INSMED Inc
Form 10-Q
August 02, 2018

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, 2018
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)
Not Applicable
(Former name, former address and former fiscal year, if changed since last report)
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

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
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x
As of July 31, 2018, there were 77,040,858 shares of the registrant's common stock, $0.01 par value, outstanding.

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FOR THE QUARTER ENDED JUNE 30, 2018

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Unless the context otherwise indicates, references in this Form 10-Q to "Insmed Incorporated" refers to Insmed Incorporated, a Virginia corporation, and "Company," "Insmed," "we," "us" and "our" refer to Insmed Incorporated together with its consolidated subsidiaries. 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, 2018 (unaudited)	As of December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$634,329	$381,165
Prepaid expenses and other current assets	10,929	8,279
Total current assets	645,258	389,444
In-process research and development	58,200	58,200
Fixed assets, net	17,881	12,432
Other assets	2,905	1,971
Total assets	$724,244	$462,047
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$15,966	$14,671
Accrued expenses	29,046	29,339
Other current liabilities	630	646
Total current liabilities	45,642	44,656
Long-term debt, net	307,156	55,567
Other long-term liabilities	805	765
Total liabilities	353,603	100,988
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 77,038,788 and 76,610,508 issued and outstanding shares at June 30, 2018 and December 31, 2017, respectively	770	766
Additional paid-in capital	1,472,699	1,318,181
Accumulated deficit	(1,102,846)	(957,885)
Accumulated other comprehensive income (loss)	18	(3)
Total shareholders' equity	370,641	361,059
Total liabilities and shareholders' equity	$724,244	$462,047

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,	
	2018	2017	2018	2017
Revenues	$—	$—	$—	$—
Operating expenses:				
Research and development	35,722	26,871	65,820	49,125
General and administrative	37,160	16,644	69,813	30,359
Total operating expenses	72,882	43,515	135,633	79,484
Operating loss	(72,882)	(43,515)	(135,633)	(79,484)
Investment income	2,729	169	4,769	323
Interest expense	(6,488)	(1,489)	(12,130)	(2,963)
Loss on extinguishment of debt	—	—	(2,209)	—
Other income, net	244	200	330	105
Loss before income taxes	(76,397)	(44,635)	(144,873)	(82,019)
Provision for income taxes	40	37	88	67
Net loss	$(76,437)	$(44,672)	$(144,961)	$(82,086)
Basic and diluted net loss per share	$(1.00)	$(0.72)	$(1.89)	$(1.32)
Weighted average basic and diluted common shares outstanding	76,767	62,209	76,693	62,126
Net loss	$(76,437)	$(44,672)	$(144,961)	$(82,086)
Other comprehensive (loss) income:				
Foreign currency translation (losses) gains	(21)	5	21	23
Total comprehensive loss	$(76,458)	$(44,667)	$(144,940)	$(82,063)

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,	
	2018	2017
Operating activities		
Net loss	$(144,961)	$(82,086)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,698	1,454
Stock-based compensation expense	12,303	8,591
Amortization of debt issuance costs	585	61
Accretion of debt discount	7,252	—
Accretion of back-end fee on debt	50	342
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(3,653)	128
Accounts payable	1,981	767
Accrued expenses and other	1,794	(2,415)
Net cash used in operating activities	(122,951)	(73,158)
Investing activities		
Purchase of fixed assets	(8,212)	(854)
Net cash used in investing activities	(8,212)	(854)
Financing activities		
Proceeds from exercise of stock options	5,785	2,434
Loss on extinguishment of debt	(2,209)	—
Payment of debt	(55,000)	—
Proceeds from issuance of 1.75% convertible senior notes due 2025	450,000	—
Payment of debt issuance costs	(14,235)	—
Net cash provided by financing activities	384,341	2,434
Effect of exchange rates on cash and cash equivalents	(14)	51
Net increase (decrease) in cash and cash equivalents	253,164	(71,527)
Cash and cash equivalents at beginning of period	381,165	162,591
Cash and cash equivalents at end of period	$634,329	$91,064
Supplemental disclosures of cash flow information:		
Cash paid for interest	$1,276	$2,574
Cash paid for income taxes	$93	$41

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 amikacin liposome inhalation suspension (ALIS), 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 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), the Netherlands, and Japan. 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 unaudited interim consolidated financial 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, 2017.

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

The Company had $634.3 million in cash and cash equivalents as of June 30, 2018 and reported a net loss of $145.0 million for the six months ended June 30, 2018. 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 may 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.

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 may 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.

2. Summary of Significant Accounting Policies

The following are the required interim disclosure updates to the Company's significant accounting policies described in Note 2 of the notes to the consolidated financial statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017:

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:

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

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

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

Each major category of financial assets and liabilities measured at fair value on a recurring basis is 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 financial assets and liabilities which were measured at fair value as of June 30, 2018 and December 31, 2017 were Level 1 assets comprised of cash and cash equivalents of $634.3 million and $381.2 million, respectively. The estimated fair value of the liability component of the 1.75% convertible senior notes due 2025 (the Convertible Notes) (categorized as a Level 2 liability for fair value measurement purposes) was 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 following table shows certain assets and liabilities and their carrying values and fair values:

	As of June 30, 2018	
	Carrying Value	Fair Value
	(in millions)	
Level 1		
Cash and cash equivalents	$634.3	$634.3
Level 2		
Convertible Notes ($450.0 face value)	$307.2*	$411.1

* The carrying value of the Convertible Notes excludes $133.6 million of the unamortized portion of the debt discount.

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 an original maturity of three months or less from the date of purchase. As of June 30, 2018, the Company's cash and cash equivalents balance included US treasury bills of $399.9 million.

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 six months ended June 30, 2018 and 2017, respectively.

As of June 30, 2018 and December 31, 2017, 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 Share - Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares and other dilutive securities outstanding during the period. Potentially dilutive securities from stock options, restricted stock units (RSUs) and convertible debt securities would be anti-dilutive 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.

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The following table sets forth the reconciliation of the weighted average number of common shares used to compute basic and diluted net loss per share for the three and six months ended June 30, 2018 and 2017:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share amounts)			
Numerator:				
Net loss	$(76,437)	$(44,672)	$(144,961)	$(82,086)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share:	76,767	62,209	76,693	62,126
Effect of dilutive securities:				
Common stock options	—	—	—	—
RSUs	—	—	—	—
Convertible debt securities	—	—	—	—
Weighted average common shares outstanding used in calculation of diluted net loss per share	76,767	62,209	76,693	62,126
Net loss per share:				
Basic and Diluted	$(1.00)	$(0.72)	$(1.89)	$(1.32)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average common shares outstanding as of June 30, 2018 and 2017 as their effect would have been anti-dilutive (in thousands):

	As of June 30,	
	2018	2017
Stock options to purchase common stock	9,578	8,621
Unvested RSUs	236	47
Convertible debt securities	11,492	—

Recently Adopted Accounting Pronouncements - In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which addressed eight specific cash flow issues with the objective of reducing the existing diversity in practice. Among the updates, the standard requires debt extinguishment costs to be classified as cash outflows for financing activities. This standard update is effective as of the first quarter of 2018. As a result of the adoption of the standard, in the first quarter of 2018, the Company reported a $2.2 million loss on extinguishment of debt in the financing activities section of its consolidated statement of cash flows. The Company had no material debt extinguishment costs prior to the first quarter of 2018. There were no other significant impacts as a result of adopting this standard.

