INSMED Inc
Form 10-Q
November 06, 2014
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

For the transition period from to

Commission File Number 0-30739

INSMED INCORPORATED

(Exact name of registrant as specified in its charter)

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

(908) 977-9900

(Registrant s telephone number including area code)

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

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

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

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

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

As of October 31, 2014, there were 49,664,996 shares of the registrant s common stock, $0.01 par value, outstanding.

Table of Contents

INSMED INCORPORATED

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2014

INDEX

In this Form 10-Q, we use the words Insmed Incorporated to refer to Insmed Incorporated, a Virginia corporation, and we use the words Company, Insmed, Insmed Incorporated, we, us and our to refer to Insmed Incorporated and its consolidated subsidiaries. IPLEX is a registered trademark of Insmed Incorporated. ARIKAYCE and INSMED 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.

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

INSMED INCORPORATED

Consolidated Balance Sheets

(in thousands, except par value and share data)

	As of September 30, 2014 (unaudited)	As of December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 167,311	$ 113,894
Prepaid expenses and other current assets	3,532	2,269
Total current assets	170,843	116,163
In-process research and development	58,200	58,200
Fixed assets, net	5,982	1,812
Other assets	418	323
Total assets	$ 235,443	$ 176,498
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 8,867	$ 5,929
Accrued expenses	3,547	3,905
Accrued compensation	3,032	2,839
Accrued lease expense, current	317	307
Deferred rent	321	129
Capital lease obligations, current	16	64
Current portion of long term debt	5,178	3,283
Total current liabilities	21,278	16,456
Accrued lease expense, long-term	185	380
Debt, long-term	14,713	16,338
Total liabilities	36,176	33,174
Shareholders equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 49,605,544 and 39,137,679 issued and outstanding shares at September 30, 2014 and December 31, 2013, respectively	496	391
Additional paid-in capital	651,904	534,554
Accumulated deficit	(453,133)	(391,621)
Total shareholders equity	199,267	143,324
Total liabilities and shareholders equity	$ 235,443	$ 176,498

See accompanying notes to consolidated financial statements

Table of Contents

INSMED INCORPORATED

Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Other revenue	$	$	$	$ 11,500
Operating expenses:				
Research and development	15,200	12,095	41,493	34,654
General and administrative	8,204	4,747	22,806	16,267
Total operating expenses	23,404	16,842	64,299	50,921
Operating loss	(23,404)	(16,842)	(64,299)	(39,421)
Investment income	12	40	41	141
Interest expense	(594)	(525)	(1,795)	(1,802)
Other (expense) / income, net	(4)		152	2
Loss before income taxes	(23,990)	(17,327)	(65,901)	(41,080)
Benefit from income taxes			(4,389)	(1,221)
Net loss and comprehensive loss	$ (23,990)	$ (17,327)	$ (61,512)	$ (39,859)
Basic and diluted net loss per share	$ (0.54)	$ (0.46)	$ (1.50)	$ (1.19)
Weighted average basic and diluted common shares outstanding	44,082	37,389	40,882	33,577

See accompanying notes to consolidated financial statements

Table of Contents

INSMED INCORPORATED

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

	Nine months ended September 30, 2014		2013	
Operating activities				
Net loss	$	(61,512)	$	(39,859)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		697		475
Stock based compensation expense		8,592		6,410
Gain on sale of asset, net				(2)
Amortization of debt discount and debt issuance costs		283		256
Accrual of the end of term charge on the debt		86		126
Changes in operating assets and liabilities:				
Prepaid expenses and other assets		(1,358)		(1,078)
Accounts payable		2,546		(2,399)
Accrued expenses and deferred rent		(825)		3,908
Accrued lease expenses		(185)		(190)
Accrued compensation		192		(254)
Net cash used in operating activities		(51,484)		(32,607)
Investing activities				
Purchases of fixed assets		(3,814)		(713)
Proceeds from sale of asset				2
Maturity of certificate of deposit				2,153
Net cash (used in) / provided by investing activities		(3,814)		1,442
Financing activities				
Payments on capital lease obligations		(48)		(80)
Proceeds from exercise of stock options		847		1,471
Net proceeds from issuances of common stock		108,016		67,017
Payment of debt issuance costs		(100)		
Net cash provided by financing activities		108,715		68,408
Increase in cash and cash equivalents		53,417		37,243
Cash and cash equivalents at beginning of period		113,894		90,782
Cash and cash equivalents at end of period	$	167,311	$	128,025
Supplemental disclosures of cash flow information:				
Cash paid for interest	$	1,403	$	1,416
Cash received for taxes	$	4,389	$	1,221
Supplemental disclosures of non-cash investing and financing activities:				
Value of warrant exercised by converting the warrant into shares of common stock (net issuance method)	$		$	790

