets its primary endpoint, we intend to seek accelerated marketing approval for ALIS in the US. We intend to seek marketing approvals for ALIS in certain countries outside the US, when sufficient data are available. If approved, we expect ALIS would be the first inhaled antibiotic specifically indicated for the treatment of refractory NTM lung infections caused by MAC in North America, Japan and Europe. • If approved, we plan to commercialize ALIS in the US, Japan, certain countries in Europe, and certain other countries.
INS1007 (oral reversible inhibitor of DPP1) 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. • We are in preparations for the WILLOW study, a global phase 2, randomized, double-blind, placebo-controlled, parallel-group, multi-center clinical study to assess the efficacy, safety and tolerability, and	• Pending the IND becoming effective, we expect to commence enrollment in the WILLOW clinical study of INS1007. We currently expect enrollment to commence in the second half of 2017.

	pharmacokinetics of INS1007 administered once daily for 24 weeks in subjects with non-CF bronchiectasis.	
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.

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Our Strategy

Our strategy focuses on the needs of patients with rare diseases. We are currently primarily focused on the development and commercialization of ALIS. We are not aware of any inhaled products specifically indicated to treat refractory NTM lung disease in North America, Japan or Europe. While we believe that ALIS has the potential to treat a number of different bacterial infections, we are prioritizing securing US regulatory approval of ALIS 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;

- Subject to the results of the CONVERT study, preparing a New Drug Application (NDA) for submission to the FDA for ALIS based on the primary endpoint of that study;

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

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

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

- Supporting further research and lifecycle management strategies for ALIS, including exploring the potential use of ALIS as part of a front-line, multi-drug regimen and as maintenance monotherapy to prevent recurrence (defined as true relapse or reinfection) of NTM lung disease;

- Starting enrollment of the WILLOW phase 2 study of INS1007 in non-CF bronchiectasis pending the IND becoming effective;

- Generating preclinical findings from our earlier-stage program(s); and

- Expanding our rare disease pipeline through corporate development.

Product Pipeline

ALIS for patients with NTM lung disease

Our lead product candidate is ALIS, 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. ALIS s ability to deliver high levels of amikacin directly to the lung distinguishes it from intravenous amikacin. ALIS is administered once-daily, using a portable aerosol delivery system, via an optimized, investigational eFlow® Nebulizer System manufactured by PARI.

The FDA has designated ALIS as an orphan drug, a breakthrough therapy, and a QIDP for NTM lung disease. Orphan designation features seven years of post-approval marketing exclusivity in the approved indication, and QIDP features an additional five years of post-approval exclusivity in the approved indication. As a result, ALIS 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 and 312 study

ALIS 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 ALIS 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

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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 or who have a history of lung transplantation. We achieved our enrollment objective for the CONVERT study in 2016 and, in July 2017, we reported that all remaining patients had progressed beyond the Month 6 visit.

After a screening period of approximately 10 weeks, eligible patients were randomized 2:1 to once-daily ALIS plus a multi-drug regimen or a multi-drug regimen without ALIS. 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 ALIS plus multi-drug regimen arm to the proportion of patients who achieve culture conversion in the arm in which patients receive a multi-drug regimen without ALIS. 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 CONVERT study in September 2017 plus or minus one month. Subsequent analyses will examine off-treatment assessments to evaluate the durability of the anti-mycobacterial effect on sputum culture by assessing the durability of culture conversion at 3 months and 12 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 12 months following the first negative sputum culture that defined 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, 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 ALIS 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).

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 PMDA. 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 product candidate based on a surrogate or intermediate endpoint, provided (i) we commit to study the product candidate further to verify and describe the confirmatory data of its clinical benefit and (ii) the FDA concurs with other aspects of the NDA. 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. We expect that full approval would be contingent on FDA review of, among other things, the final analyses of sustainability and durability of culture conversion for converters.

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 ALIS 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 ALIS 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 ALIS plus the same multi-drug regimen. The study also included 28-day and 12-month off-ALIS 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 ALIS 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. ALIS did not meet the pre-specified level for statistical significance although there was a positive trend (p=0.072) in favor of ALIS. The p-value for the key secondary endpoint of culture conversion to negative at Day 84 was 0.003, in favor of ALIS. A shorter time to first negative sputum culture was also observed with ALIS 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

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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 ALIS (10 during the double-blind phase and seven after entering the open-label phase, of which six received ALIS 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 ALIS 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 ALIS 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 ALIS in the open-label phase demonstrated a reduced rate of decline from baseline.