In May 2014, the FASB issued ASU 2014-9, Revenue from Contracts with Customers (Topic 606) which amended the existing accounting standards for revenue recognition. ASU 2014-9 establishes principles for recognizing revenue upon the transfer of promised goods or services to customers, in an amount that reflects the expected consideration received in exchange for those goods or services. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2014-9 in the first quarter of 2018 and the impact of adoption is not material to its consolidated financial statements.

New Accounting Pronouncements (Not Yet Adopted)—In February 2016, the FASB issued ASU 2016-2, Leases (Topic 842) in order to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous generally accepted accounting principles. ASU 2016-2 requires a lessee to recognize a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term on the balance sheet. ASU 2016-2 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) and early adoption is permitted. The standard requires a modified retroactive approach, but use of certain practical expedients is permitted. The Company expects to use the package of practical expedients that allows it to not reassess: (1) whether any expired or existing contracts are or

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contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any expired or existing leases. The Company additionally expects to use the practical expedient that allows it to treat the lease and non-lease components of its leases as a single component. The Company expects to adopt ASU 2016-2 in the first quarter of 2019 and is in the process of evaluating the impact of adoption on its consolidated financial statements.

3. Identifiable Intangible Asset

The Company believes there are no indicators of impairment relating to its in-process research and development intangible asset as of June 30, 2018. The Company will begin to amortize the intangible asset upon US Food and Drug Administration (FDA) approval of ALIS, if received, and include the expense in the Company's consolidated statement of comprehensive loss.

4. Accrued Expenses

Accrued expenses consist of the following:

	As of June 30, 2018	As of December 31, 2017
	(in thousands)	
Accrued clinical trial expenses	$5,772	$ 7,837
Accrued compensation	7,371	12,197
Accrued professional fees	6,743	4,500
Accrued technical operation expenses	3,324	2,182
Accrued interest payable	3,391	423
Accrued construction costs	1,336	1,719
Other accrued expenses	1,109	481
	$29,046	$ 29,339

5. Debt

In January 2018, the Company completed an underwritten public offering of the Convertible Notes, in which the Company sold $450.0 million aggregate principal amount of Convertible Notes, including the exercise in full of the underwriters' option to purchase additional Convertible Notes of $50.0 million. The Company's net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses of $14.2 million, were approximately $435.8 million. The Convertible Notes bear interest payable semiannually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The Convertible Notes mature on January 15, 2025, unless earlier converted, redeemed, or repurchased.

On or after October 15, 2024, until the close of business on the second scheduled trading day immediately preceding January 15, 2025, holders may convert their Convertible Notes at any time. Upon conversion, holders may receive cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's option. The initial conversion rate is 25.5384 shares of common stock per $1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately $39.16 per share of common stock). The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest.

Holders may convert their Convertible Notes prior to October 15, 2024, only under the following circumstances, subject to the conditions set forth in an indenture, dated as of January 26, 2018, between the Company and Wells Fargo Bank, National Association (Wells Fargo), as trustee, as supplemented by the first supplemental indenture, dated January 26, 2018, between the Company and Wells Fargo (as supplemented, the Indenture): (i) during the five business day period immediately after any five consecutive trading day period (the measurement period) in which the trading price per $1,000 principal amount of convertible notes, as determined following a request by a holder of the convertible notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the common stock and the conversion rate on such trading day, (ii) the Company elects to distribute to all or substantially all holders of the common stock (a) any rights, options or warrants (other than in connection with a stockholder rights plan for so long as the rights issued under such plan have not detached from the associated shares of common stock) entitling them, for a period of not more than 45 days from

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the declaration date for such distribution, to subscribe for or purchase shares of common stock at a price per share that is less than the average of the last reported sale prices of the common stock for the 10 consecutive trading day period ending on, and including, the trading day immediately preceding the declaration date for such distribution, or (b) the Company's assets, debt securities or rights to purchase securities of the Company, which distribution has a per share value, as reasonably determined by the board of directors, exceeding 10% of the last reported sale price of the common stock on the trading day immediately preceding the declaration date for such distribution, (iii) if a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs, or if the Company is a party to (a) a consolidation, merger, combination, statutory or binding share exchange or similar transaction, pursuant to which the common stock would be converted into, or exchanged for, cash, securities or other property or assets, or (b) any sale, conveyance, lease or other transfer or similar transaction in one transaction or a series of transactions of all or substantially all of the consolidated assets of the Company and its subsidiaries, taken as a whole, all or any portion of the Convertible Notes may be surrendered by a holder for conversion at any time from or after the date that is 30 scheduled trading days prior to the anticipated effective date of the transaction, (iv) if during any calendar quarter commencing after the calendar quarter ending on March 31, 2018 (and only during such calendar quarter), the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day, or, (v) if the Company sends a notice of redemption, a holder may surrender all or any portion of its Convertible Notes, to which the notice of redemption relates, for conversion at any time on or after the date the applicable notice of redemption was sent until the close of business on (a) the second business day immediately preceding the related redemption date or (b) if the Company fails to pay the redemption price on the redemption date as specified in such notice of redemption, such later date on which the redemption price is paid.

The Convertible Notes can be settled in cash, common stock, or a combination of cash and common stock at the Company's option, and thus, the Company determined the embedded conversion options in the convertible notes are not required to be separately accounted for as a derivative. However, since the Convertible Notes are within the scope of the accounting guidance for cash convertible instruments, the Company is required to separate the Convertible Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated equity component. The fair value was based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments. The carrying amount of the equity component representing the embedded conversion option was determined by deducting the fair value of the liability component from the gross proceeds of the Convertible Notes. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of a similar liability that does not have an associated equity component using the effective interest method. The equity component is not remeasured as long as it continues to meet the conditions for equity classification in the accounting guidance for contracts in an entity's own equity. The fair value of the liability component of the Convertible Notes on the date of issuance was estimated at $309.1 million using an effective interest rate of 7.6%, and accordingly, the residual equity component on the date of issuance was $140.9 million. The discount is being amortized to interest expense over the term of the Convertible Notes and has a remaining period of approximately 6.5 years.