See accompanying notes to consolidated financial statements

Table of Contents

INSMED INCORPORATED

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

Insmed is a biopharmaceutical company currently focused on developing and commercializing inhaled therapies for patients battling serious lung diseases that are often life threatening. The Company s lead product candidate, ARIKAYCETM, or liposomal amikacin for inhalation, is an inhaled antibiotic treatment that delivers a proven and potent anti-infective directly to the site of serious lung infections.

The Company was incorporated in the Commonwealth of Virginia on November 29, 1999. On December 1, 2010, the Company completed a business combination with Transave, Inc. (Transave), a privately held, New Jersey-based pharmaceutical company focused on the development of differentiated and innovative inhaled pharmaceuticals for the treatment of serious lung infections (the Merger). The Company s continuing operations are based on the technology and products historically developed by Transave. The Company s principal executive offices are located in Bridgewater, New Jersey.

The accompanying unaudited interim consolidated financial statements have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States for complete consolidated financial statements have been condensed or are not included herein. The interim statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s Form 10-K for the year ended December 31, 2013.

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

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Transave, LLC, Insmed Pharmaceuticals, Incorporated, Insmed Limited, and Celtrix Pharmaceuticals, Incorporated. All intercompany transactions and balances have been eliminated in consolidation.

Subsequent Events - The Company has evaluated all events and transactions since September 30, 2014 through the date of this report.

2. Summary of Significant Accounting Policies

The following are interim updates to certain of the policies described in Note 2 to the Company s audited consolidated financial statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2013:

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

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

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

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

Each major category of financial assets and liabilities measured at fair value on a recurring basis are categorized in the tables below 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.

Table of Contents

The following table presents assets and liabilities measured at fair value as of September 30, 2014 and December 31, 2013 (in thousands):

			Fair Value Measurements at Reporting Date Using					
	Total		Quoted Prices in Active Markets for Identical Assets (Level 1)		Quoted Prices in Inactive Markets for Identical Assets (Level 2)		Significant Unobservable Inputs (Level 3)	
As of September 30, 2014:								
Assets:								
Cash and cash equivalents	$	167,311	$	167,311	$		$	
	$	167,311	$	167,311	$		$	
As of December 31, 2013:								
Assets:								
Cash and cash equivalents	$	113,894	$	113,894	$		$	
	$	113,894	$	113,894	$		$	

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

The Company recognizes transfers between levels within the fair value hierarchy, if any, at the end of each quarter. There were no transfers in or out of Level 1, Level 2 or Level 3 during the three and nine months ended September 30, 2014 and 2013, respectively.

As of September 30, 2014 and December 31, 2013, 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.

Revenue Recognition Other revenue during the nine months ended September 30, 2013 solely consists of an $11.5 million payment the Company received from Premacure (now Shire plc) in exchange for the Company s right to receive future royalties under its license agreement with Premacure. The Company recorded this as Other revenue during the three months ended June 30, 2013, since all four revenue recognition criteria were met at that time and the Company had no continuing performance obligations related to the payment received. Also see Note 11 of the Company s audited consolidated financial statements on Form 10-K for the year ended December 31, 2013 for more information.