Approximately 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 ALIS experienced, among others, 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.

Further research and lifecycle management for ALIS

We are currently exploring and supporting research and lifecycle management programs for ALIS beyond refractory NTM lung infections caused by MAC. Specifically, we are evaluating future study strategies focusing on the MAC disease treatment pathway, including front-line treatment and monotherapy maintenance to prevent recurrence (defined as true relapse or reinfection) of NTM lung disease. If the data from the CONVERT study is sufficient to support our marketing authorization applications and regulatory bodies approve ALIS for the treatment of refractory NTM lung disease caused by MAC, such lifecycle management studies could enable us to reach more potential patients. These initiatives may include new clinical studies sponsored by us or investigator-initiated studies, which are clinical studies initiated and sponsored by physicians or research institutions with funding from us.

Japan NTM lung disease market opportunity

We are currently exploring the NTM market opportunity for ALIS in Japan. If the data from the CONVERT study is sufficient to support our marketing authorization applications, and the FDA approves ALIS for the treatment of refractory NTM lung disease caused by MAC, we expect our second regulatory filing after the US to be in Japan. We plan to establish a presence in Japan in 2018 assuming positive data from the CONVERT study, including hiring local employees to closely manage our regulatory and pre-commercial footprint.

Under the Japanese regulatory system administered by the PMDA, pre-marketing approval and clinical studies are required for all pharmaceutical products. To obtain manufacturing/marketing approval, a Company must submit an application for approval to the Ministry of Health, Labour and Welfare (MHLW) with results of nonclinical and clinical studies to show the quality, efficacy and safety of a new product candidate. A data compliance review, on-site inspection for good clinical practice, audit and detailed data review for compliance with current

good manufacturing practices are undertaken by the PMDA. The application is then discussed by the committees of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC). Based on the results of these reviews, the final decision on approval is made by MHLW. In Japan, the National Health Insurance system maintains a Drug Price List specifying which pharmaceutical products are eligible for reimbursement, and the MHLW sets the prices of the products on this list. After receipt of marketing approval, negotiations regarding the reimbursement price with MHLW would begin. Price would be determined within 60 to 90 days unless the applicant disagrees, which may result in extended pricing negotiations. The government generally introduces price cut rounds every other year and also mandates price decreases for specific products. New products judged innovative or useful, that are indicated for pediatric use, or that target orphan or small population diseases, however, may be eligible for a pricing premium. The government has also promoted the use of generics, where available.

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 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 release active neutrophil serine proteases in excess 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.

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Non-CF bronchiectasis is a rare, progressive pulmonary disorder in which the bronchi become permanently dilated due to chronic inflammation and infection. Currently, there is no cure, and we are not aware of any approved therapies for non-CF bronchiectasis.

The WILLOW study

We are in preparations for the WILLOW study, a global phase 2, randomized, double-blind, placebo-controlled, parallel group, multi-center clinical study to assess the efficacy, safety and tolerability, and pharmacokinetics of, INS1007 administered once daily for 24 weeks in subjects with non-CF bronchiectasis. Pending the IND becoming effective, we expect to commence enrollment in the study in the second half of 2017. In addition, we are evaluating the potential of INS1007 in other indications.

Phase 1 study results

In a phase 1 study of healthy volunteers conducted by AstraZeneca, 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.

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.

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KEY COMPONENTS OF OUR STATEMENT OF OPERATIONS

Research and Development (R&D) Expenses

R&D expenses consist 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(s) 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(s) for clinical study are primarily related to activities at contract manufacturing organizations (CMOs) that manufacture our product candidates for our use, including purchases of active pharmaceutical ingredients. Our expenses related to clinical trials are primarily related to activities at contract research organizations that conduct and manage clinical trials on our behalf.