For the three and six months ended June 30, 2018, total interest expense related to the Convertible Notes was $6.5 million and $11.2 million, respectively, which includes the contractual interest coupon payable semi-annually in cash, the amortization of the issuance costs, and accretion of debt discount, as described in the table below. The following table presents the components of the Company's debt balance as of June 30, 2018 (in thousands):

1.75% convertible senior notes due 2025	$450,000
Debt issuance costs, unamortized	(9,206)
Discount on debt	(133,638)

Long-term debt, net	$307,156

As of June 30, 2018, future principal repayments of the debt for each of the fiscal years through maturity were as follows (in thousands):

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Year Ending December 31:	
2018	$—
2019	—
2020	—
2021	—
2022	—
2023 and thereafter	450,000
	$450,000

In February 2018, the Company used part of the net proceeds from the issuance of the Convertible Notes to pay off its outstanding debt to Hercules Capital (Hercules). The payments to Hercules consisted of $55.0 million for the principal amount and an additional $3.2 million in back-end fees, outstanding interest, and prepayment penalty fees, which resulted in a $2.2 million loss on extinguishment of debt in the quarter ended March 31, 2018.

Interest Expense

The following table sets forth the total interest expense recognized in the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Contractual interest expense	$1,971	$1,288	$4,243	$2,560
Amortization of debt issuance costs	286	30	585	61
Accretion of back-end fee on debt	—	171	50	342
Accretion of debt discount	4,231	—	7,252	—
Total interest expense	$6,488	$1,489	$12,130	$2,963

6. Shareholders' Equity

Common Stock — As of June 30, 2018, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 per share and 77,038,788 shares of common stock issued and outstanding. In addition, as of June 30, 2018, the Company had reserved 9,577,825 shares of common stock for issuance upon the exercise of outstanding stock options and 235,815 shares of common stock for issuance upon the vesting of RSUs. The Company has also reserved 11,492,280 shares of common stock for issuance upon conversion of the Convertible Notes, subject to adjustment in accordance with the Indenture.

In January 2018, the Company completed an underwritten public offering of $450.0 million aggregate principal amount of Convertible Notes, including the exercise in full of the underwriter's option to purchase additional Convertible Notes. The fair value of the liability component of the Convertible Notes on the date of issuance was estimated at $309.1 million, and accordingly, the equity component (included in additional paid-in capital) on the date of issuance was calculated as $140.9 million using the residual method, as further described in Note 5 Debt.

In September 2017, the Company completed an underwritten public offering of 14,123,150 shares of the Company's common stock, which included the underwriter's exercise in full of its over-allotment option of 1,842,150 shares, at a price to the public of $28.50 per share. The Company's net proceeds from the sale of the shares, after deducting the underwriter's discount and offering expenses of $24.8 million, were $377.7 million.

Preferred Stock — As of June 30, 2018, the Company had 200,000,000 shares of preferred stock authorized with a par value of $0.01 per share and no shares of preferred stock were issued and outstanding.

The following table summarizes the changes in total shareholders' equity for the six months ended June 30, 2018 (in thousands):

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Balance at December 31, 2017	$361,059
Net loss for the period	(144,961)
Proceeds from exercise of stock options	5,785
Equity component of Convertible Notes	136,434
Stock-based compensation expense	12,303
Change in cumulative translation adjustment	21
Balance at June 30, 2018	$370,641

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 canceled, terminated unearned, expired, were forfeited, lapsed for any reason or were settled in cash without the delivery of shares. As of June 30, 2018, 3,501,366 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 to new hires, which awards are made pursuant to the NASDAQ inducement grant exception. During the six months ended June 30, 2018, the Company granted inducement stock options covering 236,730 shares of the Company's common stock 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 during the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Volatility	67%-68%	73%	67%-68%	73%-74%
Risk-free interest rate	2.55%-2.82%	1.74%-1.88%	2.25%-2.82%	1.74%-1.99%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term (in years)	5.19	6.25	5.08	6.25
Weighted average fair value of stock options granted	$15.18	$11.02	$16.93	$10.20

For each period presented, the volatility factor was based on the Company's historical volatility during the expected option term. Estimated forfeitures are based on the actual percentage of option forfeitures since the closing of the Company's merger with Transave, Inc. in December 2010. The expected option term for these grants was determined using the Company's historical exercise behavior.

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, 2018, the Company had performance-condition 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, 2018:

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	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2017	8,608,921	$ 14.08		
Granted	1,430,200	$ 29.22		
Exercised	(381,366)	$ 15.17		
Forfeited or expired	(79,930)	$ 17.30		
Options outstanding at June 30, 2018	9,577,825	$ 16.27	7.27	$ 79,204
Vested and expected to vest at June 30, 2018	8,598,142	$ 15.75	7.10	$ 74,151
Exercisable at June 30, 2018	4,905,928	$ 13.16	6.15	$ 51,474

The total intrinsic value of stock options exercised during the three months ended June 30, 2018 and 2017 was $4.7 million and $1.6 million, respectively, and during the six months ended June 30, 2018 and 2017 was $4.9 million and $2.1 million, respectively.

As of June 30, 2018, there was $38.1 million of unrecognized compensation expense related to unvested stock options which is expected to be recognized over a weighted average period of 2.6 years. Included in unrecognized compensation expense was $1.1 million related to outstanding performance-condition options. These performance-condition options will vest, and compensation expense will be recognized, in the period in which FDA approval of ALIS is received in the US. The following table summarizes the range of exercise prices and the number of stock options outstanding and exercisable as of June 30, 2018:

Outstanding as of June 30, 2018				Exercisable as of June 30, 2018	
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	960,038	4.13	$ 3.60	960,038	$ 3.60
$6.90 $6.90	127,903	4.64	$ 6.90	90,403	$ 6.90
$6.96 $10.85	998,827	7.81	$ 10.77	481,411	$ 10.68
$11.14 $12.58	1,035,336	5.59	$ 12.16	795,493	$ 12.17
$12.66 $13.67	1,007,519	8.14	$ 13.60	317,446	$ 13.53
$13.94 $16.07	1,139,846	7.07	$ 15.26	711,531	$ 15.11
$16.09 $17.16	1,458,791	8.17	$ 16.70	523,127	$ 16.53
$17.24 $22.76	1,318,770	6.72	$ 21.23	992,480	$ 21.32
$22.84 $28.51	381,245	9.31	$ 25.00	33,999	$ 23.72
$30.46 $32.46	1,149,550	9.42	$ 30.58	—	$ —

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, 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 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 RSU awards on a straight-line basis over the requisite service period of these awards. As of June 30, 2018, there was $4.6 million of unrecognized compensation expense related to unvested RSU awards which is expected to be recognized over a weighted average period of 3.0 years. The following table summarizes the Company’s RSU award activity during the six months ended June 30, 2018:

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	Number of RSUs	Weighted Average Grant Price ($)
Outstanding at December 31, 2017	46,914	$ 17.16
Granted	236,077	29.79
Released	(46,914)	17.16
Forfeited	(262)	30.46
Outstanding at June 30, 2018	235,815	$ 29.79

The following table summarizes the aggregate stock-based compensation expense recorded in the consolidated statements of comprehensive loss related to stock options and RSUs during the three and six months ended June 30, 2018 and 2017, respectively:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in millions)			
Research and development expenses	$2.7	$1.5	$4.6	$3.0
General and administrative expenses	3.9	3.1	7.7	5.6
Total	$6.6	$4.6	$12.3	$8.6

8. Income Taxes

The Company’s provision for income taxes was $40,000 and $88,000 for the three and six months ended June 30, 2018, respectively, and $37,000 and $67,000 for the three and six months ended June 30, 2017, 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, 2018 and 2017. 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.