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

The following table sets forth the reconciliation of the weighted average number of shares used to compute basic and diluted net loss per share for the three and nine months ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands, except per share amounts)			
Numerator:				
Net loss	$ (23,990)	$ (17,327)	$ (61,512)	$ (39,859)
Denominator:				
Weighted average common shares used in calculation of basic net loss per share:	44,082	37,389	40,882	33,577
Effect of dilutive securities:				
Common stock options				
Restricted stock and restricted stock units				

Table of Contents

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
	(In thousands, except per share amounts)			
Common stock warrant				
Weighted average common shares outstanding used in calculation of diluted net loss per share	44,082	37,389	40,882	33,577
Net loss per share:				
Basic and Diluted	$ (0.54)	$ (0.46)	$ (1.50)	$ (1.19)

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average common shares outstanding as of September 30, 2014 and 2013 as their effect would have been anti-dilutive (in thousands):

	2014	2013
Stock options to purchase common stock	4,674	3,439
Restricted stock and restricted stock units	21	106

3. Identifiable Intangible Assets

The Company believes there are no indicators of impairment relating to its in-process research and development intangible assets as of September 30, 2014.

4. Accrued Expenses

Accrued expenses consist of the following:

	As of September 30, 2014	As of December 31, 2013
	(in thousands)	
Accrued clinical trial expenses	$ 2,057	$ 2,484
Accrued technical operation expenses	319	1,220
Accrued professional fees	1,017	24
Accrued interest payable	154	159
Other accrued expenses		18
	$ 3,547	$ 3,905

5. Debt

On June 29, 2012, the Company and its domestic subsidiaries, as co-borrowers, entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. (Hercules) that allowed the Company to borrow up $20.0 million in $10.0 million increments (Loan Agreement). The Company borrowed the first and second $10.0 million increments by signing two Secured Promissory Notes (Note A and Note B and collectively, the Notes) on June 29, 2012 and December 27, 2012, respectively. Notes A and B bear interest at 9.25%. Note A was originally scheduled to be repaid over a 42-month period with the first twelve monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. Note B was originally scheduled to be repaid over a 36-month period with the first six monthly payments representing interest only followed by thirty monthly equal payments of principal and interest. The Loan Agreement provided that in certain circumstances the Company could delay the first principal payment by five months. In July 2013, subsequent to the completion of certain ARIKAYCE-related development milestones, the Company elected to extend the interest only period under the Notes from July 31, 2013 to December 31, 2013 and delay the first monthly principal repayments for Notes A and B from August 1, 2013 to January 1, 2014. On November 25, 2013, the Company and Hercules entered into an amendment (the Amendment) of the Loan Agreement. The Amendment initially extended the interest-only period through June 30, 2014 and called for the first monthly principal payment on July 1, 2014. The Amendment also allowed the Company to further extend the interest-only period through December 31, 2014 and delay the first payment of principal until January 1, 2015, so long as the Company paid a $100,000 fee and obtained positive data from its phase 2 clinical trial of ARIKAYCE in patients who have lung infections caused by nontuberculous mycobacteria (NTM). In June 2014, the Company paid the $100,000 fee and exercised its option to extend the interest-only period and delay the first payment of principal to January 1, 2015. The election and amendment did not change the maturity date for Notes A and B, which is January 1, 2016.

Table of Contents

In connection with the Loan Agreement, the Company granted the lender a first position lien on all of the Company s assets, excluding intellectual property. Prepayment of the loans made pursuant to the Loan Agreement is subject to penalty and the Company is required to pay an end of term charge of $390,000, which is being charged to interest expense (and accreted to the debt) using the effective interest method over the life of the Loan Agreement. Debt issuance fees paid to the lender were recorded as a discount on the debt and are being amortized to interest expense using the effective interest method over the life of the Loan Agreement. Debt issuance fees paid to third parties were capitalized and are being amortized to interest expense using the effective interest method over the life of the Loan Agreement.

The Loan Agreement also contains representations and warranties by the Company and the lender and indemnification provisions in favor of the lender and customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but no financial covenants), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the lender s security interest or in the collateral, and events relating to bankruptcy or insolvency). Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lender may terminate its lending commitment, declare all outstanding obligations immediately due and payable, and take such other actions as set forth in the Loan Agreement. In addition, pursuant to the Loan Agreement, the lender has the right to participate, in an amount of up to $1.0 million, in certain future private equity financing(s) by the Company.

In conjunction with entering into the Loan Agreement, the Company granted a warrant to the lender to purchase shares of the Company s common stock. Since the warrant was granted in conjunction with entering into the Loan Agreement, the relative fair value of the warrant was recorded as equity and debt discount. The debt discount is being amortized to interest expense over the term of the related debt using the effective interest method.