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 including for pre-commercial planning activities such as non-branded disease awareness, 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 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 June 30, 2017 and 2016

Net Loss

Net loss for the quarter ended June 30, 2017 was $44.7 million, or ($0.72) per common share basic and diluted, compared with a net loss of $36.6 million, or ($0.59) per common share basic and diluted, for the quarter ended June 30, 2016. The $8.1 million increase in our net loss for the quarter ended June 30, 2017 as compared to the same period in 2016 was due to:

- Increased R&D expenses of $3.0 million primarily resulting from an increase in expenses related to INS1007 and higher compensation and related expenses due to an increase in headcount as compared to the prior year period. These increases were partially offset by decreases in ALIS manufacturing-related expenses at our CMOs as compared to the prior year period; and

- Increased general and administrative expenses of $4.4 million resulting from an increase in consulting fees relating to pre-commercial planning activities and higher compensation and related expenses due to an increase in headcount as compared to the prior year period.

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 June 30, 2017 and 2016 were comprised of the following (in thousands):

	Quarters Ended June 30,		Increase (decrease)	
	2017	2016	$	%
External Expenses				
Clinical development & research	$ 9,832	$ 8,432	$ 1,400	16.6%
Manufacturing	4,862	5,812	(950)	-16.3%
Regulatory and quality assurance	928	731	197	26.9%
Subtotal external expenses	$ 15,622	$ 14,975	$ 647	4.3%
Internal Expenses				

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	Quarters Ended June 30,		Increase (decrease)	
	2017	2016	$	%
Compensation and related expenses	$ 8,047	$ 6,825	$ 1,222	17.9%
Other internal operating expenses	3,202	2,071	1,131	54.6%
Subtotal internal expenses	$ 11,249	$ 8,896	$ 2,353	26.5%
Total	$ 26,871	$ 23,871	$ 3,000	12.6%

R&D expenses increased to $26.9 million during the quarter ended June 30, 2017 from $23.9 million in the same period in 2016. The $3.0 million increase was primarily due to an increase of $1.4 million in external clinical development expenses, specifically $2.4 million of start-up phase 2 clinical trial expenses related to INS1007, partially offset by a decrease in research expenses and ALIS clinical trial expenses. In addition, compensation and related expenses increased by $1.2 million due to an increase in headcount. These increases were partially offset by a $1.0 million decrease in manufacturing expenses. The $1.0 million decrease in manufacturing expenses included a $2.2 million decrease in ALIS manufacturing-related expenses at our CMOs as compared to the prior year period, partially offset by purchases of $1.2 million of clinical materials related to INS1007 in the second quarter of 2017. In addition, medical grants and sponsorships increased by $1.1 million in the quarter ended June 30, 2017 as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses for the quarter ended June 30, 2017 and 2016 were comprised of the following (in thousands):

	Quarters Ended June 30,		Increase (decrease)	
	2017	2016	$	%
General & administrative	$ 9,355	$ 8,667	$ 688	7.9%
Pre-commercial expenses	7,289	3,595	3,694	102.8%
Total general & administrative expenses	$ 16,644	$ 12,262	$ 4,382	35.7%

General and administrative expenses increased to $16.6 million during the quarter ended June 30, 2017 from $12.3 million in the same period in 2016. The $4.4 million increase was primarily due to an increase of $3.1 million in consulting fees relating to pre-commercial planning activities, including non-branded disease awareness, and other professional fees and an increase of $1.2 million due to higher compensation costs related to an increase in headcount.

Interest Expense

Interest expense was $1.5 million for the quarter ended June 30, 2017 as compared to $0.6 million in the same period in 2016. The $0.9 million increase in interest expense in the quarter ended June 30, 2017 as compared to the prior year quarter relates to an increase in borrowings from Hercules Capital, Inc. (Hercules) during the second half of 2016. We entered into an Amended and Restated Loan Agreement (A&R Loan Agreement) with Hercules in September 2016 which increased our borrowing capacity by an additional $30.0 million to an aggregate total of $55.0 million, and we used this increased borrowing capacity to fund the upfront payment to AstraZeneca for the exclusive global rights to INS1007 in October 2016.

Comparison of the Six Months Ended June 30, 2017 and 2016

Net Loss

Net loss for the six months ended June 30, 2017 was $82.1 million, or ($1.32) per common share basic and diluted, compared with a net loss of $70.1 million, or ($1.13) per common share basic and diluted, for the six months ended June 30, 2016. The $12.0 million increase in our net loss for the six months ended June 30, 2017 as compared to the same period in 2016 was primarily due to:

- Increased R&D expenses of $4.7 million primarily resulting from an increase in expenses related to INS1007 and higher compensation and related expenses due to an increase in headcount as compared to the prior year period. These increases were partially offset by decreases in ALIS manufacturing expenses at our CMOs as compared to the prior year period; and

- Increased general and administrative expenses of $5.6 million primarily resulting from an increase in pre-commercial planning activities and higher compensation and related expenses due to an increase in headcount as compared to the prior year period.