Following adoption of the Tax Cuts and Jobs Act during the fourth quarter of 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21%. The Company recorded a provisional amount of $94.0 million as of December 31, 2017 related to the re-measurement of certain deferred tax balances, which was completely offset by a full valuation allowance. Upon further analyses of certain aspects of the Tax Cuts and Jobs Act and refinement of the Company's calculations during the six months ended June 30, 2018, the Company determined that the provisional amount would not need to be adjusted.

In addition to local taxes in foreign jurisdictions, the Company is subject to US federal, US state, and US tax on foreign earnings. In regard to the US tax on foreign earnings, the Company was subject to a one-time transition tax based on its total earnings and profits, which were generally deferred from US income taxes under previous US law. Due to the aggregate loss position of the Company's foreign subsidiaries, the Company did not record any provisional amount for the one-time transition tax liability at December 31, 2017. Additionally, the global intangible low-taxed income tax and base erosion provisions in the Tax Cuts and Jobs Act are effective for taxable years beginning after December 31, 2017. The Company does not currently expect these provisions to have a material impact (i) due to the aggregate loss position of its foreign subsidiaries and (ii) because the Company currently expects to be below the gross receipts threshold for purposes of the base erosion provisions.

The Company is subject to US federal and state income taxes and the statute of limitations for tax audit is open for the Company's federal tax returns for the years ended 2014 and later, and is generally open for certain states for the years 2013 and later. The Company has incurred net operating losses since inception, except for the year ended December 31, 2009. Such loss carryforwards would be subject to audit in any tax year in which those losses are utilized, notwithstanding the year of origin. As of June 30, 2018 and December 31, 2017, 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

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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 $1.5 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 $1.7 million.

Rent expense charged to operations was $0.4 million and $0.3 million for the three months ended June 30, 2018 and 2017, respectively, and $0.8 million and $0.7 million for the six months ended June 30, 2018 and 2017, respectively. Future minimum rental payments required under the Company's operating leases for the period from July 1, 2018 to December 31, 2018 and for each of the five years thereafter are as follows (in thousands):

Year Ending December 31:	
2018 (remaining)	$768
2019	1,421
2020	477
2021	498
2022	—
2023	—
	$3,164

Legal Proceedings

From time to time, the Company is a party to various 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.

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 that involve substantial risks and uncertainties. "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 risks, uncertainties and other factors include, among others, the following:

- risks that data from the remainder of the treatment and off-treatment phases of the CONVERT study (the CONVERT study or the 212 study) will not be consistent with the six-month results of the study;

- uncertainties in the research and development of our existing product candidates, including due to delays in data readouts, such as the full data from the CONVERT study, patient enrollment and retention or failure of our preclinical

studies or clinical trials to satisfy pre-established endpoints, including secondary endpoints in the CONVERT study and endpoints in the CONVERT extension study (the 312 study);

- risks that subsequent data from the 312 study will not be consistent with the interim results;
- failure to obtain, or delays in obtaining, regulatory approval from the US Food and Drug Administration (FDA), Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA),

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the European Medicines Agency (EMA), and other regulatory authorities for our product candidates or their delivery devices, such as the eFlow Nebulizer System, including due to insufficient clinical data, selection of endpoints that are not satisfactory to regulators, the outcome of the upcoming advisory committee meeting, extensions of action dates under the Prescription Drug User Fee Act (PDUFA), or complexity in the review process for combination products;

- imposition of significant post-approval regulatory requirements on our product candidates or failure to maintain regulatory approval for our product candidates, if received, due to a failure to satisfy post-approval regulatory requirements, such as the submission of sufficient data from confirmatory clinical studies;
- safety and efficacy concerns related to our product candidates;
- lack of experience in conducting and managing preclinical development activities and clinical trials necessary for regulatory approval, including the regulatory filing and review process;
- uncertainties in the rate and degree of market acceptance of product candidates, if approved;
- inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of our product candidates, if approved;
- inaccuracies in our estimates of the size of the potential markets for our product candidates or limitations by regulators on the proposed treatment population for our product candidates;
- failure of third parties on which we are dependent to conduct our clinical trials, to manufacture sufficient quantities of our product candidates for clinical or commercial needs, including our raw materials suppliers, or to comply with our agreements or laws and regulations that impact our business;
- 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;
- failure to develop, or to license for development, additional product candidates, including a failure to attract experienced third-party collaborators;
- uncertainties in the timing, scope and rate of reimbursement for our product candidates;
- changes in laws and regulations applicable to our business and failure to comply with such laws and regulations;
- inability to repay our existing indebtedness or to obtain additional capital when needed on desirable terms or at all;
- failure to obtain, protect and enforce our patents and other intellectual property and costs associated with litigation or other proceedings related to such matters;
- restrictions imposed on us by license agreements that are critical for our product development, including our license agreements with PARI Pharma GmbH (PARI) and AstraZeneca AB (AstraZeneca), and failure to comply with our obligations under such agreements;
- competitive developments affecting our product candidates and potential exclusivity related thereto;
- the cost and potential reputational damage resulting from litigation to which we are or may be a party;
- loss of key personnel; and
- lack of experience operating internationally.

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Any forward-looking statement is based on information current as of the date of this Quarterly Report on Form 10-Q and speaks only as of the date on which such statement is made. Actual events or results may differ materially from the results, plans, intentions or expectations anticipated in these forward-looking statements as a result of a variety of factors, many of which are beyond our control. More information on factors that could cause actual results to differ materially from

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those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (SEC), including, but not limited to, those described in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. 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, 2017.

OVERVIEW

We are a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. Our lead product candidate is amikacin liposome inhalation suspension (ALIS), 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: ALIS, INS1007, and INS1009.