The following table presents the components of the Company s debt balance as of September 30, 2014 (in thousands):

Debt:		
Notes payable	$	20,000
Accretion of end of term charge		290
Issuance fees paid to lender		(202)
Discount from warrant		(197)
Current portion of long-term debt		(5,178)
Long-term debt	$	14,713

As of September 30, 2014, future principal repayments of the two Notes for the period October 1, 2014 to December 31, 2014 and in each of the years ending December 31, 2015 and 2016 were as follows (in thousands):

Year Ending in December 31:		
2014	$	
2015		7,430
2016		12,570
	$	20,000

The estimated fair value of the debt (categorized as a Level 2 liability for fair value measurement purposes) is determined using current market factors and the ability of the Company to obtain debt at comparable terms to those that are currently in place. The Company believes the estimated fair value at September 30, 2014 approximates the carrying amount.

6. Stockholders Equity

Common Stock As of September 30, 2014, the Company had 500,000,000 shares of common stock authorized with a par value of $0.01 and 49,605,544 shares of common stock issued and outstanding. In addition, as of September 30, 2014, the Company had reserved 4,674,146 shares of common stock for issuance upon the exercise of outstanding common stock options and 20,960 for issuance upon the vesting of restricted stock units.

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

On July 22, 2013, the Company completed an underwritten public offering of 6,900,000 shares of the Company s common stock, which included the underwriter s exercise in full of its over-allotment option of 900,000 shares, at a price to the public of $10.40 per share. The Company s net proceeds from the sale of the shares, after deducting the underwriter s discount and offering expenses of $4.7 million, were $67.0 million.

Warrant - In conjunction with entering into the Loan Agreement (See Note 5 Debt), the Company granted a warrant to the lender to purchase 329,932 shares of the Company s common stock at an exercise price of $2.94 per share. The fair value of the warrant of $0.8 million was calculated using the Black-Scholes warrant-pricing methodology at the date of issuance and was recorded as equity and as a discount to the debt and is being amortized to interest expense over the term of the related debt using the effective interest method. On April 30, 2013, the lender exercised the warrant in full via the net issuance method specified in the warrant agreement. In accordance with such provisions, the Company issued and delivered 223,431 shares of common shares to the lender on May 1, 2013. As a result of the exercise, the warrant is no longer outstanding and there are no additional shares issuable under this instrument.

7. Stock-Based Compensation

The Company currently has one equity compensation plan, the 2013 Incentive Plan, which was approved by shareholders at the Company s Annual Meeting of Shareholders on May 23, 2013 (the 2013 Incentive Plan). The 2013 Incentive Plan is administered by the Compensation Committee and the Board of Directors of the Company. Under the terms of the 2013 Incentive Plan, the Company is authorized to grant a variety of incentive awards based on its common stock, including stock options (both incentive stock options and non-qualified stock options), performance options/shares and other stock awards, as well as the payment of incentive bonuses to all employees and non-employee directors. As of September 30, 2014, 363,378 shares of the Company s common stock were reserved for future grants (or issuances) of restricted stock, restricted stock units, stock options, and stock warrants under the 2013 Incentive Plan. The 2013 Incentive Plan will terminate on April 16, 2023 unless it is extended or terminated earlier pursuant to its terms.

During the first quarter of 2013, the Company completed a review of equity compensation awards granted under its previous equity compensation plan and determined that it had inadvertently exceeded the annual per-person sub-limits involving certain awards previously made to certain of its current and past officers and directors (the excess awards). The aggregate amount of common stock represented by these excess awards, which consisted of Restricted Stock Units (RSUs) and stock options, was approximately 1.4 million shares. These awards were deemed to be granted outside of the plan and as such the Company applied liability accounting to these awards. On May 23, 2013 (the date of the Company s 2013 Annual Meeting of Stockholders), the Company s shareholders approved the grants associated with the excess awards, which as of that date, allowed the excess awards to be deemed granted under the previous equity compensation plan. As a result, the excess awards were remeasured at fair value on May 23, 2013 and the liability was reclassified to additional paid-in capital. The unrecognized fair value calculated for the excess awards as of May 23, 2013 is recognized as compensation expense ratably over the remaining requisite service period for each award.

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 stock options granted under its equity compensation plans:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013