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In addition, there was a $1.7 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 six months ended June 30, 2017 and 2016 were comprised of the following (in thousands):

	Six Months Ended June 30,		Increase (decrease)	
	2017	2016	$	%
External Expenses				
Clinical development & research	$ 18,307	$ 16,638	$ 1,669	10.0%
Manufacturing	7,606	9,276	(1,670)	-18.0%
Regulatory and quality assurance	1,896	965	931	96.5%
Subtotal external expenses	$ 27,809	$ 26,879	$ 930	3.5%
Internal Expenses				
Compensation and related expenses	$ 15,698	$ 13,377	$ 2,321	17.4%
Other internal operating expenses	5,618	4,162	1,456	35.0%
Subtotal internal expenses	$ 21,316	$ 17,539	$ 3,777	21.5%
Total	$ 49,125	$ 44,418	$ 4,707	10.6%

R&D expenses increased to $49.1 million during the six months ended June 30, 2017 from $44.4 million in the same period in 2016. The $4.7 million increase was due to a $1.7 million increase in external clinical development expenses, specifically $3.0 million of start-up phase 2 clinical trial expenses related to INS1007, which was partially offset by a decrease in research expenses. In addition, compensation and related expenses increased by $2.3 million due to an increase in headcount. These increases were partially offset by a $1.7 million decrease in manufacturing expenses. The $1.7 million decrease in manufacturing expenses included a $2.9 million decrease in ALIS manufacturing-related expenses at our CMOs as compared to the prior year period, partially offset by purchases of $1.2 million of clinical materials related to INS1007 in the second quarter of 2017. In addition, medical grants and sponsorships increased by $1.5 million in the six months ended June 30, 2017 as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2017 and 2016 were comprised of the following (in thousands):

	Six Months Ended June 30,		Increase (decrease)	
	2017	2016	$	%
General & administrative	$ 18,009	$ 17,692	$ 317	1.8%

Pre-commercial expenses	12,350	7,090	5,260	74.2%
Total general & administrative expenses	$ 30,359	$ 24,782	$ 5,577	22.5%

General and administrative expenses increased to $30.4 million during the six months ended June 30, 2017 from $24.8 million in the same period in 2016. The $5.6 million increase was primarily due to an increase of $3.9 million in consulting fees relating to pre-commercial planning activities, including non-branded disease awareness, and other professional fees and an increase of $1.7 million due to higher compensation expenses related to an increase in headcount.

Interest Expense

Interest expense was $3.0 million during the six months ended June 30, 2017 as compared to $1.2 million in the same period in 2016. This increase in interest expense relates primarily to the increase in our borrowings from Hercules in the second half of 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. We had $91.1 million in cash and cash equivalents as of June 30, 2017 and reported a net loss of $82.1 million for the six months ended June 30, 2017. Historically we have funded our operations through public offerings of equity securities and debt financings. To date, we have not generated material revenue from ALIS. We do not expect to generate revenue unless or until marketing approval is received for ALIS. Accordingly, we expect to continue to incur losses while funding R&D activities, regulatory submissions, potential commercial launch activities and general and administrative expenses. We expect our future cash requirements to be substantial, and we will need to raise additional capital to fund operations, to develop and

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commercialize ALIS, to develop INS1007 and INS1009 and to develop, acquire, in-license or co-promote other products that address orphan or rare diseases.

If we are unable to obtain sufficient additional capital, we believe we currently have sufficient funds to meet our financial needs for at least the next 12 months, if we make significant reductions in spending. We will seek additional capital within the next 12 months and may do so through equity or debt financing(s), strategic transactions or otherwise. The source, timing and availability of any future financing or other transaction will depend principally upon continued progress in our regulatory, development and pre-commercial activities. Any equity or debt financing(s) will also be contingent upon equity and debt market conditions and interest rates at the time. 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 will be forced to delay, restrict or eliminate all or a portion of our R&D programs, pre-commercialization activities, or dispose of assets or technology. The source, timing and availability of any future financing or other transaction will depend on and will likely be affected by a number of factors, including:

- the results of the CONVERT study and timing of the readout of the CONVERT study results;

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

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

- the costs associated with commercializing ALIS, if we receive marketing approvals; including the costs of establishing the sales and marketing capabilities to be prepared for potential commercial launches of ALIS, 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; 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.