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Product Candidate/Target Indications	Status	Next Expected Milestones
ALIS for NTM lung infections	• We announced top-line data for the CONVERT study in September 2017. The CONVERT study met its primary endpoint of culture conversion, which we defined as three consecutive negative monthly sputum cultures by month six with statistical and clinical significance, with 29% of patients in the ALIS plus current guideline-based therapy (GBT) arm achieving culture conversion, compared to 9% of patients in the GBT-only arm ($p<0.0001$). • We announced interim data from the CONVERT study and the 312 extension study in January 2018, which we view as consistent with the six-month results of the CONVERT study. The data included interim long-term durability data for the CONVERT study and interim efficacy data for the 312 study. • We filed a new drug application (NDA) for approval of ALIS with the FDA at the end of March 2018, and the FDA accepted the filing for priority review, pursuant to Section 506(c) of the Federal Food Drug and Cosmetic Act and 21 C.F.R. Part 314 Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) (Subpart H) based on the six-month data from the CONVERT study. • The FDA has designated ALIS as an orphan drug, a breakthrough therapy, and a qualified infectious disease product (QIDP), and the European Commission has granted an orphan designation for ALIS for the treatment of NTM lung disease.	• We are preparing for an FDA advisory committee meeting to review data supporting our NDA for ALIS. The advisory committee meeting is scheduled for August 7, 2018. • The FDA set a PDUFA action date of September 28, 2018 for our NDA for ALIS for adult patients with NTM lung disease caused by MAC. • We also intend to seek marketing approvals for ALIS outside the US, such as in Japan and Europe, when sufficient data are available. If approved, we expect ALIS would be the first inhaled therapy specifically indicated for the treatment of NTM lung disease 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 and other rare diseases	• We are enrolling patients in 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. • We are currently assessing regulatory	• We expect to continue to advance enrollment in the WILLOW clinical study of INS1007 during 2018. • We are exploring the potential of INS1007 in various neutrophil-driven inflammatory conditions.

	strategies which could expedite the development and regulatory reviews of INS1007 in the US and the EU.	
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.	• 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 including exploring its use as an inhaled dry powder formulation.

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 approved inhaled therapies specifically indicated to treat 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 treatment 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 and the 312 study;
- Securing approval for the ALIS NDA from the FDA, under Subpart H, based on the six-month data from the CONVERT study;
- Ensuring our product supply chain will support the commercialization, if approved, and potential future life cycle management programs 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;
- Enrolling patients in the WILLOW phase 2 study of INS1007 in non-CF bronchiectasis;
- Exploring INS1009 for use as an inhaled dry powder formulation and generating preclinical findings from our earlier-stage programs; 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 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 amikacin solution for intravenous administration, 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 designated drugs are eligible for seven years of exclusivity for the orphan indication. QIDP designation features an additional five years of exclusivity for the designated indication. As a result, if ALIS is approved in the US, we expect the FDA to grant a total of 12 years of exclusivity in the indication for which ALIS is 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 that is not a new molecular entity means the FDA's goal is to take action on the NDA within six months following receipt of the NDA. The FDA has granted our request for priority review of the NDA for ALIS for adult patients with NTM lung disease caused by MAC and set a PDUFA action date of September 28, 2018.

The CONVERT Study and 312 Study

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CONVERT Efficacy Data

The CONVERT study is a randomized, open-label global phase 3 clinical study of ALIS in adult patients with treatment refractory NTM lung disease caused by MAC. We announced top-line data for the CONVERT study in September 2017, and the full six-month data were reported at the American Thoracic Society 2018 International Conference in May 2018. The CONVERT study enrolled 336 adult patients with NTM lung disease caused by MAC who were refractory to at least six months' treatment with a multi-drug, guideline-based therapy (GBT). After a screening period of up to 10 weeks, eligible patients were randomized 2:1 to once-daily ALIS plus GBT or GBT only. The primary endpoint of the study was the proportion of patients achieving culture conversion, which we defined as three consecutive monthly negative sputum cultures, by month six. The CONVERT study met its primary endpoint, with 29% of patients in the ALIS plus GBT arm achieving culture conversion, compared to 9% of patients in the GBT-only arm ($p<0.0001$).

We have also reported data for certain secondary and exploratory endpoints for the first six months of the study. Data for the six-minute walk test indicated no statistically significant difference between patients in the two arms of the study. However, an analysis of these data (per a pre-specified exploratory endpoint) showed that patients who achieved culture conversion in either arm demonstrated an improvement in six-minute walk distance when compared to patients who did not culture convert ($p=0.0108$). The patients who achieved culture conversion in either arm had an average improvement in six-minute walk distance of 16.83 meters from baseline to six months, and non-converters had an average decrease in six-minute walk distance of 7.88 meters from baseline to six months. The secondary endpoint of time to culture conversion was analyzed using a Cox regression model to estimate the treatment effect (hazard ratio) and the results of this analysis demonstrated a hazard ratio of 3.9, suggesting that patients receiving ALIS plus GBT were 290% more likely to convert than patients receiving GBT only ($p<0.0001$). However, the time to culture conversion is not statistically significant given its position in the hierarchical testing. We are continuing our analysis of the impact of conversion on a variety of other clinical measures.

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 the PMDA. Because the CONVERT study met the primary endpoint of culture conversion at month six, we submitted an NDA for ALIS to the FDA at the end of March 2018 pursuant to Subpart H, which permits the FDA to approve a product candidate based on a surrogate or intermediate endpoint subject to the requirement that we conduct post-approval studies to verify and describe the clinical benefit of the product. The FDA has completed the filing review and determined that the application is sufficiently complete to permit a substantive review. The FDA granted our request for a priority review and set a PDUFA action date of September 28, 2018. In addition, the Division of Antimicrobial Products of the FDA is scheduled to host an advisory committee meeting on August 7, 2018 to review data supporting our NDA for ALIS. We expect that full NDA approval would be contingent on FDA review of, among other things, the final analyses of durability of culture conversion for converters.

CONVERT Safety and Tolerability Data

Approximately 98% of patients in the ALIS plus GBT arm of the CONVERT study experienced at least one treatment-emergent adverse event (TEAE), compared to 91% of patients in the GBT-only arm, with most events being mild or moderate in severity. A greater percentage of patients in the ALIS plus GBT arm than in the GBT-only arm experienced TEAEs involving dysphonia, cough, haemoptysis, dyspnoea, oropharyngeal pain, diarrhea, nausea, and fatigue. Based on our review of the study safety data, the incidence of dysphonia, cough and dyspnoea among patients in the ALIS plus GBT arm generally decreased after the second study month. Approximately 20% and 18% of patients in the ALIS plus GBT arm and GBT-only arm of the study, respectively, experienced at least one serious treatment emergent adverse event (STEAE). The table below provides additional information regarding certain STEAEs experienced by patients in the CONVERT study.

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		2:1 Randomization	
Patients Reporting STEAEs >3% in Either Arm		ALIS + GBT (n=223)	GBT (n=112)
Patients Reporting At Least One STEAE		20.2% (45)	17.9% (20)
System Organ Class	Preferred Term		
Respiratory, Thoracic, Mediastinal Disorders		11.7% (26)	9.8% (11)
	Hemoptysis	2.7% (6)	4.5% (5)
	COPD (exacerbation)	3.1% (7)	0.9% (1)
Infections and Infestations		9.0% (20)	5.4% (6)
	Pneumonia	3.6% (8)	1.8% (2)
Cardiac Disorders		0.4% (1)	4.5% (5)
Patient Deaths		2.7% (6)	4.5% (5)

There were no distinctions between treatment arms for adverse events of hearing loss or renal impairment, side effects commonly associated with the intravenous use of amikacin. As of September 2017, the overall dropout rate in the CONVERT study was 16.1%, with an 8.9% dropout rate in the GBT-only arm and a 19.6% dropout rate in the ALIS plus GBT arm. As of December 2017, the overall dropout rate in the CONVERT study was 18% (n=60/336).

CONVERT Long-Term Durability Data

In January 2018, we announced interim data on the durability of culture conversion, as defined by patients that have completed treatment and continued in the CONVERT study off all therapy for three months, which we expect will be the endpoint necessary to support full regulatory approval in the US. The following data are interim results observed through December 2017, and have not been further analyzed. As of December 2017, of the 75 patients achieving culture conversion in the CONVERT study, 53 of these patients were evaluable for durability of culture conversion three months after the completion of treatment. Interim data for durability of culture conversion as of December 2017 on these 53 patients are detailed below:

	Evaluable Number of Patients as of December 2017 (At Least Three Months Post Treatment)*	Percent with Durable Culture Conversion Three Months After Completion of All Treatment
Converters in the ALIS + GBT arm (n=65)	46	60.9% (28/46)
Converters in the GBT only arm (n=10)	7	0.0% (0/7)

* Evaluable number of patients includes all patients who reached three months post-treatment and all patients who discontinued prior to three months post-treatment.

312 Study

All non-converters in the CONVERT study, as determined at the month eight visit, may be eligible to enter the 312 study, which is a separate 12-month, single-arm, open-label study. The purpose of the 312 study is to further evaluate the safety and tolerability of long-term treatment with ALIS added to GBT. The secondary endpoints of the 312 study include evaluating the proportion of patients achieving culture conversion (three consecutive monthly negative sputum cultures) by month six and the proportion of patients achieving culture conversion by month 12 (end of treatment).

312 Study Interim Efficacy Data

In January 2018, we also announced interim data for the 312 study, which enrolled 163 adult patients with NTM lung disease caused by MAC who completed six months of treatment in the CONVERT study, but did not demonstrate culture conversion by Month 6. The following data are interim results observed through December 2017, and have not been further analyzed. Patients in the ALIS plus GBT arm of the CONVERT study and patients in the GBT-only arm of the CONVERT study who did not achieve culture conversion by Month 6 had the option to enroll in the 312 study at Month 8. Under the study protocol, non-converting patients from both arms of the CONVERT study will receive 12 months of ALIS plus GBT in the 312 study. We will also use the data from this trial to further assess the impact of the addition of ALIS to background GBT on sputum culture conversion, by Month 6.

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As of December 2017, of the 163 patients enrolled in the 312 study, 124 patients were evaluable for culture conversion. Descriptive interim culture conversion data as of December 2017 for these 124 patients are detailed below. The interim culture conversion data has not been statistically analyzed.

	Number of Patients Completing Six Months of Treatment in the 312 study as of December 2017 **	Percent Achieving Sputum Culture Conversion by Month 6 in the 312 study
Patients who received GBT only in the 212 study and crossed over to receive six months of treatment with ALIS + GBT (n=90)	67	28.4% (19/67)
Patients who received ALIS + GBT in the 212 study and crossed over to continue treatment in the 312 study, to receive a combined total of 14 months of ALIS + GBT treatment in both studies (n=73)	57	12.3% (7/57)

** Includes all patients completing six months of treatment, all patients who discontinued prior to six months and all ongoing patients prior to six months who completed two months of treatment.

312 Study Interim Safety and Tolerability Data

We have not yet performed a final analysis of any safety data for the 312 study. However, based on an interim review of the data above, we believe that STEAEs were similar to the STEAEs we reported as part of our full six-month data results for the 212 study. As of December 2017, the overall dropout rate in the 312 study was 24% (n=39/163).

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 designs 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. In addition, we are evaluating the use of ALIS to treat infections caused by non-MAC NTM species, such as M. abscessus. If the data from the CONVERT study are sufficient to support our marketing authorization applications (MAAs) and regulatory bodies approve ALIS, such lifecycle management studies could enable us to reach more potential patients. These initiatives include investigator-initiated studies, which are clinical studies initiated and sponsored by physicians or research institutions with funding from us, and may also include new clinical studies sponsored by us.

Market Opportunity for ALIS in NTM Lung Disease in 2018

NTM lung disease is associated with increased rates of morbidity and mortality, and MAC is the predominant pathogenic species in NTM lung disease in the US, Japan and Europe. The prevalence of NTM lung disease has increased over the past two decades, and we believe it is an emerging public health concern worldwide. Based on currently available information from external sources, including market research funded by us and third parties, and internal analyses and calculations, we estimate potential patient populations in the US, Japan and EU5 (comprised of France, Germany, Italy, Spain and the United Kingdom) for 2018 as follows:

Potential Market	Estimated Number of Patients with Diagnosed NTM Lung Disease	Estimated Number of Patients Treated for NTM Lung Disease Caused by MAC	Estimated Number of Patients Refractory to Treatment
United States	75,000-105,000	40,000-50,000	10,000-15,000

Japan	125,000-145,000	60,000-70,000	15,000-18,000
EU5	14,000	4,400	1,400

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We are not aware of any approved inhaled therapies specifically indicated for NTM lung disease in North America, Japan or Europe. Current guideline-based approaches for NTM lung disease, including those from the American Thoracic Society and Infectious Diseases Society of America, involve multi-drug regimens not approved for the treatment of NTM lung disease and treatment that could last two years or more. Based on a burden of illness study that we conducted in the US with a major medical benefits provider, we previously concluded that patients with NTM lung disease are costly to healthcare plans, while a recent claims-based study in the US has shown that patients with NTM lung disease have higher resource utilization and costs than their age and gender-matched controls. Accordingly, we believe that a significant market opportunity for ALIS in NTM lung disease exists in the US and internationally. We are currently exploring the NTM market opportunity for ALIS in Japan. The CONVERT study included a comprehensive pharmacokinetic sub-study in Japanese subjects in lieu of a separate local pharmacokinetic study in Japan, as agreed with the PDMA. If the data from the CONVERT study are sufficient to support our MAAs, we expect to submit regulatory filings in Japan and Europe. We have established a Japanese subsidiary and began hiring local employees in 2018, including a general manager, to closely manage our regulatory and pre-commercial activities.

INS1007

INS1007 is a small molecule, oral, reversible inhibitor of DPP1, which we 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 the neutrophil serine proteases (including 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. Non-CF bronchiectasis is a 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 FDA-approved therapies specifically indicated for non-CF bronchiectasis.

The WILLOW Study

The WILLOW study is 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. We commenced enrollment in the WILLOW study in December 2017. In addition, we are exploring the potential of INS1007 in various neutrophil-driven inflammatory conditions.

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, including exploring its use as an inhaled dry powder formulation.

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

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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 the NDA process.

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 treprostinil serum concentration was approximately 90% lower 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 of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our research and development functions, including medical affairs. 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 ALIS and INS1007. Our expenses related to manufacturing our drug candidate(s) for clinical studies and commercial inventory prior to regulatory approvals are primarily related to activities at contract manufacturing organizations (CMOs) that manufacture our product candidates for our use, including purchases of active pharmaceutical ingredients. R&D expenses also include spending to build-out the CMO facilities to prepare for our future global production requirements. Our expenses related to clinical trials are primarily related to activities at contract research organizations that conduct and manage clinical trials on our behalf.