Cash Flows

As of June 30, 2017, we had total cash and cash equivalents of $91.1 million, as compared with $162.6 million as of December 31, 2016. The $71.5 million decrease was due primarily to the use of cash in operating activities. Our working capital was $70.3 million as of June 30, 2017 as compared with $140.4 million as of December 31, 2016.

Net cash used in operating activities was $73.2 million and $57.8 million for the six months ended June 30, 2017 and 2016, respectively. The net cash used in operating activities during the six months ended June 30, 2017 and 2016, respectively, was primarily for the clinical, manufacturing and pre-commercial activities related to ALIS, as well as general and administrative expenses. In addition, the six months ended June 30, 2017 includes start-up clinical trial expenses related to INS1007.

Net cash used in investing activities was $0.9 million and $2.1 million for the six months ended June 30, 2017 and 2016, respectively. The net cash used in investing activities was primarily related to payments for the build out of our headquarters and lab facilities in Bridgewater, New Jersey.

Net cash provided by financing activities was $2.4 million and $0.1 million for the six months ended June 30, 2017 and 2016, respectively. Net cash provided by financing activities was cash proceeds received from stock option exercises.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations during the quarter or six months ended June 30, 2017 from those disclosed in Item 7, Management s Discussion and Analysis of Financial Condition and

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Results of Operations-Liquidity and Capital Resources - Contractual Obligations in our Annual Report on Form 10-K for the year ended December 31, 2016.

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

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, 2016. 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 June 30, 2017, 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 June 30, 2017, we had $55.0 million of borrowings outstanding that currently bear interest at 9.25% under the A&R Loan Agreement with Hercules. If a 10% change in interest rates had occurred on June 30, 2017, 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 six months ended June 30, 2017 and 2016, 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 June 30, 2017. 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 June 30, 2017, 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 June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 9 to our Consolidated Financial Statements Commitments and Contingencies Legal Proceedings in this Quarterly Report on Form 10-Q for a description of our material legal proceedings. From time to time, we are also party to various lawsuits, claims and other legal proceedings that arise in the ordinary course of our 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 our consolidated financial position, results of operations or cash flows.

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ITEM 1A. RISK FACTORS

There have been no material changes during the quarter ended June 30, 2017 to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 June 30, 2017.

ITEM 6. EXHIBITS

A list of exhibits to this Quarterly Report on Form 10-Q is included in the Exhibit Index, which 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: August 3, 2017

By /s/ Paolo Tombesi
Paolo Tombesi
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

3.1	Articles of Incorporation of Insmed Incorporated, as amended through June 14, 2012 (incorporated by reference from Exhibit 3.1 to Insmed Incorporated s Annual Report on Form 10-K filed on March 18, 2013).
3.2	Amended and Restated Bylaws of Insmed Incorporated (incorporated by reference from Exhibit 3.1 to Insmed Incorporated s Quarterly Report on Form 10-Q filed on August 6, 2015).
10.1	Employment Agreement, effective as of June 1, 2017, between Insmed Incorporated and Paolo Tombesi.
10.2	Employment Agreement, effective as of June 5, 2017, between Insmed Incorporated and Paul D. Streck.
10.3	Insmed Incorporated 2017 Incentive Plan.
10.4	Form of Restricted Unit Award Agreement under the Insmed Incorporated 2017 Incentive Plan.
10.5	Form of Non-Qualified Stock Option Agreement under the Insmed Incorporated 2017 Incentive Plan.
10.6	Form of Non-Qualified Stock Option Inducement Award Agreement.
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 Paolo Tombesi, Chief Financial Officer (Principal Financial and Accounting 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 Paolo Tombesi (Principal Financial and Accounting 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 June 30, 2017 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016, (ii) Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2017 and 2016, (iii) Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016, and (iv) Notes to the Unaudited Consolidated Financial Statements.