Since 2011, we have focused our development activities principally on our proprietary, advanced liposomal technology designed specifically for inhaled therapies. Our development efforts since 2015 have principally related to the development of ALIS in the NTM lung disease indication described above.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for our non-employee directors and personnel serving in our executive, finance and accounting, legal and compliance, pre-commercial, corporate development, information technology, program management and human resource functions. General and administrative expenses also include professional fees for legal services 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 income earned on our cash and cash equivalents. Interest expense consists primarily of contractual interest expense, amortization of debt issuance costs and accretion of debt discount. Debt issuance costs are amortized and the debt discount is accreted to interest expense using the effective interest rate method over the term of the debt. 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, 2018 and 2017

Net Loss

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Net loss for the quarter ended June 30, 2018 was $76.4 million, or $1.00 per share—basic and diluted, compared with a net loss of $44.7 million, or $0.72 per share—basic and diluted, for the quarter ended June 30, 2017. The $31.8 million increase in our net loss for the quarter ended June 30, 2018 as compared to the same period in 2017 was primarily due to:

- Increased R&D expenses of $8.9 million, primarily resulting from an increase in external manufacturing expenses and higher compensation and related expenses due to an increase in headcount; and
- Increased general and administrative expenses of $20.5 million, resulting from higher compensation and related expenses due to an increase in headcount, and an increase in consulting fees relating to pre-commercial planning activities.

In addition, there was a $5.0 million increase in interest expense resulting from the issuance of $450.0 million aggregate principal amount of 1.75% convertible senior notes due 2025 (the Convertible Notes) in connection with the public offering that occurred in January 2018.

R&D Expenses

R&D expenses for the quarters ended June 30, 2018 and 2017 were comprised of the following components (in thousands):

	Quarters Ended June 30,		Increase (decrease)	
	2018	2017	$	%
External Expenses				
Clinical development & research	$ 6,920	$ 9,845	$ (2,925)	(29.7)%
Manufacturing	10,946	4,862	6,084	125.1 %
Regulatory and quality assurance	3,529	2,525	1,004	39.8 %
Subtotal—external expenses	$ 21,395	$ 17,232	$ 4,163	24.2 %
Internal Expenses				
Compensation and related expenses	$ 11,593	$ 8,047	$ 3,546	44.1 %
Other internal operating expenses	2,734	1,592	1,142	71.7 %
Subtotal—internal expenses	$ 14,327	$ 9,639	$ 4,688	48.6 %
Total	$ 35,722	$ 26,871	$ 8,851	32.9 %

R&D expenses increased to $35.7 million during the quarter ended June 30, 2018 from $26.9 million in the same period in 2017. The $8.9 million increase was primarily due to an increase of $6.1 million in external manufacturing expenses, specifically related to purchases of ALIS raw materials, CMO expenses related to ALIS commercial inventory production, and construction costs relating to the build-out of a third party CMO production facility. In addition, there was a $3.5 million increase in compensation and related expenses due to an increase in headcount in the quarter ended June 30, 2018 as compared to the prior year period.

General and Administrative Expenses

General and administrative expenses for the quarter ended June 30, 2018 and 2017 were comprised of the following (in thousands):

	Quarters Ended June 30,		Increase (decrease)	
	2018	2017	$	%

General & administrative	$ 13,455	$ 9,355	$ 4,100	43.8 %
Pre-commercial expenses	23,705	7,289	16,416	225.2 %
Total general & administrative expenses	$ 37,160	$ 16,644	$ 20,516	123.3 %

General and administrative expenses increased to $37.2 million during the quarter ended June 30, 2018 from $16.6 million in the same period in 2017. The $20.5 million increase was primarily due to $10.5 million in higher compensation and related expenses due to an increase in headcount, including the hiring of our field force, and $7.5 million in consulting fees

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relating to pre-commercial planning activities in preparation for the post-approval launch of ALIS, including non-branded disease awareness, patient support planning, field operations and other professional fees. In addition, there was an increase of $1.2 million related to patient services software licenses and fees, and ongoing training costs for the field force hired during the first quarter of 2018.

Interest Expense

Interest expense was $6.5 million for the quarter ended June 30, 2018 as compared to $1.5 million in the same period in 2017. The $5.0 million increase in interest expense in the quarter ended June 30, 2018 as compared to the prior year period relates to the issuance of $450.0 million aggregate principal amount of the Convertible Notes in January 2018. The interest expense on the Convertible Notes is based on an effective interest rate of 7.6%.

Comparison of the Six Months Ended June 30, 2018 and 2017

Net Loss

Net loss for the six months ended June 30, 2018 was $145.0 million, or $1.89 per share—basic and diluted, compared with a net loss of $82.1 million, or $1.32 per share—basic and diluted, for the six months ended June 30, 2017. The $62.9 million increase in our net loss for the quarter ended June 30, 2018 as compared to the same period in 2017 was primarily due to:

- Increased R&D expenses of $16.7 million, primarily resulting from an increase in external manufacturing expenses and higher compensation and related expenses due to an increase in headcount; and
- Increased general and administrative expenses of $39.5 million, resulting from higher compensation and related expenses due to an increase in headcount, and an increase in consulting fees relating to pre-commercial planning activities for ALIS.

In addition, there was a $9.2 million increase in interest expense resulting from the issuance of $450.0 million aggregate principal amount of the Convertible Notes in connection with the public offering in January 2018.

R&D Expenses

R&D expenses for the quarters ended June 30, 2018 and 2017 were comprised of the following components (in thousands):

	Six Months Ended June 30,		Increase (decrease)	
	2018	2017	$	%
External Expenses				
Clinical development & research	$ 14,738	$ 18,320	$(3,582)	(19.6)%
Manufacturing	18,880	7,606	11,274	148.2 %
Regulatory and quality assurance	5,159	3,493	1,666	47.7 %
Subtotal—external expenses	$ 38,777	$ 29,419	$9,358	31.8 %
Internal Expenses				
Compensation and related expenses	$ 21,476	$ 15,698	$5,778	36.8 %
Other internal operating expenses	5,567	4,008	1,559	38.9 %
Subtotal—internal expenses	$ 27,043	$ 19,706	$7,337	37.2 %
Total	$ 65,820	$ 49,125	$16,695	34.0 %

R&D expenses increased to $65.8 million during the six months ended June 30, 2018 from $49.1 million in the same period in 2017. The $16.7 million increase was primarily due to an increase of $11.3 million in external manufacturing expenses, specifically related to purchases of ALIS raw materials, CMO expenses related to ALIS commercial inventory production, and construction costs relating to the build-out of a third party CMO production facility. In addition, there was a $5.8 million increase in compensation and related expenses due to an increase in headcount in the six months ended June 30, 2018 as compared to the prior year period.

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General and Administrative Expenses

General and administrative expenses for the six months ended June 30, 2018 and 2017 were comprised of the following (in thousands):

	Six Months Ended June 30,		Increase (decrease)	
	2018	2017	$	%
General & administrative	$26,974	$18,009	$8,965	49.8 %
Pre-commercial expenses	42,839	12,350	30,489	246.9 %
Total general & administrative expenses	$69,813	$30,359	$39,454	130.0 %

General and administrative expenses increased to $69.8 million during the six months ended June 30, 2018 from $30.4 million in the same period in 2017. The $39.5 million increase was primarily due to $19.4 million in higher compensation and related expenses due to an increase in headcount, including the hiring of our field force, and $15.1 million in consulting fees relating to pre-commercial planning activities in preparation for the post-approval launch of ALIS, including non-branded disease awareness, patient support planning, field operations and other professional fees. In addition, there was an increase of $2.7 million related to patient services software licenses and fees, and ongoing training costs for the field force hired in the first quarter of 2018.

Interest Expense

Interest expense was $12.1 million for the six months ended June 30, 2018 as compared to $3.0 million in the same period in 2017. The $9.2 million increase in interest expense in the six months ended June 30, 2018 as compared to the prior year period relates to the issuance of $450.0 million aggregate principal amount of Convertible Notes in January 2018. The interest expense on the Convertible Notes is based on an effective interest rate of 7.6%.

LIQUIDITY AND CAPITAL RESOURCES

Overview

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

In January 2018, we completed an underwritten public offering of $450.0 million aggregate principal amount of Convertible Notes, including the exercise in full of the underwriter's option to purchase additional Convertible Notes. Our net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses of $14.2 million, were $435.8 million.

In September 2017, we completed an underwritten public offering of 14,123,150 shares of our common stock, which included the underwriter’s exercise in full of its over-allotment option of 1,842,150 shares, at a price to the public of $28.50 per share. Our net proceeds from the sale of the shares, after deducting underwriting discounts and offering expenses of $24.8 million, were $377.7 million.

We may need to raise additional capital to fund our operations, to develop and commercialize ALIS if approved, to develop INS1007 and INS1009, and to develop, acquire, in-license or co-promote other products that address orphan

or rare diseases. We believe we currently have sufficient funds to meet our financial needs for at least the next 12 months. We may opportunistically raise additional capital and may do so through equity or debt financing(s), strategic transactions or otherwise. We expect such additional funding, if any, would be used to continue to develop our potential product candidates, to pursue the license or purchase of other technologies, to commercialize our product candidates or to purchase other products. During 2018, we plan to continue to fund further clinical development of ALIS and INS1007, support efforts to obtain regulatory approvals, and prepare for commercialization of ALIS. Our cash requirements in 2018 will be impacted by a number of factors, the most significant of which are expenses related to the CONVERT and 312 studies and pre-commercialization efforts for ALIS, and to a lesser extent, expenses related to INS1007 and future ALIS clinical trials. We expect our operating expenses to continue to significantly increase in 2018 as compared to 2017.

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Cash Flows

As of June 30, 2018, we had cash and cash equivalents of $634.3 million, as compared with $381.2 million as of December 31, 2017. The $253.2 million increase was due primarily to the net cash proceeds from our issuance of Convertible Notes in January 2018, partially offset by cash used in operating activities and, to a lesser extent, cash used in investing activities. Our working capital was $599.6 million as of June 30, 2018 as compared with $344.8 million as of December 31, 2017.

Net cash used in operating activities was $123.0 million and $73.2 million for the six months ended June 30, 2018 and 2017, respectively. The net cash used in operating activities during the six months ended June 30, 2018 and 2017 was primarily for the pre-commercial, clinical and manufacturing activities related to ALIS, as well as general and administrative expenses. In addition, net cash used in operating activities during the six months ended June 30, 2018 included clinical trial expenses related to INS1007.

Net cash used in investing activities was $8.2 million and $0.9 million for the six months ended June 30, 2018 and 2017, respectively. The net cash used in investing activities in 2018 was primarily related to the purchase of fixed assets for our long-term production capacity build-out at one of our CMOs. The net cash used in investing activities in 2017 related to payments for the build-out of our lab facility in Bridgewater, New Jersey.

Net cash provided by financing activities was $384.3 million and $2.4 million for the six months ended June 30, 2018 and 2017, respectively. Net cash provided by financing activities for the six months ended June 30, 2018 included net cash proceeds of $435.8 million from our issuance of Convertible Notes in January 2018 and cash proceeds from stock option exercises, partially offset by the February 2018 pay-off of our outstanding debt to Hercules Capital (Hercules) in the amount of $55.0 million. Net cash provided by financing activities for the six months ended June 30, 2017 was cash proceeds from stock option exercises.

Contractual Obligations

There were no material changes outside of the ordinary course of business in our contractual obligations during the six months ended June 30, 2018 from those disclosed in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Contractual Obligations” in our Annual Report on Form 10-K for the year ended December 31, 2017, except for the following:

In January 2018, we completed an underwritten public offering of $450.0 million aggregate principal amount of Convertible Notes pursuant to an indenture between the Company and Wells Fargo Bank, National Association, as trustee. Our net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses of $14.2 million, were approximately $435.8 million. The Convertible Notes bear interest payable semiannually in arrears on January 15 and July 15 of each year, beginning on July 15, 2018. The Convertible Notes mature on January 15, 2025, unless earlier converted, redeemed, or repurchased. The Convertible Notes are convertible into common stock of the Company under certain circumstances described in the indenture. See Note 5 - Debt of our consolidated financial statements for more information.

In February 2018, we used part of the net proceeds from the issuance of the Convertible Notes to pay off the outstanding debt owed to Hercules. The payments consisted of $55.0 million for the principal amount and an additional $3.2 million in back-end fees, outstanding interest, and prepayment penalties. As a result, we incurred a $2.2 million loss on the extinguishment of debt in the quarter ended March 31, 2018.

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, 2017. For the required interim disclosure updates related to our accounting policies, see

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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, 2018, our cash and cash equivalents were in cash accounts or were invested in US treasury bills and money market funds. Money market accounts are not insured by the federal government.

As of June 30, 2018, we had $450.0 million of Convertible Notes outstanding which bear interest at a coupon rate of 1.75%. If a 10% change in interest rates had occurred on June 30, 2018, it 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 six months ended June 30, 2018 and 2017, 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, 2018. 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, 2018, 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 six months ended June 30, 2018 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

From time to time, we are 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.

ITEM 1A. RISK FACTORS

There have been no material changes during the quarter ended June 30, 2018 to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

There were no unregistered sales of the Company’s equity securities by the Company during the quarter ended June 30, 2018.

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ITEM 6. EXHIBITS

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).
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, Chief Financial Officer (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, 2018 formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017, (ii) Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2018 and 2017, (iii) Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and 2017, and (iv) Notes to the Unaudited Consolidated Financial Statements.

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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 2, 2018 By /s/ Paolo Tombesi
Paolo Tombesi
Chief Financial Officer
(Principal Financial and Accounting Officer)